The pharmaceutical industry and access to essential medicines in Tanzania

Robert M. Mhamba and Shukrani Mbirigenda
Institute of Development Studies, University of Dar es Salaam

Institute of Social and Economic Research, Rhodes University, Southern and Eastern African Trade Information and Negotiation Institute (SEATINI), Training and Research Support Centre in the Regional Network for Equity in Health in East and Southern Africa (EQUINET)

EQUINET DISCUSSION PAPER 83

July 2010

With support from the Southern Africa Trust

Table of contents

Cite as: Mhamba RM and Mbirigenda S (2010) 'The drugs industry and access to essential medicines in Tanzania,' *EQUINET Discussion Paper Series 83* Training and Research Support Centre, SEATINI, Rhodes University, EQUINET: Harare.

Executive summary

This paper outlines the flows of private capital that lie behind the growth of the for-profit pharmaceutical sector in Tanzania, and analyses the policy, access and equity challenges posed by the shift to increasing private sector participation in medicine provision. The study was implemented within the Regional Network for Equity in Health in East and Southern Africa (EQUINET) by the Institute of Development Studies, University of Dar es Salaam, in a regional programme co-ordinated by the Institute for Social and Economic Research, South Africa.

The Tanzanian drug policy specifically highlights the government's intention to ensure that quality, effective essential medicines reach all Tanzanians at an affordable price. Using case study examples, this study explored the concept of access to essential medicines in four dimensions: physical availability, affordability, geographic accessibility, and acceptability (or satisfaction) defined as the fit between users' and providers' attitudes and expectations about products and services and the actual characteristics of these products and services (MSH, 2001). Three pharmaceutical companies involved in Public-Private Partnerships (PPPs) were studied — two in Dar es Salaam city (Shelys and Keko) and one in Arusha town (Tanzanian Pharmaceutical Industry (TPI)). Data was also collected from the relevant government ministries, departments, and agencies; and development partners:

Data collection included documentary reviews of various studies and reports from pharmaceutical companies, the government, donors and other stakeholders, followed by a review of the existing government policies, legislation and guidelines for the pharmaceutical sector. Documentary analysis aimed to:

- identify and analyse existing policies, legal framework, and guidelines dealing with capital flows in the pharmaceutical sector, local pharmaceutical production, marketing, and the links to local procurement; and
- examine distribution systems and the demand for the locally produced drugs to identity strengths and critical gaps.

Key-Informant interviewees were also conducted with persons from the three pharmaceutical companies (Shelys, Keko and TPI); government officials at the Ministry of Health and Social Welfare (MoHSW), the Tanzania Food and Drug Authority (TFDA); and the Development Partners i.e. Deutsche Gesellschaft für Techniese Zusammenarbeit (GTZ) and DANIDA.

The study found that the quality of medicines manufactured in Tanzania was often inadequate, with Tanzania's general manufacturing practices (GMP) being lower than international standards, and with government failing to adequately monitor even those standards. Only two of the eight pharmaceutical manufacturers are meeting the standards — in the case of TPI this is thanks to funding from development partners and in the case of Shelys, it is thanks to foreign direct investment from Aspen Holdings.

While TPI can be considered to be improving access to medicine at an affordable price in Tanzania, a substantial portion of Shelys' production (41%) is not for local consumption and is exported to other countries. Shelys is also not concerned with producing medicine at affordable prices for Tanzanians, but more interested in profit generation. TPI's production — focussed on antiretroviral, anti-malarials and anti-tuberculosis drug production — is insufficient to ensure an adequate supply and access to all essential medicines for all Tanzanians. Drug stock-outs are common in Tanzanian health facilities, distribution is inadequately monitored, and it is quite possible that medicines intended for free distribution in the public sector are leaking onto the

black market. As a result of drug stock-outs at public facilities, many Tanzanians pay out-of-pocket to retail pharmacists in order to access medicines, frequently impoverishing themselves further in the process.

Strengthening the pharmaceutical sector to produce an adequate supply of medicines in Tanzania, for Tanzanians, is also hindered by numerous constraints, including:

- since Trade Related Intellectual Property Rights' (TRIPS) flexibilities are not included in Tanzanian law, the range of generics local pharmaceutical manufacturers can produce is limited;
- lack of skilled staff;
- financial constraints (most donors are not interested in developing the pharmaceutical sector; most investors prefer to invest in purely private companies — not PPPs; and borrowing from local banks is expensive);
- poor industrial infrastructure and services, leading to high operating costs;
- weak local and international pharmaceutical industry links; and
- counterfeit medicines entering the market.

Therefore, the MoHSW must urgently step up its own monitoring systems — both for GMP and for ensuring effective distribution of medicines to health facilities. New legislation is also needed to improve quality standards, implement TRIPS flexibilities in Tanzanian law, and tackle harmful counterfeit medicines entering the market. Systems and facilities must also be put in place to skill Tanzanians to ensure:

- skilled staff are available for medicine manufacturing;
- financing facilities for drug manufacturers are adequate, more effective and streamlined; and
- industrial zones are created where manufacturers (not just in the pharmaceutical sector) can access quality infrastructure and services so as to reduce operating costs and make existing pharmaceutical production more viable.

1. Introduction

This paper outlines the flows of private capital that lie behind the growth of the for-profit pharmaceutical sector in Tanzania, and analyses the policy, access and equity challenges posed by the shift to increasing private sector participation in medicine provision. The study was implemented within the Regional Network for Equity in Health in East and Southern Africa (EQUINET) by the Institute of Development Studies, University of Dar es Salaam, in a regional programme co-ordinated by the Institute for Social and Economic Research, South Africa.

Case studies of three Tanzanian public-private partnerships (PPPs) were undertaken, focussing on the policy and legal terrain of the pharmaceutical industry and the impact on distribution of and access to medicines in Tanzania. Pharmaceutical production occurs at three levels (African Ministers of Health, 2007:7):

- **primary level:** manufacturing active pharmaceutical ingredients (APIs) and intermediates from basic chemical and biological substances;
- **secondary production** includes the production of finished dosage forms from raw materials and excipients (inactive substance); and
- **tertiary level:** limited to packaging and labelling finished products or repackaging bulk finished products.

The study established the types of production taking place in Tanzania and the distribution of resultant products for internal use and for export.

The concept of access to essential medicines was analysed in terms of (MSH, 2001):

- physical availability
- affordability
- geographic accessibility
- acceptability or satisfaction (defined as the fit between the users' and providers' attitudes and expectations about the products and services and the actual characteristics of these products and services).

Access to medicines is affected by many factors, including the quality of existing physical and social infrastructure. Even if the government creates a policy and legislative environment to ensure access to drugs and essential health care services, its ability to improve access to health care service may still be limited, unless infrastructure improves and appropriate equipment is provided. Therefore the study sought to look at a range of factors affecting access to medicine in Tanzania and make recommendations to address problems.

2. Methodology

In this study we undertook an initial literature review to obtain studies, company reports, government documents including policy and legislation from ministries, departments and agencies, and funder reports on the Tanzanian health sector. We searched the World Health Organization (WHO) website, the Open University website, and the websites of the pharmaceutical companies we were studying, where they existed. Search terms included: 'capital flows', 'pharmaceutical industry Tanzania', 'privatization Tanzania' and 'access to essential medicines Tanzania', 'Public-Private Partnerships Pharmaceutical Industry', 'Public Private Partnerships Tanzania', 'Essential Drugs List Tanzania', 'local production essential medicines Tanzania', and 'import export essential medicines Tanzania'. About twenty documents were found.

We then developed an overview of various financing mechanisms over the course of Tanzania's history, and analysed the documents further to establish the nature of capital flows in the pharmaceutical sector and the legal framework in which this takes place. Eight documents were then analysed to identify:

- institutional matters related to local pharmaceutical production and marketing;
- how this is linked to local procurement and drug distribution systems;
- the demand for locally produced drugs; and
- strengths and critical gaps.

The concept of access to essential medicines was analysed in terms of (MSH, 2001):

- physical availability
- affordability
- geographic accessibility
- acceptability or satisfaction (defined as the fit between the users' and providers' attitudes and expectations about the products and services and the actual characteristics of these products and services).

Case studies were then undertaken to examine the functioning of three pharmaceutical companies involved in Public–Private Partnerships (PPPs) — two in Dar es Salaam city (Shelys and Keko) and one in Arusha (TPI)). Nine in-depth key informant interviews (see *Table 2*) were also carried out with:

- the three pharmaceutical companies (Shelys, Keko and TPI)
- government officials at the MoHSW
- the Tanzania Food and Drug Authority (TFDA)
- the development partners, i.e. Deutsche Gesellschaft für Techniese Zusammenarbeit (GTZ) and DANIDA.

These key informants had special knowledge, status or access to special information on the pharmaceutical industry, and the interviews provided detailed information, perspectives, reflections and observations from them.

Table 1: Key informants interviewed

Name	Organisation	Position
Mr JJ Mhume	MoHSW	Chief Pharmacist and Acting Permanent Secretary on the interview day
Mr Umesh Rivankar	Shelys	Head of Sales and Marketing
Mr Kibo Maleale	Keko	Executive Director
Mr R Madabida	TPI	Executive Director
Ms Victoria Munishi	GTZ, Health Financing Support Programme	Health Financing Programme Officer
Mr Joseph Matibwi	GTZ, PPP support programme	Programme Officer
Mr James Dionis Ndege	TFDA	Librarian
Mr Akida M Khea	TFDA	Manager of Medical Devices Assessment and Enforcement
Mr Hiiti B Sillo	TFDA	Acting Director, Medicines and Cosmetics

3. Findings

3.1 Health financing in Tanzania and links to the pharmaceutical industry

The changing nature of pharmaceutical production and financing in Tanzania is closely linked to the changes in the way the whole health system was financed from the mid-1960s onwards. From mid-1960s to mid-1980s, the Tanzanian government focused developing equitable opportunities in access to essential social services — including health services — for all its citizens, in order to build an egalitarian society. This involved investment in rural health infrastructure, primary health care, and forcibly moving people from scattered hamlets and villages closer to transport networks.

While physical access to healthcare facilities increased (72% of the population lived within 5km of a health facility) (Matomora, 1989), the level of services on offer at the facilities was poor. The private health sector was disbanded and some privately owned facilities were nationalised, although a few not-for-profit private operators (mostly religious organisations) were allowed to continue operations.

Table 2: Population and health data

Population (millions)	42.5
Population growth (annual %)	2.9
Surface area (km^2) (thousands)	947.3
Life expectancy at birth (years)	55.9
Infant mortality rate (per 1,000 live births)	73.4
Literacy rate (% females ages 15–24)	76.2
GNI (current US$ billions)	19.9
GNI per capita, Atlas method (current US$)	440.0
HIV prevalence (% population age 15–49)	6.2

Source: World Bank, 2008

In the mid-1970s the government finalised a basic industry strategy, to develop domestic markets to produce for local needs with local resources (Lipumba, 1992), with massive investments in import substituting industrialisation (Wuyts, 1993). In the pharmaceutical industry, the government established two manufacturing industries i.e. Keko Pharmaceutical Industry and the Tanzania Pharmaceutical Industry (TPI). However, the mission of producing, marketing and distributing all goods and services through the government was constrained by inadequate availability of the prerequisite welfare resources, so shortages of medicines and other health care goods and services persisted (Maliyamkono and Bagachwa, 1990).The government was unable to generate and mobilise enough resources for the economy to become self-reliant.

In this period, health financing from domestic sources was dependent on implicit tax mainly from the agricultural sector and borrowing from the state owned banking system (Ellis, 1982; 1983; 1984), with a rapid increase in transferring financial surplus from peasants to the state, and an average implicit tax on peasant crop income of 26.6% (Ellis, 1983). Free medicines leaked out of the state controlled supply chain into the black market and were smuggled to neighbouring countries, which intensified in-country supply shortages. Health care supply and provision became increasingly dependent on unsustainable foreign aid and loans.

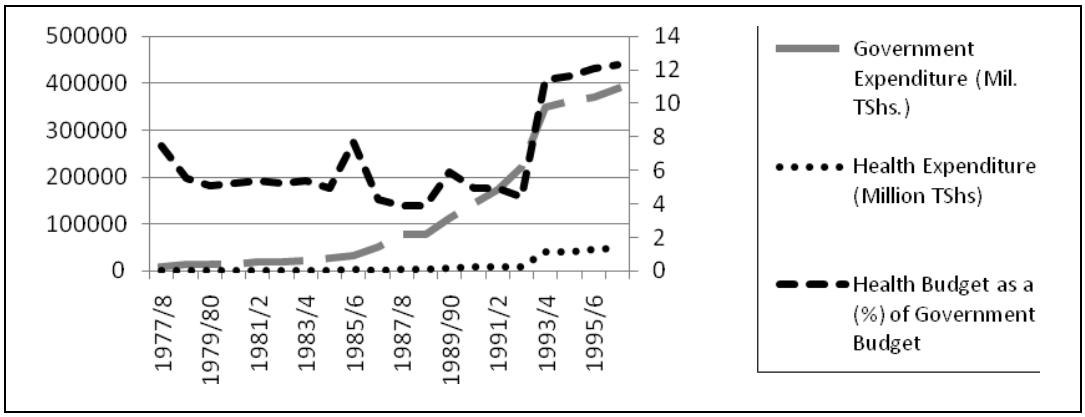
From the mid-1980s external shocks took their toll; faced with worsening government budget constraints, mounting debt and growing shortages of goods and services, Tanzania succumbed to mounting pressure to adopt the structural adjustment programs (SAPs) prescribed by the World Bank and International Monetary Fund (IMF). This marked a complete turn-around in policy orientation from state control of resource allocation to a free market: private medical practice became legal; the wholesale and retail trade in pharmaceuticals (hitherto under the monopoly of the National Pharmaceutical Company (NAPCO)) was opened to private investors; and the state imposed user fees for health services at public hospitals.

In 1997 the Tanzania government privatised its two pharmaceutical industries (TPI and Keko). Tanzania became a member of World Trade Organization (WTO), subjected to the Trade Related Intellectual Property Rights (TRIPS) agreement (WTO, 1994). TRIPS directly affects rights to manufacture generic versions of patented medicine. Tanzania has asked for an extension to January 2013 on the original 2006 deadline to become TRIPS compliant through legislation, and the Doha Declaration (WTO, 2001) has extended TRIPS compliance for pharmaceuticals to 2016.

Currently, around 12% of government spending is allocated to health (see *Figure 1*) (below the Abuja Target of 15%). According to a key informant in the Ministry of Health and Social Welfare (MoHSW), the budget allocation to health has increased by 5% in the last ten years (from 10 billion Tanzanian shillings in 1999 to 53 billion Tanzanian Shillings in 2009), mainly due to:

- increase in population size;
- worsening burden of disease — especially from malaria, HIV and AIDS, tuberculosis; and
- availability of donor funding e.g. from the Global Fund and PEPFAR.

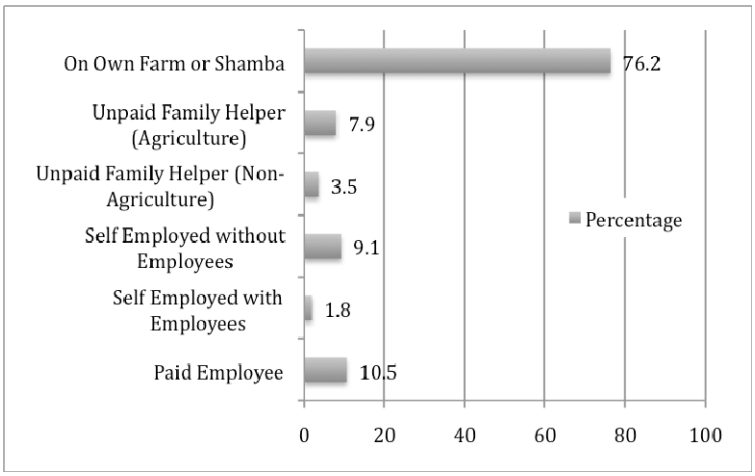
Figure 1: Relative importance of the health sector on overall government expenditure



Source: Ministry of Health and Social Welfare (MoHSA) 2009

Most households (76.2%) in the country earn income from private traditional agriculture (National Bureau of Statistics, 2001) (see *Figure 2*).

Figure 2: Distribution of Sources of Income in Tanzania, 2006



Source: National Bureau of Statistics, 2006

According to the assessment of the health financing system in Tanzania conducted in 2007, households contributed 47% of health system financing in 2001. The government — including donor funding — contributed about 45 % of health system financing (22% government funds; 23% donor funds). Contributions by firms, in the form of contributions to private health insurance, accounted for only 3% of total health sector financing. Individual purchase of private health insurance forms an even smaller proportion of overall health financing (Mtei et al, 2007). A study by the International Labour Organization (ILO) shows that in 2002–2006, donor funding contributed 45% of the national health system financing (ILO, 2008:33).

Table 3: Source of financing by population category

Financing source		Population category	Proportion
Tax-based		All citizens	±11% of government expenditure and 4% of GDP in 2006/7
User fees		People in private traditional agriculture, private informal sector, home duties and a large part of the formal private sector	>80% of the population
Insurance schemes	NHIF*	Employees of central/ local government, state agencies and organisations, including spouses and 4 children	5.7% of work force (2.6% in central/local government; 3.1% in parastatals)
	NSSF+	NSSF members, spouses and 4 children	±3.4% of the total active membership of NSSF in 2005
	CHF#	Mostly rural populations	29 of 113 districts access CHF and matching grants from MoHSW
	PIS⊕	Private sector employees; mainly large corporate companies	<8.6% (the proportion of the workforce employed in the formal private sector)
	Other	Informal sector	Exact information is not available, but includes micro-insurance and savings schemes common in the informal private sector where groups pool resources to help combat unforeseen events like illness

** National Health Insurance Fund; + National Social Security Fund; #Community Health Fund; ⊕Private Insurance Scheme*

Though the CHF scheme in Tanzania started almost a decade ago, coverage is still very low. A study (TGPSH, 2008) in Tanga region shows a declining trend in enrolment, and enrolment of only 6% of households in Handeni district, 8.6%, in Muheza 18.3% in Pangani, 6.9% Lushoto and 0.4% in Korogwe districts. Regional coverage was only about 8%. The review also revealed a declining trend in enrolment annually. With CHF contributions ranging from 5,000 to 20,000 TZN shillings annually, and average household, and a per capita annual household income of only 18,542 TZN shillings in rural areas (National Bureau of Statistics, 2001), CHF schemes remain beyond the reach of poor households. Poor quality health care at CHF facilities, drug and supply shortages, shortages of adequate staff (TGPSH, 2008; Kamuzora and Gilson, 2007), poor management and accountability of CHF schemes, and low capacity and little experience in community mobilisation (Mtei et al, 2007; MoHSW, 2006) continue to hinder CHF schemes.

3.2 The pharmaceutical market in Tanzania

In 1997 the Tanzania government privatised its two pharmaceutical industries, TPI and Keko Pharmaceutical industries, and there are six other local private pharmaceutical industries in the country, including the largest pharmaceutical industry in east and central Africa, Shelys Pharmaceutical Industry (see *Table 4*).

Table 4: Nature of ownership of the sample pharmaceutical industries

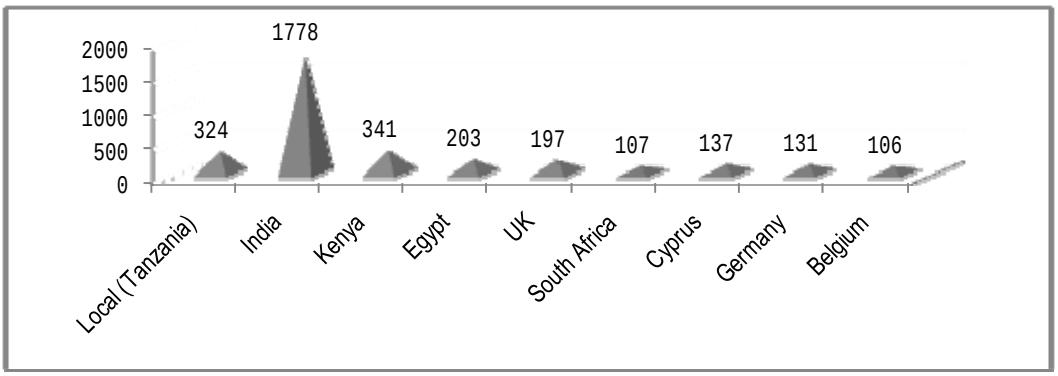
Name	Nature of ownership
TPI	Public until 1997 (Current shares: 60% private; 40% public)
Keko Pharmaceutical Industry	Public until 1997 (Current Shares: 60% private; 40% public)
Shelys Pharmaceutical Industry	100% private (ASPEN Holdings–South Africa majority holding; Sumaria Industries (original owner) minority shareholder)

Privatisation stems from the neo-liberal ideology that focuses on market efficiency, accountability, alternative financing of state/public goods and services from the private sector, and end-user contributions through cost-sharing (e.g. user fees). The aim is to minimise government expenditures and apply private sector managerial skills. Privatisation of Tanzanian pharmaceutical industries has taken the forms of:

- **liquidation:** government sold shares of state-owned industries to the private sector;
- **indirect subsidisation:** using tenders for international and local procurement to distribute essential medicines free-at-point-of-use for strategic medicines (e.g. ARTs and TB drugs) with resources from the Global Fund and PEPFAR); and
- **contracting-out by tendering:** MSD contracts the private sector to supply medicines.

Tanzania imports about 70% of the national drug requirement and local production accounts for about 30%. The pharmaceutical sector in Tanzania consists of eight manufacturing industries all producing generic pharmaceutical products using *imported* active pharmaceutical ingredients (APIs). Most of the APIs are imported from India and China. Local pharmaceutical production in Tanzania therefore takes place at the secondary level, with some tertiary level activities also undertaken. Most of the pharmaceutical production concentrates on less sophisticated medicines such as simple antibiotics, cough and cold preparations, analgesics and antipyretics, sedatives, nutraceuticals, anthelmintics and antimalarials. More technologically sophisticated pharmaceutical products like IV fluids, indictable, and more advanced antibiotics like cepholosporins are not produced by local industries, which still lack that competence. However, TPI currently produces ARVs and Shelys is planning to start ARV production. By 2008, there were 3,388 drugs registered by 41 companies; *Figure 3* shows the amounts by country of origin.

Figure 3: Number of drugs registered by TFDA by 2008

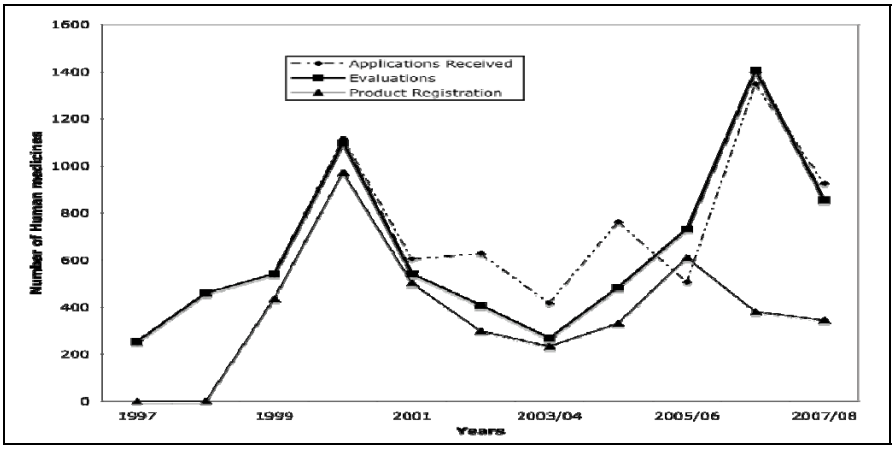


Source: TFDA, 2008

Pharmaceutical products from India dominate the share of drugs in the local market registered by the Tanzania food and rugs administration (see *Figure 3*). Most (53.4%) registered essential medicines in 2008 were from India, followed by Kenya (10.3%), with the locally produced drugs at 10% of those registered. Notably registration does not automatically translate into the volume

of drugs produced or imported, explaining the difference with the 30% share of drug requirements from local production. Indian companies used to export to Africa through European companies such as Mission Pharma, Helm, Troge, but now export directly to Africa through local logistics partner (usually local importers/distributors, country managers or medical representatives) (Chaudhuri, 2008). However, many more applications for registration are received than are actually registered, often due to poor quality (see *Figure 4*). The number of applications rose dramatically from 2003/4 onwards, but after an initial slight increase in the number of drugs registered, registration gradually declined from 2005/6 onwards.

Figure 4: Market authorisation of human medicines in Tanzania



Source: MoHSW, 1997–2002; TFDA, 2003–2008.

Tanzania has 700 pharmacists, 300 pharmaceutical technicians, 250 pharmaceutical assistants and a Pharmacist per population ratio of 1:50,000. Pharmaceutical products are distributed by the public medical stores department (MSD) and 291 TFDA-registered private wholesalers (see *Table 5*). The private wholesalers procure from international and local suppliers and distribute to:

- MSD (through tenders)
- 352 registered retail pharmacies
- 6,000 Duka la Dawas (drug stores licensed to sell only non-prescription medicines)
- directly to hospitals.

Pharmacy retail outlets in Tanzania are of two types: *Part I* pharmacies sell both prescription-only and over-the-counter (OTC) medicines and must be operated by a registered pharmacist; *Part II* pharmacies are those that are licensed to sell OTC medicines; some general stores also market a limited range of OTC medicines.

Table 5: Number of registered private wholesalers in Tanzania, 2003–2009

	2003/4	2004/5	2005/6	2006/7	2007/8	2008/9
Number of companies	193	204	220	247	273	291

Source: TFDA, 2009.

3.3 Regulatory and legislative environment

3.3.1 National policy and legislation

The overall objective of the existing Tanzania Drug Policy of 1991 is to make available to all Tanzanians 'essential pharmaceutical products, which are of quality, proven effectiveness and acceptable safety at a price that the individual and the community can afford'. It aims to

develop and support national pharmaceutical industries to increase local production and thereby encourage self-reliance. The policy contains provisions for:

- **Drug selection:** the policy aims to select pharmaceutical products in accordance with the concept of *essential* drugs to be distributed as generic drugs.
- **Procurement:** the policy prioritises essential drugs and preferentially supports local manufacturing companies (who have 15% leeway on prices over international suppliers), and aims to achieve self-reliance by shifting away from imports.
- **Distribution:** essential medicines should always be available to those who need them and should be distributed in the most cost-effective manner.
- **Quality assurance:** facilitated by the TFDA providing free technical support and regularly inspecting industries (although this is limited due to budget constraints). Local industries must register all drugs produced every year after showing that they have achieved GMP.

The policy also requires all drugs to bear their generic International Non-Proprietary Names (INN) even when available under brand names only.

All imported medicines in Tanzania are currently procured and distributed by 291 local private wholesalers. The wholesalers deliver to public health facilities through the MSD competitive public tendering process and to private retail pharmacies and health facilities through direct private procurement processes. Procurement of locally produced essential medicines is also undertaken by the wholesalers together with MSD. Public procurement is done on a competitive basis without any special treatment and or discrimination against entirely private companies and those in which the government holds 40% shares. Less than half (30%-40%) of locally produced essential medicines are marketed directly to local wholesalers, private retail pharmacies and healthcare facilities (Euro Health Group and MSH, 2007).

However, the policy is outdated — dating back to 1991 — and a revised/ updated National Drug Policy and Pharmaceutical Master Plan is still awaited. Although the National Essential Medicine List/ Treatment Guidelines were revised in 2006, the list is far too long, containing over 700 items (MoHSW, 2007a). This provides minimal protection for local pharmaceutical industries as there are many internationally produced products to choose from. At the same time the *Drug Tracking Study* (Euro-Health Group and MSH, 2007) found that Health Teachnical Committees (HTCs) are not functioning optimally in hospitals and monitoring of drug utilisation in not taking place.

Tenders

Tanzanian bidders enjoy preferential treatment when the Tanzanian government issues a tender, and then only need to comply with Tanzanian Good Manufacturing Practices (GMP) standards) set by the TFDA. The MSD runs the tenders and gives a 15% preferential treatment for national suppliers — both local producers and wholesalers. However, allocation of public funds to procure essential medicines for the public sector are less than US$1 per capita (in the 2005/6 Fiscal Year). Though public expenditure on essential medicines has been increasing there is also a counter-acting growing need for medicines due to population growth and a higher disease burden (MoHSW, 2008a; MoHSW, 2008b).

International donors issue most medicine tenders, and bidders on these tenders must comply with international standards. Findings from this study shows that none of the Tanzanian producers complies with international standards yet except Shelys, which also relatively sales a larger share of the essential medicines to MSD compared to other industries, and is the only industry that has been able to penetrate the export market. This implies that, though, Tanzanian producers have potentially a substantial local market access advantage over foreign produced

medicines through the MSD tendering process, have limited access to the local market for essential medicines.

A drug tracking study (Euro Health Group and MSH, 2007) shows that the MoHSW covers 85–90% of essential drug expenditures for health facilities' individual accounts. The remaining essential medicine financing comes from NHIF, CHFs (including the government top-up) and formal user charges. According to key informants, most local pharmaceutical manufacturers depend on the local demand (see *Box 1*). Public procurement through the MSD is the most reliable market for locally produced essential medicines.

Box 1: Market share of locally produced pharmaceutical products in Tanzania

TPI: 100% local market; 100% public ARV market (and large share of other essential medicines) to MSD;
Keko: 100% local market — 70% to MSD (public); 30% to sales agents/ distributors (private)
Shelys: 59 % local market — of which 60% to MSD (public) and 25% local private outlet; 41% export — to Uganda, Kenya, Zambia, Malawi, DRC, Madagascar, Mozambique, Mauritius, Rwanda and Burundi.

3.3.2 International agreements

Global brand name pharmaceutical corporations seek to:

- restrict generic manufacturers from producing and distributing essential medicines; and
- ration access, which results in a widening access gap, if safeguards are not developed and implemented (Sell, 2007).

International intellectual property regulations, such as TRIPS (WTO, 1994), allow multi-national pharmaceutical companies to block production of generics on drug innovation for twenty years. However, due to the detrimental effects of such regulations on producing affordable, life-saving, essential medicines, the TRIPS agreement provides three flexibilities to improve access:

- **Parallel imports:** the rights to import brand name products when they are sold at lower prices in other countries.
- **Compulsory licensing:** the right to grant a license, without permission from the license holder, on various grounds of general interest including public health.
- **'Bolar exception' (early working):** the right of a generic producer to conduct tests and obtain approval from a health authority before the expiration of the patent, so that cheaper generic drugs are available immediately upon patent expiration.

However, these safeguards are not automatic, but must be written into national law to become applicable. Tanzania's national drug policy only covers drug regulatory control, registration, procurement and quality assurance. It does not effectively utilise the flexibilities to guarantee increased local production of essential drugs. Drugs procurement in Tanzania is not currently affected by intellectual property issues, as many of the TFDA registered drugs are generic.

3.4 Case studies

3.4.1 Shelys

Shelys Pharmaceutical was established in Tanzania in 1984 when Tanzania embarked on its liberalisation policy and allowed private investors to invest in industrial production. Shelys Africa Limited is the holding company of a group of east African pharmaceutical companies ('the Shelys Group'), with major industrial operations in Tanzania (Shelys Pharmaceuticals) and Kenya (Beta Healthcare International) (Aspen Holdings, 2009a; 2009b). Shelys' manufacturing facility in Dar-es-Salaam is capable of manufacturing solids, liquids, capsules and penicillin, and its product portfolio includes: pain and fever management, coughs and cold, anti-malarials, antibiotics, antimicrobials and contraceptives. Beta Healthcare has its origins in the British Boots International and joined the Shelys Group in 2003. Its product portfolio comprises mostly over-

the-counter drugs and a few branded pharmaceutical products. Beta Healthcare's domestic customer base is spread throughout Kenya, and export sales are generated in east and central Africa, including Tanzania, Uganda, Rwanda and Congo (ibid).

Private capital flow to Shelys constitutes both Foreign Portfolio Investment (FPI) flows and foreign direct investment (FDI) flows (Aspen Holdings (2008a and 2008b). Through FDI, Aspen Pharmacare Holdings Limited — a South African Pharmaceutical company listed on the Johannesburg Stock Exchange (JSE) — acquired 60% of the share capital of Shelys Africa Limited in 2008 (Aspen 2008a). Capital flow from Aspen Holdings to Shelys Pharmaceutical industry has been used to upgrade the company's manufacturing capability to produce solids, liquids, capsules and penicillin.

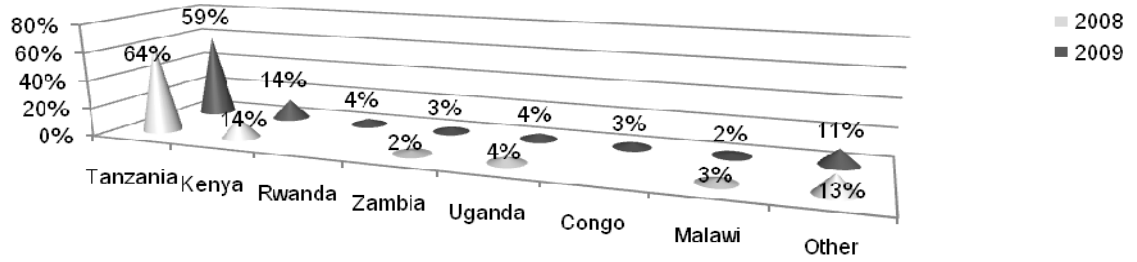
Box 2: Aspen Holdings

Aspen is Africa's largest pharmaceutical manufacturer (with operations in South Africa, Australia, India, Brazil, Mexico, Venezuela, Kenya, Tanzania, Uganda, Mauritius and Britain) and a leading supplier of branded and generic pharmaceutical, health care and nutritional products in territories across the globe. It is sub-Saharan Africa's largest generic ARV manufacturer, the largest generics manufacturer in the southern hemisphere and one of the top twenty generic manufacturers worldwide.

Between June 2008 (when 1% of Aspen Holding's revenue was from east Africa) and June 2009, revenue from east Africa increased by 3% to a total of 4%. Aspen has been significantly enhanced, with effect from 30 June 2008, by its acquisition for £170 million of four globally branded products: Eltroxin™, Lanoxin™, Imuran™ and Zyloric™ from GlaxoSmithKline (GSK). The global product range was also supplemented by two licensing transactions for branded products with US-based Iroko Pharmaceuticals (ibid). According to Aspen Holdings (2008), the recent expansion of its activities has raised its net borrowings to R4,937 million, including a five-year loan facility of US$385 million from a consortium of banks, entered into in October 2008 with a fixed interest rate of 6,11% per annum over 90% of its term.

Although Shelys/Aspen is the leading supplier of locally produced essential medicines in Tanzania, it does **not** have an explicit policy or strategy focused on meeting the needs of the poor by providing access to essential medicines through local production and/or affordable pricing. A decreasing share of Shelys Pharmaceutical products are now marketed in Tanzania (from 65% in 2008 to 59% in 2009), due to increased export to new markets (e.g. Rwanda and Democratic Republic of Congo) and a larger share of export to Zambia (see *Figure 6*) (ibid).

Figure 6: Shelys sales share (%) in sub-Saharan Africa, 2008 and 2009



3.4.2 Tanzania Pharmaceutical Industry (TPI)

TPI was established in 1977 as a state-owned pharmaceutical company, assisted by the Finnish government. Lack of operating capital and other financial constraints led to closure in the early 1990s, and it was then privatised in 1995 with 40% government ownership. Since then TPI has undergone re-engineering to become Good Manufacturing Practices (GMP) compliant. In 2009

it was the second largest pharmaceutical industry in Tanzania, accounting for about 20% of the value of pharmaceutical production.

TPI, with Action Aid Medeor (a charitable non-governmental medical aid organisation based in Germany that depends on donor support to provide services globally), implements two projects:

- manufacturing affordable artemisinin-based anti-malarial drugs for adults and paediatrics, (started in 2003); and
- producing good quality and affordable ARV fixed-dose combination, TT-virus (started in 2005).

ARV production is a €6 million project, financed through a €5 million grant from the *EU Aid for Poverty-Related Diseases in Developing Countries* and TPI's €1 million contribution. The TT-virus is a generic antiretroviral drugs (ARV) fixed-dose combinations, which the World Health Organisation (WHO) has chosen as the first regimen treatment for HIV and AIDS patients in poor countries. TPI imports APIs from China, formulates the off-patent triple combination product, and packages the ARVs, so there are no significant TRIPs implications. The drug developer, Dr Kraisintu, provided technical assistance and know-how to TPI, which contributed to reducing ARV prices to affordable levels for developing countries.

Besides building local manufacturing capacity for anti-malarials and ARVs, the TPI and Medeor partnership facilitates building technical expertise, creates incentives for technical cooperation, and warms up the local market. Local manufacturing capacity building takes place through a contractual arrangement which specifies that ARVs produced will be made available to the public health sector at low cost for 40 months, after which the facility will be handed over to TPI.

Capital flow (donor money) into TPI has focused on achieving public value. Its investment and marketing strategies are focused on realising the national health policy and, particularly, drug policy objectives — ensuring that all people have access to adequate medicines, at an affordable price and acceptable quality. TPI's focus on producing anti-malarials, ARVs and anti-TB drugs at affordable prices and the 100% local marketing of drugs, supports this claim.

3.4.3 Keko Pharmaceutical Industries

Keko Pharmaceuticals was set up in 1968 as a unit under the MoHSW to supply tablets, capsules and large volume parenterals to the government procurement agency, Central Medical Stores (now MSD). At that time, its products were distributed at public healthcare facilities (Chaudhuri, 2008). In 1997 the government sold off 60% of Keko to the private sector, putting Keko under the administration and management of the private investor.

Keko is the fourth largest pharmaceutical industry in Tanzania accounting for 11% of manufactured pharmaceutical products in the country. It produces only generic medicines using APIs procured from open markets. Keko does not have any collaborative arrangements or partnerships to facilitate external commercial or non-commercial capital flows into the company. However, Keko is a PPP, with 40% government-owned shares and a 15% preferential treatment in the MSD tendering process. Keko makes an indirect contribution to public health by making essential medicines physically available in the local pharmaceutical market and by supplying essential medicines to public health care facilities through the MSD public tendering processes.

3.5 Constraints on access to medicines

Local production of pharmaceuticals for domestic use — especially in the public sector — is constrained by numerous factors, including the national and international policy and legislative environment already described. Other factors, identified by key informants, include:

- human resource constraints
- poor infrastructure
- high operating costs
- weak links between local and international pharmaceutical industries
- counterfeit drugs
- high cost of local commercial capital
- poor price controls (adapted from t' Hoen, 2002).

These are discussed in more detail in the sections *3.2.1* to *3.2*.7.

3.5.1 Human resources

Human resource gaps in the pharmaceutical industries in Tanzania exist at all levels from senior management down to production and packaging. In the case study industries, the first level i.e. Senior Management posts in the entirely private industry (Shelys) are filled with foreign staff, while the second and third (factory) lines are filled with locals. Both TPI and Keko, which operate under PPPs, are staffed entirely by locals. However, all pharmaceutical industries in the case study have difficulty finding qualified technical staff, especially pharmaceutical technicians. As the TPI Executive Director pointed out in his interview:

> *Pharmaceutical industries are challenged by the difficulty developing a constant quality concept among the technical staff in the factories, which demands artisans with a mind set to handle the precision machines.*

With Tanzania's education system continuing to deteriorate over time, with the curriculum lacking quality and relevance, producing technically adequate staff is a challenging. Tanzania stopped training pharmaceutical technicians in the late 1990s, thinking they were no longer needed, and since no private institution has filled the training gap, this cadre is thinning out in the labour market. Although the number of students enrolled in relevant training has increased over the last decade, there is no commensurate expansion of teaching staff and teaching and learning materials at the higher learning institutions.

3.5.2 Poor infrastructure

Access to medicines and pharmaceutical manufacture is affected by the existence and quality of physical and social infrastructure. For example, poor roads, poor communication infrastructure and lack of transport impair physical access to healthcare particularly in the rural areas. Even if the government creates a policy and legislative environment to ensure access to drugs and essential health care services, it might still be constrained in its ability to improve access to health care service unless roads and infrastructure improve and transport equipment such as ambulances are provided.

3.5.3 High operating costs

The pharmaceutical industry in Tanzania experiences higher operational costs due to poor infrastructure to support development. For example access to clean water is critical to achieving the GMP, but clean water is not available: tap water, considered safe by government and development partners, is brown and contains many impurities, so pharmaceutical manufacturers incur additional water purification costs. Since the government has not established industrial zones — where utilities could be easily provided for all businesses — economic growth and development through private sector investment is not supported.

3.5.4 Weak local and international industry links

Local pharmaceutical manufacturers mostly have weak links with their international counterparts. Local production depends on APIs, as local manufacturers mostly formulate APIs and package medicines (e.g. for ARVs as shown by GTZ (2007). Even though the government has wavered

import duties on pharmaceutical capital goods, raw materials, and packaging, the prices remain high. It is also difficult for local pharmaceutical manufacturers to:

- reliably source pharmaceutical ingredients and raw materials;
- obtain relevant packaging, as this is mostly not manufactured in the country;
- access support for certain equipment that requires regular servicing and calibration; and
- get spare parts for machinery.

This makes it difficult for local pharmaceutical industries to compete with imported medicines.

3.5.5 Counterfeit drugs

Access to essential, safe medicines is also constrained by the growing presence of counterfeit and substandard medicines. Anti-infectious agents, particularly antibiotics and anti-parasitic agents are the most counterfeited products in developing countries (Kelesidis et al, 2007). The import market has supplied most counterfeit medicines in Tanzania for the last five years (except in 2007) (see *Table 6*). Tanzania does not have mechanisms to withdraw counterfeit batches from the market, which exposes consumers to harmful medicine — contrary to government policy provision. The 2007 drug tracking study (Euro Health Group and MSH, 2007) shows that stock recording and monitoring practices are very weak at all levels; it is therefore unclear if MSD stocks are all received by hospitals and if those received actually reach patients.

Table 6: Identified counterfeit medicines, 2004–2009

	Imported	Locally produced
2004	Erythromyzin tablets Ciprofloxacin tablets Osteocalcium tablets Aminophyline tablets Levamisole tablets Millica tablets Labsten V tablets	None
2005	Gentrisone cream Halfan tablets	None
2006	None	None
2007	Cialis tablets Vicks Kingo lozenges	Ampishel capsules Eusol solution Hydrogen Peroxide 3% solution Hydrogen Peroxide 6% solution
2008	Celestamine tablets Ampicillin Trihydrate capsules Gentrisone cream Zestril tablets Primolut N tablets Ketoconazole tablets Piperazine Citrate powder Coccivet powder Egg boost formula 500g powder Chickmycin 100g powder Broiler boost formula powder	None
2009	Metakelfin tablets	None

Source: Euro Health Group and MSH, 2007.

3.5.6 High cost of local commercial capital

Access to commercial credit in the local banks is another key determinant of capital flow to the pharmaceutical industries. High interest rates (over 15% in 2008/9) crowds out local investors and government borrowing crowds out the private sector, as interest rates are set at government borrowing rates. Due to these high interest rates, it is difficult for local pharmaceutical industries to borrow from local commercial banks in Tanzania.

3.5.7 Price controls

Prices for essential medicine determine consumer access to essential medicines. Price controls of essential medicines in Tanzania only takes place through the MSD tender procedures, but this price control does not guarantee that consumers can access the medicine at the lower price. The existing policy framework and government structures, systems and processes do not guarantee any particular price to the consumer. Although user fee waivers exist for children under five and adults over 60 years old, there are no procedures in place for the chronically poor, vulnerable and disadvantaged to access a user-fee-waiver. In any case, user-fee-waivers are only applicable at public health care facility level, where eligible patients are exempt from paying registration, consultation and laboratory test fees. Patients must still usually pay out-of-pocket for prescribed medicine, as medicines are usually not available at health care facilities. The health insurance schemes available to the poor and disadvantaged also do not guarantee access to medicine and do not cover purchases of medicine from retail pharmaceutical shops.

Laing et al (2003) concluded that drug prices put essential medicines out of reach of people in developing countries; three of the five ARV products were more expensive in Tanzania than in Norway, with similar prices for the other two products. Health Action International (2007) also showed the total price for thirteen drugs was US$277 in Canada and US$409 in Tanzania — in Canada, an unskilled worker would have to work eight days to buy the basket, but an unskilled Tanzanian worker would have to work 215 days for the same basket. The *Medicines Price Monitor* (MoHSW, 2007b) also found that prices:

- in urban public health facilities were 10% higher than rural public health facilities;
- in urban private health facilities were the same as at rural private health facilities;
- in rural private health facilities and mission health facilities are similar;
- in urban mission health facilities were 32% higher than in rural mission facilities;
- in urban private health facilities were 30% higher than in urban public health facilities; and
- in rural private health facilities were 32% higher than rural public health facilities.

URT, EU and WHO (2004) also revealed that some medicines were more expensive than necessary across all sectors (public, private and non-profit) and therefore out-of-pocket purchases of most medicines are not affordable to most Tanzanians. The 2004/5 Demographic and Health Survey (National Bureau of Statistics et al, 2005) also found that 40% of women said money was a barrier to accessing health care.

4. Discussion

Essential medicines save lives and improve health outcomes only if they are available, affordable and properly used. Although the Tanzanian drugs policy intends to ensure Tanzanians access ‘essential pharmaceutical products [...] of quality, proven effectiveness and acceptable safety at a price that the individual and the community can afford’, providing low cost essential medicines in Tanzanian public health facilities is hampered by numerous constraints. Investments in human resources, infrastructure-utilities and a clean water supply free from

impurities are still major challenges for pharmaceutical producers. Studies show that Tanzanians pay out-of-pocket for health care, including medicines (Smithson 2006) — buying from retail pharmacists instead of accessing medicines in public facilities. This health spending leads to further impoverishment of the low income groups (Smithson 2006). Legislated price controls are entirely lacking, with widely varying prices for medicines across the country (between rural and urban areas) and across sectors (public, private, not-for-profit).

While one Tanzanian pharmaceutical manufacturer — TPI — produces essential ARVs, anti-malarials and anti-TB drugs for the public sector using donor funding, the bulk of capital flows into the Tanzania pharmaceutical industry occur mainly through foreign portfolio investments (FPI) and foreign direct investments (FDI). Foreign investors in pharmaceutical manufacturing — other than development partners — are more likely to be attracted to entirely private industries, not PPPs. And despite the support all Tanzania drug manufacturers receive from the government — in terms of preferential buying at a 15% higher price on tender bids than international competitors — all except TPI focus on profit, not accessibility and price. In Tanzania, privatisation and PPPs in local medicine production have not:

- enhanced government oversight;
- led to a more development-focused allocation of public spending to support the private sector — e.g. developing skills in Tanzania to attract foreign investors; nor
- protected public interest.

The privatisation of local manufacturers, even with PPPs, has not proved an adequate and successful model for ensuring medicine supply to patients in Tanzania – particularly the poor. While the government provides 60% to 70% of the local market for local pharmaceutical manufacturers, local producers are unable to accumulate savings for reinvestment and are rarely profitable. Too many local pharmaceutical manufacturers compete with each other for the same government tenders, and the low production quality standards in the local industry mean that local producers are only granted market authorisation for only one or two years, while imported medicines are granted market authorisation for four or five years. Therefore, transaction costs for importing wholesale traders are much lower than the costs for the local producers. Those that have attracted foreign investments — through FDI (e.g. Shelys) or donor grants (e.g. TPI) — do better by attaining GMP faster than those who have no access to foreign funds, but government's GMP standards are below the standards required by international partners, who are major purchasers and distributors of medicine in Tanzania. Therefore money that could be spent on locally produced medicine, leading to capital flow to local pharmaceutical manufacturers, instead goes to international producers.

In addition, poor monitoring of quality standards — in terms of the GMP — means potentially poor quality medicines could be reaching patients in Tanzania, with possibly detrimental effects on health. Low quality standards also lead to constrained access to external markets for local companies, thereby limiting potential for growth in the Tanzanian pharmaceutical sector. Of the companies in the case study, only Shelys has access to external markets, thanks to technical support and capital flows from Aspen Holdings.

Even if quality standards were being suitably monitored, the Tanzania Drug Policy of 1991 is outdated and does not include TRIPS flexibilities. This hinders local manufacturers from producing generics of patented essential medicine for local use. The implementation of the concept of essential medicines is intended to be flexible; exactly which medicines are regarded as essential remains a national responsibility (WHO, 2009):

> *'Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on*

efficacy and safety, and comparative cost-effectiveness. [···] Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford'.

However, in Tanzania, the long essential drugs list is problematic as having so many entries (700) creates opportunities for wholesalers to import a wide range of medicines, thereby stiffening competition for local producers. It also renders the *National Essential Drug List* an inappropriate national instrument for selecting, procuring and distributing essential medicines, as almost all medicines are considered essential.

The concept of essential medicine then becomes meaningless, especially in a situation like the one in Tanzania where medicines often run out at district stores due to supply delays from MSD. A drug tracking study (Euro Health Group and MSH-Tanzania, 2007) shows that it can take more than three months for money to get from the Ministry of Finance to individual facility accounts. Disbursements of the drug budget appear to be random, and service providers are often unsure when and how much drugs central authorities are going to disburse, making planning difficult. Drug procurement resources are also under-utilised by 12%.

Essential drugs at MSD were consistently out-of-stock in the eighteen months prior to this study; which encouraged a system of rationing throughout the supply chain, with erroneous over-ordering from zonal stores and facilities when stocks were available. This then led to fluctuations in demand which were difficult for MSD to manage. However, a 2008/9 policy decision to allocate 30% of the drug procurement budget to health facilities may help address stock outs, by allowing facilities to procure from private pharmacies if the MSD runs out of stock. This flexibility might help the system adapt to delays when they occur. Creating district stores for medicine would also help resolve stock outs. However, unless facility drug procurement is matched with improved monitoring systems for delivery of medicine to public facilities, medicines could leak onto the black market instead of reaching the poor.

Therefore it is clear that the policy and legislative environment around drugs and drug production is inadequate, the Tanzanian government cannot sustain the number of private manufacturers, and private production for profit does not meaningfully make essential medicine available to poor Tanzanians.

5. Conclusion

Peasants and the poor continue to bear the burden of financing health care in Tanzania (Ellis, 1983). While neo-liberal policies have increased the availability of health care goods and services, they have not resolved procurement problems, nor alleviated the burden of healthcare financing that the poor carry. Health care policy-making in Tanzania must be revisited, with a particular focus on promoting access and affordability of medicine for the poor and vulnerable, which can only be achieved through resource pooling.

The MoHSW must urgently update the Tanzanian drug policy to address several gaps, including:

- making use of TRIPS flexibilities to open possibilities for more generic production;
- improving the GMP standards so that medicine production quality matches international producers; and
- giving attention to training and skills development to address the human resources gap in the pharmaceutical sector.

The MoHSW must also work close with other relevant sectors to ensure that industrial zones are demarcated, so that high quality services can be centrally provided for local manufacturers, including pharmaceutical manufacturers.

It also essential that the MoHSW undertake to better monitor and implement improvements with regards to quality medicine production and effective distribution of medicine to health facilities across the country. This requires an evaluation of why existing monitoring systems are not functioning effectively, as well as a budget and human resources to implement changes. Existing funding mechanisms for pharmaceutical manufacturers are not viable either for profit-making or for ensuring medicine reaches poor Tanzanians without them incurring further costs that can lead to worsening poverty. Therefore, funding mechanisms should be explored further, possibly bringing several different partners together to ensure enough essential medicines are produced at an affordable price. Price controls should also be explored as a means to keep medicines affordable for all Tanzanians.

The pharmaceutical industry in Tanzania must also make a commitment to Tanzanians and to the government to ensure all Tanzanians can access essential pharmaceutical products of quality, proven effectiveness and acceptable safety at a price that the individual and the community can afford (MoHSW, 1991).

References

1. African Ministers of Health (2007) 'Pharmaceutical manufacturing plan for Africa,' *Third Session of the African Union Conference of Ministers of Health: Strengthening of Health Systems for Equity and Development in Africa, 9–13 April 2007, Johannesburg, South Africa.* African Union: Addis Ababa.
2. Aspen Holdings Group (2008) *Aspen Holdings Group Annual Results for the years ending June 2008*. Aspen Holdings Group: Johannesburgh, available at: http://www.aspenpharma.com/
3. Aspen Holdings Group (2008b) *Interim financial results for the six months ended 31 December 2008: Internationalisation of the group*. Aspen Holdings Group: Johannesburg, available at: http://www.aspenpharma.com/
4. Aspen Holdings Group (2009a) *Aspen Holdings Group Annual Results for the years ending June 2009*. Aspen Holdings Group: Johannesburg, available at: http://www.aspenpharma.com/
5. Aspen Holdings Group (2009b) *Aspen Holdings Reviewed Preliminary Group Financial Results for the Year ended 30 June 2009*. Aspen Holdings Group: Johannesburg, available at: http://www.aspenpharma.com/
6. Center for Pharmaceutical Management Sciences for Health (MSH)(2001) 'Access to essential medicines: Tanzania,' *Strategies for Enhancing Access to Medicines Program*. Center for Pharmaceutical Management: Arlington, USA.
7. Chaudhuri S (2008) 'Global Strategies of Indian pharmaceutical companies, pharmaceutical prices and industry in Africa,' *Access to Medicines Workshop*, Bagamoyo, 7 June 2008. Indian Institute of Management: Calcutta, available at: http://www.open.ac.uk/ikd/events/workshop7/global_strategies_chaudhuri.pdf
8. Ellis F (1982) 'Agriculture price policy in Tanzania,' *World Development* 10(4): 263–283.
9. Ellis F (1983) 'Agricultural marketing and peasant-state transfers in Tanzania,' *The Journal of Peasant Studies* 10(4): 214–242.
10. Ellis F (1984) 'Relative agricultural price and the urban bias model: A comparative analysis of Tanzania and Fiji,' *Journal of Development Studies* 20(3): 28–51.
11. Euro Health Group and MSH-Tanzania (2007) *United Republic of Tanzania Drug Tracking Study Report*. United Republic of Tanzania (URT): Dar es Salaam.
12. GTZ (2007) *Trade Related Aspects of Intellectual Property Rights: The Viability of Local Production of Pharmaceuticals in Tanzania*. GTZ: Eschborn.
13. Health Action International (2007) *Medicine Price Monitor*. HAI: Nairobi.
14. International Labour Organization (2008) *National Profile of Working Conditions in the United Republic of Tanzania*. ILO: Geneva.
15. Kamuzora P and Gilson L (2007) 'Factors influencing implementation of the Community Health Fund in Tanzania,' *Health Policy and Planning* 22(2): 95–102, available at: http://heapol.oxfordjournals.org/cgi/content/full/22/2/95
16. Kelesidis T, Kelesidis I, Rafailidis PI and Falagas ME (2007) 'Counterfeit or substandard antimicrobial drugs: A review of the scientific evidence,' *Journal of Antimicrobial Chemotherapy* 60: 214–236.
17. Laing R, Waning B, Gray A, Ford N and 't Hoen E (2003) '25 Years of the WHO Essential Medicines Lists: Progress and challenges,' *The Lancet* 361(9370): 1723–1729.
18. Lipumba NHI (1992) 'The nature of current economic reforms in Tanzania: An overview,' in Bagachwa MSD, Mbele AVY and van Arkadie B (eds) *Market Reforms and Parastatal Restructuring*

in Tanzania. Economics Department and Economic Research Unity, University of Dar es Salaam: Dar es Salaam.

19. Maliyamkono TL and Bagachwa MSD (1990) *The Second Economy in Tanzania*. James Currey: London.
20. Matamoro MK (1989) 'A people-centered approach to primary health care implementation in Mvumi, Tanzania,' *Social Science and Medicine* 28(10):1031–7.
21. Ministry of Health and Social Welfare (1991) *Tanzania Drug Policy*. URT: Dar es Salaam.
22. MoHSW (1997–2002) *Pharmaceutical Board Annual Reports*. YRT: Dar es Salaam.
23. MoHSW (2006) *The Community Health Fund Facilitative Supervision Report*. URT: Dar es Salaam.
24. MoHSW (2007a) *Standard Treatment Guidelines and The National Essential Medicines List for Mainland Tanzania*. URT: Dar es Salaam.
25. MoHSW (2007b) *Medicines Price Monitor June–July 2007*. URT: Dar es Salaam.
26. MoHSW (2008a) *Health Sector Performance Profile Report (2008) Updated: Mainland Tanzania July 2007–June 2008*. URT: Dar es Salaam.
27. MoHSW (2008b) *Health Sector Performance Profile Report: Mainland Tanzania July 2006-June 2007*. URT: Dar es Salaam.
28. Mtei G, Mulligan J, Ally M, Palmer N and Mills A (2007) 'An assessment of the health financing system in Tanzania: Report on Shield Work Package 1,' *6th World Congress of the International Health Economics Association (IHEA): Explorations in Health Economics,* Copenhagen, 8–11 July 2007. IHEA: Copenhagen, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=993421
29. National Bureau of Statistics and the National Evaluation Team for the Comprehensive Community Mental Health Services Program for Children and Their Families (ORC Macro) (2005) *Tanzania Demographic and Health Survey* 2004–2005. URT and USAID: Dar es Salaam, available at: http://www.measuredhs.com/pubs/pub_details.cfm?ID=566
30. National Bureau of Statistic (2001) *Household Budget Survey 2001/2*. URT: Dar es Salaam.
31. National Bureau of Statistics (2006) *Integrated Labor Force Survey*.URT: Dar es Salaam.Sell SK (2007) 'TRIPS-Plus Free Trade *Agreements and access to med*icines,' *Liverpool Law Review* 28(1): 41–75.
32. Smithson, P (2006) Fair's Fair: Health Inequalities and Equity in Tanzania, Ifakara Centre for Health Research and Development and Women's Dignity Project, Dar Es Salaam
33. 't Hoen E (2000) 'Statement from Méde*cins Sans Frontières: Campaign for* Acc*ess to Essential Med*icines at the Health Issues Group,' EC DG Trade Health Issues gro*up, 26 June 2000.*
34. *Tanzania Food and Drug Auth*ority (2003–2009) *Annual Reports*. URT: Dar es Salaam.
35. Tanzanian German Programme to Support Health (TGPSH) (2008) TANGA Regional Health Management Team Peer Review Report: TGPSH Programme Progress. URT: Dar es Salaam.
36. URT, The European Union and WHO (2004) *Survey of the Medicines Prices in Tanzania*. URT: Dar es Salaam.
37. World Bank (2008) *World Development Indicators.* World Bank: New York, available at: http://data.worldbank.org/indicator
38. World Health Organization (2009) *Essential Medicines*. WHO: Geneva, accessed on 26 October 2009 at: http://www.who.int/topics/essential_medicines/en/
39. World Trade Organisation (1994) 'Agreement on Trade-Related Aspects of Intellectual Property Rights,' *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, 15 April 1994. WTO: New York.

40. WTO (2001) 'Ministerial declaration,' Doha WTO Ministerial 2001 WT/MIN(01)/DEC/1, adopted on 14 November 2001. WTO: New York, available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

41. Wuyts M (1993) 'Accumulation, industrialization and the peasantry: A reinterpretation of the Tanzanian experience,' *The Journal of Peasant Studies* 21(2): 159–193.

Acronyms

AIDS	Acquired immune-deficiency syndrome
API	Active pharmaceutical ingredient
ART	Anti-retroviral therapy
ARV	Anti-retroviral
CHF	Community Health Fund
DRC	Democratic Republic of Congo
EQUINET	The Regional Network for Equity in Health in East and Southern Africa
EU	European Union
FDI	Foreign Direct Investment
FPI	Foreign Portfolio Investment
HIV	Human immuno-deficiency virus
HTC	Health Teachnical Committees
GMP	Good Manufacturing Practices
GTZ	Deutsche Gesellschaft für Techniese Zusammenarbeit
ILO	International Labour Organization
IMF	International Monetary Fund
INN	International Non-Proprietary Names
MoHSW	Ministry of Health and Social Welfare
MSD	Medical stores department
MSH	Center for Pharmaceutical Management Sciences for Health
NAPCO	National Pharmaceutical Company
NHIF	National Health Insurance Fund
NSSF	National Social Security Fund
OECD	Organisation for Economic Development
OTC	Over-the-counter
PEPFAR	US President's Emergency Plan for AIDS Relief
PIS	Private Insurance Scheme
PPP	public-private partnership
SAP	structural adjustment program
TB	Tuberculosis
TFDA	Tanzania Food and Drug Authority
TGPSH	Tanzanian–German Programme to Support Health
TPI	Tanzania Pharmaceutical Industry
TRIPS	Trade Related Intellectual Property Rights
URT	United Republic of Tanzania
WHO	World Health Organization
WTO	World Trade Organization

Acknowledgements

The authors acknowledge the financial support of the Southern African Trust and EQUINET through SIDA and thank EQUINET, ISER, TARSC and SEATINI colleagues for support and advice. Thanks to the external reviewers for valuable comments.

Equity in health implies addressing differences in health status that are unnecessary, avoidable and unfair. In southern Africa, these typically relate to disparities across racial groups, rural/urban status, socio-economic status, gender, age and geographical region. EQUINET is primarily concerned with equity motivated interventions that seek to allocate resources preferentially to those with the worst health status (vertical equity). EQUINET seeks to understand and influence the redistribution of social and economic resources for equity oriented interventions, EQUINET also seeks to understand and inform the power and ability people (and social groups) have to make choices over health inputs and their capacity to use these choices towards health.

EQUINET implements work in a number of areas identified as central to health equity in east and southern Africa

- Protecting health in economic and trade policy
- Building universal, primary health care oriented health systems
- Equitable, health systems strengthening responses to HIV and AIDS
- Fair Financing of health systems
- Valuing and retaining health workers
- Organising participatory, people centred health systems
- Social empowerment and action for health
- Monitoring progress through country and regional equity watches

For further information on EQUINET please contact the secretariat:
Training and Research Support Centre (TARSC)
Box CY2720, Causeway, Harare, Zimbabwe
Tel + 263 4 705108/708835 Fax + 737220
Email: admin@equinetafrica.org
Website: www.equinetafrica.org

Series Editor: Rene Loewenson
Issue Editor: Greg Ruiters, Rebecca Pointer