CASE STUDY 04

Access to Medicines in Southern Africa

Problem description

The production and sale of medicines is a contested yet lucrative global industry, considering that the use of certain drugs is not optional. Medicine is not subject to normal economic perceptions of price and demand elasticity. There are specific dominant players in the market, including large pharmaceutical corporations, distributors and pharmacies, which often collude with one another in environments where government regulation is weak.

Governments in the Southern African Development Community (SADC) region aim to control prices and standards through local medical regulatory authorities (MRAs, also known as drug regulatory agencies or DRAs).[1]

1 MRAs establish standards of manufacturing and evaluation of safety and efficacy for medicines. Regulatory standards are not as advanced and also subject to WHO pre-qualifications, as a prerequisite for WHO accreditation. These qualifications are not prescriptive to local conditions and can be requested on demand.

Apart from their regulatory function, MRAs are also responsible for some sourcing of medicines. The private sector and donor agencies are also involved: the Global Fund and the President's Emergency Plan for AIDS Relief (PEPFAR) both do extensive sourcing of medicines as organisations or through procurement agencies in individual countries.

Africa's three killer diseases are HIV/AIDS, tuberculosis (TB) and malaria. The World Health Organization (WHO) says that more than two-thirds of new HIV infections occur in sub-Saharan Africa. In 2012, there were an estimated 207 million cases. Approximately 8.6 million new TB cases were reported in 2012 (in 1.1 million cases, those infected were also HIV-positive) and an estimated 1.3 million deaths were reported (including those of 320 000 people with HIV). All regions other than Africa and Europe are on track to achieve the target of a 50% decline in mortality by 2015 set by the Stop TB Partnership.[2] In Africa, malaria killed about 627 000 people in 2012 – most of them children under five.

In addition, the African middle class is showing an increasing burden of non-communicable diseases, including diabetes, cardiovascular diseases and cancer. The combination of communicable and non-communicable diseases poses substantial risks and challenges to patients, medical practitioners, pharmaceutical producers and sector regulators on the continent. There are various reasons for the high disease burden – genetics, lifestyle, poverty, lack of interest by pharmaceutical research and development, increases in average income, and environment. African countries urgently need to tackle disease prevention and treatment head-on.

Access to medicines remains a challenge in sub-Saharan Africa. One of the contributing factors is the impact of small markets and weak and differing medicine registration policies in Southern Africa, which poses a challenge for pharmaceutical companies wanting to register medicines in multiple countries in the region. The distribution and use of generics would be advisable in poorer communities, but there is a marked shortage of quality control laboratories. This influences the purchase and testing of generic medicines. Generics are also inexpensively manufactured in other countries, such as India and China. In addition, there is a lack of cohesion between industry policies and medicine procurement, as well as variations in import and export tariffs.

Barriers to the movement of pharmaceutical products include making legislation compliant with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement[3] – 14 of the 15 SADC countries are members of the WTO and 57% of countries have modified their legislation to comply with TRIPS. Most SADC countries have a procurement policy giving

2 This is an international body with its secretariat housed at the WHO whose mission is to accelerate progress on access to TB diagnosis and treatment; research and development for new TB diagnostics, drugs and vaccines; and tackling drug resistant- and HIV-associated TB.

3 Under the TRIPS agreement, contracting states are obliged to grant protection to all patented products, including medicines, leading to medicines becoming unaffordable for many. However, the same agreement contains flexibilities elaborated in the Doha Declaration, allowing countries to issue compulsory licences for essential medicines and to parallel import medicines from other countries where they are less expensive than in the domestic market.

priority to domestic suppliers, and none gives preference to suppliers from other SADC countries. An additional challenge is the extension of drug patents and new patents, should current patents be denied based on TRIPS regulations. This calls into question the ethics of intellectual property rulings for pharmaceutical products.

Regulatory capacity in various sectors in the SADC region remains difficult if not elusive. The need for SADC to act on and rectify the situation is evident in the pharmaceutical industry. The growth of a local pharmaceutical production sector producing sub-standard or falsified medication poses a threat to people's health and governments' ability to fight the disease burden effectively. Typically, inter-governmental organisations, including the New Partnership for Africa's Development (NEPAD), the SADC Secretariat and the Southern Africa Regional Programme on Access to Medicines and Diagnostics, support efforts towards harmonisation, but admit that attempts at harmonisation have not shown great results.

- The African Medicines Registration Harmonisation Initiative was launched by the NEPAD and Pan-African Parliament consultation meeting in February 2009 in Johannesburg, South Africa. The initiative attracted representatives from nine African regional economic communities (RECs) and over 40 national MRAs. This consultative body provides support to RECs to lead the regulatory harmonisation of medicines in their respective countries and to respond to the challenges of increasing access to essential medicines.
- The SADC Medicine Regulatory Authority Forum was established to enhance the capacities of national MRAs in member states. MRAs are tasked to ensure the quality, safety and efficacy of medicines pending their approval, including regulating and monitoring their clinical development, manufacture, approval for marketing, distribution, procurement, import, export, supply, sale and promotion. Local capacity for regulation is often lacking in SADC member states. The SADC MRA Forum is expected to be the main driver of establishing minimum regulations in SADC member states and of policy harmonisation at the regional level.
- SADC's regional integration agenda specifically addresses the need to increase access to medicines. The SADC MRA Forum and the SADC Pharmaceutical Business Plan both seek to increase access to medicines by working with MRAs, government, civil society and the private sector. Most member state MRAs and national pharmaceutical societies work with ministries of health and academics on leadership, oversight and governance of the pharmaceutical sector. There is little progress in terms of engagement with major pharmaceuticals and practitioners, who remain the direct link to communities in need of access to medicines. The establishment of a regional DRA or pharmaceutical association to unite national pharmaceutical societies is still under discussion.

Regional registration harmonisation is expected to benefit countries through the adoption of similar approaches to the evaluation of documentation for registration and inspection of pharmaceutical manufacturing facilities and imported products, potentially bringing economies of costs in inspection and registration to the region. Pharmaceutical suppliers will be encouraged, through suitable incentives, to enter the regional market, leading to greater competition and expected lower prices for consumers. However, significant investments need to be made at the member state level to prepare for a region-wide approach.

Although regional regulatory co-ordination could be effective at rationalising the duplication of regulatory practices, there are several obstructions to its implementation.

- Many member states could be reluctant to relinquish their national sovereignty in terms of the perceived independence of their regulatory affairs.
- Smaller states could assume that their views will be ignored and their agendas marginalised in favour of stronger states, which could dominate the agenda.
- Member states may anticipate that the integration process will lead to job losses at their national regulatory authorities.
- Local products within the region may be favoured over comparable (cheaper) non-local products – which may have the effect of eroding states' current pricing advantages.

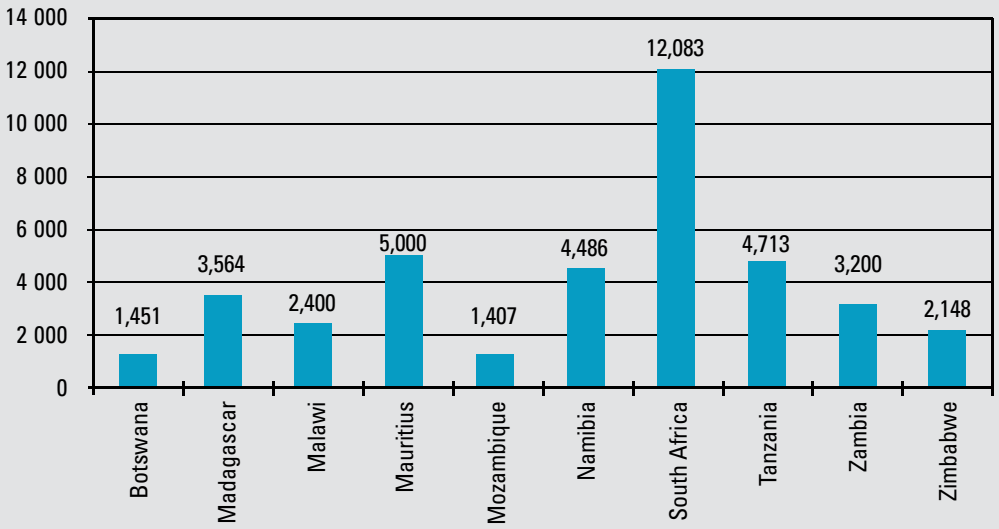
In terms of the last point, it is vital that local and regional pharmaceutical sectors be strengthened. Despite this, local industries are challenged by the presence of imported generics, eg, from India. Indian pharmaceutical products are subsidised and cheaper to import, and India is described as the engine room of global generic manufacturing. Another suggestion would be for collaboration with the BRICS (Brazil, Russia, India, China, South Africa) countries to ensure a unified approach to pharmaceutical product co-operation, but these countries are unlikely to collaborate on competitive aspects of pharmaceutical trade as they will be competing directly for revenues.

Political economy analysis

It is clear that patients would benefit from stronger medicines policy regulation and harmonisation throughout the Southern African region, through the increased safety of products on the market and the reduction in and stability of medication costs. It is unclear why the three main actors in the field have not actively advocated such harmonisation. Governments can also call for co-ordinated policy processes, considering SADC's mandate to merely harmonise policy instead of implementing it. Response is driven by national governments and they have the capacity to negotiate similar policy and trade processes.

The pharmaceutical industry has traditionally been a strong lobbying group, especially in developed countries such as the US and the United Kingdom. There is, however, no visible push by the industry to harmonise SADC policies. The reasons for this could be that the SADC market is insignificant in comparison with those of developed economies, or it could be that the relative lack of regulation in the region is to its advantage. The other two large actors, ie, distributors and pharmacies, presumably also benefit from weaker control, as it allows them to source from preferred suppliers and set prices to their advantage rather than to a regional norm. Without an effective regional watchdog or public interest in the matter, their practices go unnoticed. Without the necessary push factor, governments are likely to focus on domestic health issues, which typically lean more towards access to health care than its quality regulation, especially at the regional level.

Figure 1: Number of medicines registered



Source: WHO (World Health Organization), Development of country profiles and monitoring of the pharmaceutical situation in countries, 2014, http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index3.html

Box 1: Regional harmonisation: The role of South Africa

Regional regulatory co-ordination will increase patients' access to affordable and safe drugs, as it will allow for fewer price discrepancies and greater confidence in distributed medication. Regional harmonisation of regulations is, however, progressing very slowly. Not all member states are eager to enter into negotiations, afraid that larger member states (such as South Africa) will dominate the agenda and play a larger role in forming the final regulations.

However, this might be exactly what the process needs. Firstly, South Africa has the largest and most advanced pharmaceutical sector in the region.[4] About 40% of the 101 pharmaceutical manufacturers in the SADC region are currently located in South Africa, and the country has the highest amount of registered medicines in the region.[5] Secondly, South Africa is the only country in the region with the capacity to produce generic drugs.[6] In African countries, access to generic drugs

4 Avafia T, Berger J & T Hartzenberg, 'The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries'.

5 WHO (World Health Organization), *Baseline Assessment of the Pharmaceutical Situation in Southern African Development Community Countries, Fact Book 2009*, WHO/EMP/MPC/2011.2. Geneva: WHO, 2011. Stellenbosch: tralac, 2006.

6 Avafia T, Berger J & T Hartzenberg, *op. cit.*

has absolute priority over access to branded medicine, due to the large differences in price between the two (generics are typically 20 – 90% less expensive than the branded original). Moreover, through market competition, greater availability of cheaper generics will eventually bring down the price of original, branded medicines, which could lead to great improvements in terms of access.[7]

Thirdly, South Africa has the most advanced regulatory framework. It is furthest in implementing different TRIPS flexibilities in its national regulations. This means that there are provisions for government to overrule certain aspects of intellectual property rights when this benefits national health. These provisions have been included in the national regulations.[8] Although no use has been made of TRIPS flexibilities to date, it is believed that their mere presence in national regulations has assisted generic producers in negotiating licences to produce their products at affordable rates.[9]

The way forward

Pharmaceutical procurement and regulation in the SADC region face barriers in terms of the harmonisation and distribution of medicines, include the granting and processing of import permits; the presence and authority of multiple drug regulatory authorities; bioequivalence studies for generics in local populations, which amounts to a technical barrier to entry; drug registration fees; community-specific requirements; government procurement policies; and the WTO TRIPS agreement on drug access and its implementation. There is a regional push for local regulation of procurement procedures and access to medicines, but a lot of work remains in terms of regulatory barriers, competition with external importers and exporters, and harmonising and implementing regional policy. Raising awareness in the public domain about the lack of harmonisation in the region and its adverse impact on patients could result in greater commitment to regional harmonisation. Highlighting the issue during SADC services negotiations could also result in greater efforts towards harmonisation.

7 'SADC creates new association for generics', Pharmaceutical and Cosmetic Review, January 2012.

8 Avafia T, Berger J & T Hartzenberg, *op. cit.*

9 *Ibid.*

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