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# South-South Collaboration in Pharmaceuticals: Manufacturing Anti-retroviral Medicines in Mozambique

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## Introduction

Back in 2003, Brazil's and Mozambique's presidents, Luiz Inácio Lula da Silva and Joaquim Chissano, agreed to set up the first pharmaceutical factory in Mozambique, to be entirely owned by the national government. The project – widely known as the Brazil-Mozambican anti-retroviral factory because of its commitment to produce AIDS drugs – still represents the single most expensive and eye-catching project of Brazil's South-South cooperation programme in the health sector.

Part I of this book examines the complexities of African pharmaceutical markets and some practical aspects of setting up and developing pharmaceutical industries in the subcontinent. This chapter's contribution is to present the experience of establishing a pharmaceutical factory in Mozambique through industrial and official development collaboration between two national governments. Uniquely, this is a case study of an attempt to kick-start, through an innovative South-South partnership, pharmaceutical production in a country that previously had none. This chapter therefore discusses an experience sharply distinct from most of the countries' experiences discussed in the book, since they have pharmaceutical industries dating back to the 1950s, and with substantial numbers of firms in their industries.

This chapter draws on multiple sources such as official technical cooperation documents and the published literature on the subject, as well

as on the authors' direct experience of the Mozambican pharmaceutical markets, of Brazil's development cooperation programme and of the factory's implementation project. It aims chiefly to discuss whether foreign lessons about the development of the pharmaceutical sectors can be learned for African countries, and the extent to which similar experiences of industrialization and health policy development can be exported from Brazil to the complex African environment. Two main contributions to the making medicines in Africa debate emerge from the analysis of this case study: one is the absolutely key role of the innovative South-South collaboration to the nascent pharmaceutical industry in Mozambique in terms of both financial subsidy and technical support. The other is that, while the technical collaboration with Brazil remains highly positive, the link to the market in Mozambique seems to have been a major problem, as the health-industry link so fundamental in the Brazilian pharmaceutical development experience seems to have worked less well here, at least in the early years of the project.

After a description of the evolution of the cooperation project and of the collaboration between the two countries to set up a factory in Mozambique, this chapter presents details of the technical investment needed to start such a complex enterprise in a country with a less-than-ideal business environment. The crucial link between the factory and the local as well as regional pharmaceutical markets is then analysed. The chapter ends with a discussion of the issues still hampering the development of the factory in Mozambique, and of the insight to be gained from such an experience, including insights for those countries in the subcontinent with a rather more established pharmaceutical industry.

### **The Brazil-supported pharmaceutical factory in Mozambique**

Official reports show that back in 2003, the initiative to set up a pharmaceutical factory in Mozambique originally had the following stated objectives. It aimed to secure the supply of anti-retroviral medicines (ARVs) for HIV/AIDS treatment in the country, and to jump-start pharmaceutical generics' manufacturing in Mozambique, enabling the fulfilment of the objectives of the national primary care and pharmaceutical policies. It also aimed to reduce the country's dependence on pharmaceutical donations and imports and to contribute to the creation of local capacity for pharmaceutical production and industrial management (de Oliveira, 2013).

Following an informal agreement between the two presidents, diplomatic and international cooperation efforts were stepped up from both the Brazilian and Mozambican governments to iron out the details of the project from 2003 onwards. Figure 5.1 summarizes the long timeline of the project from its inception to 2014.

The Oswaldo Cruz Foundation (Fiocruz) – Brazil’s leading public health institution (Roa and Baptista e Silva, 2015) – was appointed in 2004 to conduct the factory’s feasibility study. This was completed and approved three years later. *Farmanguinhos* – Fiocruz’s pharmaceutical arm, and a key instrumental actor in Brazil’s national pharmaceutical policy – was charged with the pharmaceutical technological transfer, technical training and the wider project implementation. These two institutions are directly linked to the Brazilian Ministry of Health and have been credited with playing a pivotal role in the development of domestic

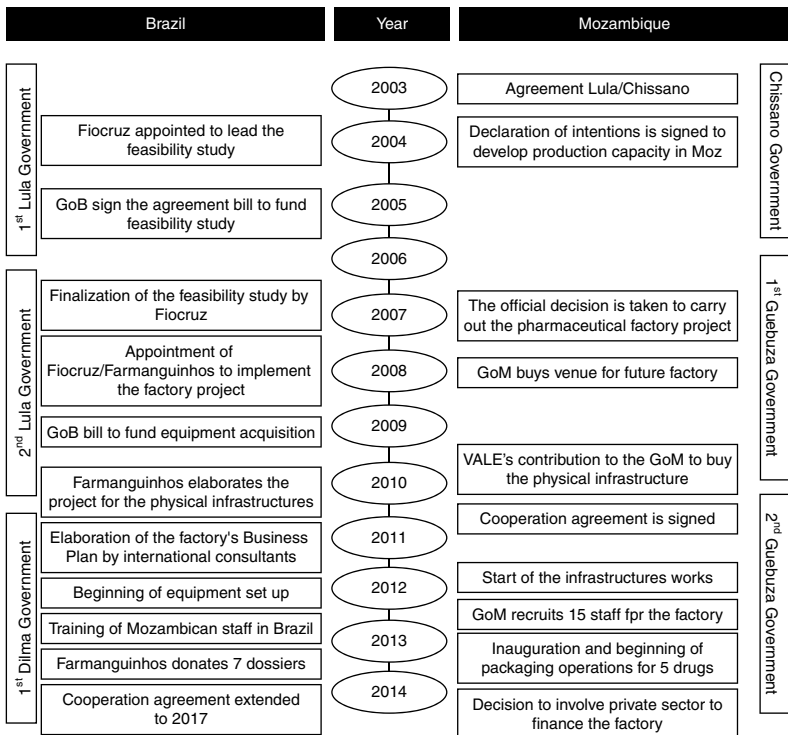


Figure 5.1 Timelines for the implementation of the factory project

Source: drawn by the authors.

pharmaceutical regulation as well as of the pharmaceutical market in Brazil (Flynn, 2008). (Their role is discussed further in Chapter 9). These institutions' early involvement in the factory project in Mozambique was considered instrumental in seeking to replicate that experience back home.

Meanwhile, in the field, a number of cooperation agreements and spending authorizations had to be sought by both the Mozambican and Brazilian sides, as the project was to be funded through multiple sources. The process was lengthy. VALE S.A. – Brazil's largest mining company with ongoing operations in Mozambique – was also recruited by President Lula to support the national government in financing the factory's infrastructure works, which were only finalized in 2012. In the same year, the majority of the pharmaceutical equipment was procured in the international market, donated by *Farmanguinhos*, and shipped to the future factory venue. The government of Mozambique recruited the first 15 local staff in the same year, and *Farmanguinhos* donated the pharmaceutical production technology files and provided the technical assistance required to start production of Nevirapine, Lamivudine, Captopril and Hydrochlorothiazide in 2013 (Russo et al., 2014).

In 2008, the enterprise was officially registered as Mozambique Pharmaceuticals Ltd (*Sociedade Moçambicana de Medicamentos*, SMM), as it planned to extend production beyond anti-retroviral drugs. SMM is owned by the government of Mozambique's State Assets Management Institute (IGEPE), which appoints the executive director and chair of its administrative board from candidates put forward by the Mozambican Ministry of Health (MISAU). In addition to the short-term Brazilian technical assistance necessary for training and setting up operations, four full-time Brazilian consultants in pharmaceutical manufacturing, quality assurance, technical engineering and maintenance have been appointed for the coming years, with the objective of steering the factory towards sustainable production and WHO Quality Certification (Russo et al., 2014).

According to official documents (de Oliveira, 2012), the government of Brazil (GoB) originally agreed to take responsibility for the project's staff training, for procuring equipment and raw materials, for providing technical assistance and for designing the factory and managing the project. Meanwhile the government of Mozambique (GoM) was to be responsible for purchasing the physical infrastructure for the factory, for undertaking rehabilitation works, for funding the factory's recurrent expenditures and for buying the bulk of the factory's pharmaceutical output. The first three-year cooperation agreement was signed in

2011. Extensions of the original 2011 agreement were to be negotiated every three years through official Complementary Agreements (*Ajustes complementares*).

In 2014, procurement contracts were signed by MISAU for the acquisition of locally produced hospital serum bags and imported but locally packaged generic drugs from the factory. Although disruptions were experienced in 2014 in the production lines, a fresh cooperation agreement was signed the same year to extend Brazil's support to the factory until 2017. Towards the end of the same year, following a visit of Mozambican officials to the Brazilian Ministry of Health and Ministry of Foreign Trade, Industry and Development, a decision was taken by IGEPE – the institution in responsible for the factory – to seek capital to finance the factory from the Mozambican banking sector, and at the time of writing this seems to be the path identified for the development of the project in the near future (Figure 5.1). In the process of developing the factory, more than ten years and three presidential terms have elapsed both in Mozambique and Brazil, and administrative, political and foreign affairs details have had to be ironed out across two countries and four different political administrations.

The new pharmaceutical factory is located in Matola City within Mozambique's capital's metropolitan outskirts, on a 20,000-square-metres allotment close to the capital's commercial port and to the South African border. The factory currently engages both in secondary and tertiary pharmaceutical production. That is, it produces its own formulations from imported active pharmaceutical ingredients (APIs) and raw materials, as well as packing imported finished formulations. Twenty-one generic drugs are planned to be produced in the next two years, including ARVs (Nevirapine, Zidovudine and Lamivudine combinations), hypertension drugs (Captopryl and Propanolol) and a list of antibiotics, antimycotics and anti-diabetic compounds specifically requested by the MISAU as currently in wide use in the country's public National Health Service (NHS). Such a list can be expanded on demand to include generic drugs to meet the WHO requirements for ARV treatment and generic formulation to be sold by third parties. All the formulations (pharmaceutical dossiers) belong to *Farmanguinhos* and are transferred for free to MISAU. A laboratory for the control of medicine quality has been already established, equipped to test drugs for efficacy and safety. When fully functional, the laboratory will be capable of providing information on the quality of all the drugs imported into the country and of contributing to the development of new drug testing methodologies.

## The technical investment

So far the factory's overall set-up costs have been estimated at US\$ 39.6 million (de Oliveira, 2013). Capital investment (land, infrastructures, machinery and implementation of production lines) amounted to approximately 46.5% of overall expenditures and pledged funds, while technological transfers and technical assistance represented a substantial cost item (13.0%), including the value of compounds dossiers for the 21 generic drugs, as well as personnel costs for the expatriate staff who helped setting up the operations. Running costs for the first year (API procurement, training and maintenance) represented 23.7% of present and future expenditures (Table 5. 1).

Although the Brazilian government funded the majority of the project's set up costs (62.7%), the government of Mozambique contributed through buying up land and some existing infrastructure for the establishment of the factory, while a donation from VALE, a Brazilian mining company operating in Mozambique, supported personnel and infrastructure expenditures (Table 5.1).

As Brazil still lacks a comprehensive legal framework to provide funds and procure goods for its international cooperation programme (Cabral, Russo and Weinstock, 2014), funds for the project had to be channelled through the implementing public institutions linked to the Brazilian Ministry of Health – Fiocruz, Fiotec and Farmanguinhos – and through the Brazilian Development Cooperation Agency (ABC), linked to the Ministry of Foreign Affairs (*Itamaraty*). On the Mozambican side, the costly acquisition of the infrastructure from a former hospital serum bags factory (*Final Farmacêutica*) was directly managed by the government, while IGEPE funded the capital rehabilitation and maintenance costs. The donation to the venture by VALE S.A. was expressly solicited by the government of Brazil and channelled through the government of Mozambique Treasury to set up the factory's early production lines and pay for some Brazilian personnel as part of the running costs. With the extension of the cooperation agreement to 2017, both governments agreed to further the funding of the project.

Although according to the business plan the factory would require 88 full-time staff to manufacture at full capacity (24 for direct production, 4 for quality-control-related services, and 18 for management and administration), at the time of writing only 55 had been recruited, and a team of 8 Brazilian technical assistants based in Maputo were still providing key management and technical expertise for the factory's operations. Given the limited development of industrial capabilities in Mozambique,

Table 5.1 Estimated cost of setting up the factory (current US\$ million)

Source of funding	Implementing agencies	Activities	Type of expenditures	Spending (to 2013)	Pledged (2017)	Total
Government of Brazil	Fiotec/Fiocruz/MoH of Brazil	Transfer of Technologies; Technical assistance	Technology transfer	6.3	6.7	13.0
	Farmanguinhos/Fiocruz/MoH of Brazil	Equipment	Capital	4.0	1.0	5.0
	Brazilian Cooperation Agency / Ministry of Foreign Relations (ABC/Itamaraty)	Procurement of raw products	Running costs	1.0	2.0	3.0
		Capacity building	Running costs	0.2	0.5	0.7
Government of Mozambique	GoM	Purchase of land and infrastructure from Final Farmacêutica Lda	Capital	8.0		8.0
	IGEPE	Maintenance of infrastructures	Running costs	2.0	2.0	4.0
		Development of existing infrastructure	Capital	1.4		1.4
VALE S.A.	Support to the GoM for the project	Setting up production lines	Capital	4.0		4.0
	Support to the GoM for personnel expenses	Payment of Brazilian technical director for 4 years	Running costs	0.250*	0.250*	0.5*
<b>Total</b>				<b>27.2</b>	<b>12.5</b>	<b>39.6</b>

Note: \*SMM Accounting Report SMM.

Sources: Respective implementing agencies, unless otherwise stated.

technical personnel as well as senior managers for the new factory had to be either summoned from the Brazilian public sector or recruited in the local market and provided for extra training abroad.

In terms of technological transfer, until March 2015, *Farmanguinhos* had donated for free 10 out of 21 technological dossiers for the production of specific pharmaceuticals, to include results from pharmaceutical equivalence tests, quality control procedures for APIs and other ingredients, manufacturing process specifications and test failure reports. The next steps for technological production are still under way and include:

- adaptation of the Brazilian dossiers to the MISAU's specifications;
- training local personnel to the local production of the pharmaceutical dossier;
- assisting production for the drugs' first three pilot batches, following production as well as commercialization of the products;
- establishing a pharmacovigilance system.

In terms of pharmaceutical production equipment, 18 high-tech pieces have been procured internationally by *Fiocruz/Farmanguinhos* and donated by Brazilian cooperation. This included main production line equipment such as compression, coating and blender machines, packing equipment – blisters, labelling and capping machines – as well as quality and in-process control equipment – tablets' hardness and dissolution testers, chromatography and centrifuges. Given the total absence of up-to-date manufacturing machinery in the infrastructures inherited from *Final Farmacêutica*, basic non-specific equipment such as water purification machines also had to be brought in.

The machines presently installed in the factory in Maputo have an estimated market value of US\$4 million, with an additional list of equipment worth approximately US\$1 million to be procured and bought by 2017. All the machines were purchased by *Farmanguinhos/Fiocruz* through international tenders and donated to the government of Mozambique, including installation services and personnel training for its use and maintenance. SMM technical personnel were all trained in Brazil on the use of the specific machines, and on-site ongoing technical assistance is provided for specific manufacturing.

## **The company and the market**

This section details a key – and often overlooked – aspect of the Brazil-Mozambique collaboration to produce pharmaceuticals: the link to



the market. A feasibility study was conducted in 2007 looking at the likely costs of setting up the factory in Maputo and its specific production capacity for ARVs, but it failed to analyse the market conditions in Mozambique and in the wider Sub-Saharan region (Fiotec/Fiocruz, 2007).

Mozambique's pharmaceutical policy in the 1970s and 1980s focussed on procuring and using generic drugs, to extract the best possible value from its drugs budget (Barker, 1983). However, as Mozambique became after Independence one of the world's largest recipients of health-aid funds, international finance for drugs began to be handled, first through an externally managed Drugs Common Fund (Pavignani and Durão, 1999), and subsequently through an MoH-managed Sector Wide Approach common fund agreement (PROSAUDE). Currently, with the global push for AIDS fight and the introduction of anti-retroviral treatment (ART) in 2003, the country is enjoying a considerable injection of AIDS funds, with anti-retroviral drugs procured in the international market by organizations such as the Global Fund, the World Bank and USAID.

In 2012, the national drugs market in Mozambique was estimated to be worth approximately US\$140 million in terms of the value of drugs imported (COWI, 2012), which represented a drugs expenditure of US\$5.55 per capita. Eighty-five per cent of the total market value was represented by public sector imports, mostly funded by external funds and donations, some of them managed by the local Ministry of Health through the sector budget support fund, PROSAUDE (CMAM, 2011). In recent years public drugs expenditures have gone from US\$78 million in 2004 to US\$122 million in 2012 (Table 5.2), the increase being driven by in-kind AIDS drugs donations that rose from the original US\$4 million to the current US\$49 million in eight years (COWI, 2012).

As shown in Table 5.2, AIDS drugs represent the largest single item of the national public pharmaceutical expenditures, and enter the country exclusively as in-kind donations procured and managed directly by foreign organizations. Public funds pay for roughly a quarter of the overall public sector drug expenditures, with North-America-based organizations (USAID, Supply Management Systems and the Clinton Health Access Initiative) contributing to purchase 67% of all the public sector drugs procured in the country. In this respect, the local funding environment appears still to represent a critical limitation for pharmaceutical production in Mozambique. Given the typical consumer's limited ability to pay, and the relatively small size of the local private

*Table 5.2* Public sector drug import value, by source and type of health programme (2012 US\$)

<b>Health programme and associated drugs</b>	<b>Internal and external funds managed by MISAU (drug pool and state budget)</b>	<b>In-kind donations</b>	<b>Total</b>
Hospital drugs	11,861,471	1,200,883	13,062,354
Primary care drug kits	8,708,824	0	8,708,824
Community health	3,870,588	7,217,900	11,088,488
STD and HIV-SIDA	0	48,750,977	48,750,977
TB	0	249,550	249,550
Malaria	0	24,124,599	24,124,599
Blood banks	967,647	0	967,647
Oral health	290,294	0	290,294
Surgical supplies	10,111,912	0	10,111,912
Laboratory supplies	2,497,000	0	2,497,000
Imaging devices and supplies	1,741,765	0	1,741,765
<b>Total</b>	<b>40,049,500</b>	<b>81,543,908</b>	<b>121,593,408</b>

*Source:* CMAM, 2012.

sector, selling to the public sector is obviously the only way for local producers to go to scale and access a local market worth in excess of US\$140 million. However, the lack of flexibility of the international drugs financing environment is pointed to by many as a key limiting factor for the development of local production of pharmaceuticals in the country; even if locally produced drugs were made available at competitive prices, the manner in which external funds for AIDS drugs are currently regulated would stand in the way of procuring, or offering preferential procurement terms to buy, locally produced drugs. As a side effect, free internationally procured ARVs also end up crowding out the local private sector, which is traditionally a key customer for locally produced goods (Herzer and Grimm, 2012; Rajan and Subramanian, 2011).

Little consolidated data exist about the private pharmaceutical market in Mozambique. Some estimates put it at approximately US\$20 million, calculated on the basis of the drugs value declared on the import documents submitted to the pharmaceutical department in 2012 (COWI, 2012). Although 54 private importers are officially registered

in Mozambique, a 2010 study found that the private sector is highly concentrated, with the four largest firms handling more than 50% of the drugs imported (Russo and McPake, 2010).

As for the regional market, according to some industry pundits (IMS, 2012), with its 10.6% yearly growth rate by volume, Africa is the world's fastest-growing pharmaceutical market after Asia, and is estimated to reach a value of US\$30 billion next year. With specific reference to the ARVs market in the Southern African Development Community, the SMM business plan estimated in 2012 that a sufficiently homogeneous regional demand for ARVs existed for SMM to serve. Previous studies of the regional market (COWI, 2012) suggested that across the neighbouring countries of Mozambique, Tanzania, Zambia and Zimbabwe, AIDS treatment lines were relatively similar and reliant on standard Lamivudine-Zidovudine-Nevirapine combinations. This would have implied access to sizeable market for HIV/AIDS drugs of approximately 6 million treatment doses per year across the four countries. However, there is little recognition in SMM's viability study and subsequent business plans of the complexity of those markets, of the possible regional and international competition to be faced, as well as of their regulation and of the role played by national governments in supporting the local industry.

Currently, SMM's business plan expects to sell its products in the Mozambican market in the short term, particularly to the NHS. It aims to sell into the regional pharmaceutical market only in the medium term, once the required certifications are obtained to allow the firm to compete in international tenders (COWI, 2012; SMM and Farmanguinhos, 2013). SMM unit prices, listed in Table 5.3, reflect the initial production costs calculated on the basis of APIs imported from Brazil. As production goes to scale and APIs are bought in from the global competitive market, SMM is projecting lower selling prices reflecting the lower API costs. SMM also enjoys most of the standard preferential policy interventions already adopted in the East Africa Community: an ad hoc tax exemption regulation on imported APIs and other manufacturing product and a preferential buying regime from the government, according to which, when procuring drugs for the National Health care Service, the National Drugs Acquisition Agency is required to give preference to locally produced drugs as long they are no more than 15% more expensive than the products of their international competitors.

The prices listed in Table 5.3 represent SMM's factory gate selling prices for public procurement; a comparison with the Management Science for Health international median reference prices for procurement is

also shown. It is worth noting that although in the same price range, SMM prices for ARVs, particularly those involving Lamivudine, appear to compare less favourably with international reference prices than do those for the other generic drugs (Table 5.3).

The factory's business plan predicted wholesale selling price levels at which the factory would break even, on the basis of the cost structure model used for the production of ARVs in Brazil's state pharmaceutical factories adapted to the Mozambican context (Pinheiro et al., 2006). Although SMM drugs face higher costs because of Mozambique's burdensome import duties on non-API production materials, as well as high maintenance costs, according to the factory's business plan these will be offset by lower capital costs and smaller operating margins, typical of a state-owned company (MacDonald and Yamey, 2001).

*Table 5.3* Unit price for selected SMM drugs (US\$)

<b>Product</b>	<b>Package (Units)</b>	<b>SMM's selling price to the NHS (US\$)</b>	<b>MSH* median price (US\$)</b>
Amoxicillin caps 500 mg cx c/500	500	0.0502	0.0313
Glibenclamide tab 5 mg cx c/500	500	0.0035	0.0042
Hydrochlorothiazide tab 50 mg cx c/500	500	0.0047	0.0050
Metronidazole tab 250 mg cx c/1000	1000	0.0116	0.0061
Prednisone tab 5 mg cx c/500	500	0.0077	0.0108
Lamivudine 150 mg 60 tab – 3TC	60	0.1152	0.0508
Lamivudine 150 + Zidovudine 300 mg 60 tab	60	0.4354	0.1714
Lamivudine 150 mg + Zidovudine 300 mg + Nevirapine 200 mg	60	0.2754	0.1654
Lamivudine 30 mg + Zidovudine 60 mg + Nevirapine 50 mg	60	0.1015	0.0726
Nevirapine 200 mg 60 tab – AD	60	0.0849	0.0611

*Note:* \*Management Science for Health Drug Price Database.

*Source:* SMM.

According to the factory's business plan, SMM furthermore will be able to sell its products at prices comparable to those from the international market, thanks to savings in the initial investment in infrastructures and equipment, donated by the Brazilian cooperation, and in national transport charges and taxes, which are particularly favourable to business in Mozambique, since the original tax rate on chemical products was scrapped. In comparison to the typical cost structure for ARVs (Pinheiro et al., 2006), SMM's production costs will be largely driven by active pharmaceutical ingredients' (APIs) import prices, and less by taxes, profit margins, research and development and local production mark-ups (SMM and Farmanguinhos, 2013).

### **The South–South collaboration in context**

'Emerging donors' and 'South-South cooperation' are terms usually referring to providers of development assistance and forms of cooperation that have recently become prominent in the international aid architecture, due to a recent expansion in resources allocated to development cooperation with poor countries (Manning, 2006). Thanks to their recent economic growth, emerging economies like China, India and Brazil are boosting their cooperation programmes (Brautigam, 2009; Cabral, 2010), and according to one estimate, the volume of aid from emerging donors reached between US\$9.5 billion and US\$12 billion in 2006, corresponding approximately to 8–10% of total aid flows. The recent literature on the subjects shows that some common features among these emerging aid players are discernible. One of the most salient is the emphasis on horizontal (South-South) cooperation between developing countries and the principle of non-interference in the internal affairs of recipient countries. Related to this aspect, emerging donors tend to have no policy-related conditionality, such as standards of governance and macroeconomic requirements, and fewer procedural conditions, such as counterpart funding or separate bank accounts, relative to traditional donors. More controversially, there is a more evident and openly acknowledged association between commercial interests, geo-strategic objectives and development cooperation than is the case for traditional donors (Kragelund, 2008).

Brazil's overall cooperation programme is still relatively small, estimated to be worth between US\$350 million and US\$1 billion per year, with a substantial component of support to international organizations and humanitarian assistance and a smaller proportion directed to technical cooperation projects (IPEA, 2011). South-South relations play an

important part in Brazil's strategy of diversification of diplomatic and economic relations, and technical cooperation provides an expedient way of taking forward such an agenda. Brazil's South-South technical cooperation programme has as key features the emphasis on exchange of experiences between equal partners (or 'horizontal cooperation', as it is usually referred to), respect for the partner country's sovereignty and non-conditionality of support, with a dominant but not exclusive geographical focus on Latin American and Portuguese-speaking African countries and on the agriculture, education and health sectors (Cabral, Russo and Weinstock, 2014).

Government figures put the value of Brazilian technical health cooperation at approximately US\$12 million between 2006 and 2009. However, recent independent reports estimated that Brazil spent between US\$12 million and US\$14 million in technical health cooperation projects in Portuguese-speaking African countries alone for the same period (Russo, Cabral and Ferrinho, 2013). Brazil's health-sector-specific characteristics and claimed principles suggest some important departures from the ways in which development cooperation has been traditionally practised. A key feature of Brazil's cooperation is that it is openly driven by foreign policy goals, and development cooperation is seen as instrumental in promoting Brazil's image and interests abroad. Brazil openly adopts the notion of 'health diplomacy' for its health projects (Roa and Baptista e Silva, 2015), implying that health development cooperation can be informed by international health objectives, following the recognition that national health problems need to be dealt with in the global health arena. Brazilian cooperation officials also dispute the use of the term 'aid' to define their work, as that would impose industrialised countries' 'world views, agendas and pre-defined objectives' (Buss, 2011). Instead, 'horizontal partnership' is Brazil's preferred terminology to indicate the wish to draw on principles of non-interference and mutual advantage. Brazilian projects are also claimed to promote 'structural cooperation in health', a concept defined by some as building local capacity for development (Buss, 2011). It begins from the premise that health cooperation should focus on integrating human resources for health and institutional development, developing local capacity to avoid dependency from foreign expertise and promoting internal collaboration between local health institutions to elaborate their own health system development agenda.

As for the relation between national business interests and cooperation goals, Brazilian cooperation in health openly claims to be inspired by the concept of the 'health-industrial complex for health development',

according to which individual countries need to invest in the national health care industry and R&D capacity if they want to develop their health systems (see also Chapter 9). Such an emphasis on self-sufficiency is also aimed at avoiding costly dependency on foreign health care technologies (Gadelha, 2006). This approach happens to be particularly relevant for the pharmaceutical and biotechnology business in Brazil, as, besides being worth approximately US\$24.5 billion in 2012, these two sectors are considered to be instrumental in the implementation of the Brazilian Unified Healthcare System's objectives of free and equitable access to health care services (Gadelha et al., 2013). Brazil's position on HIV/AIDS drugs appears in line with its support for strong government involvement in the provision of health care services, underpinned by a constitutional framework that establishes a universal citizen right to health and places a duty of health care provision on the state. The growing roles of the Brazil's Ministry of Health research and training agency, *Fiocruz*, and its pharmaceutical arm, *Farmanguinhos*, influential government institutions behind the development of the ARV industry in Brazil as well as in the factory project in Mozambique, are exemplifications of the strength of this paradigm of state-led health development (see Chapter 9).

### **Local production of pharmaceuticals: issues raised by the case study**

In contrast to the experiences described in other chapters, the Maputo factory story provides a case study of an attempt to kick-start, through an innovative South-South partnership, pharmaceutical production in a country that previously had none. Our narrative of development and implementation of the project has shown the key role of the innovative South-South collaboration for the nascent pharmaceutical industry in Mozambique in terms of both financial subsidy and technical support. However, while the technical collaboration with Brazil remains highly positive, the link to health markets in Mozambique seems to have been a major problem, as the health-industry link so fundamental in the Brazilian pharmaceutical development experience seems to have worked less well here, at least for these early years.

The experience of the Brazil-Mozambique collaboration details the challenges of starting up such a complex enterprise from scratch, in an environment often lacking the basic infrastructural pillars for industry development. Human resources were identified as the single most important bottleneck for SMM development. As the majority of the

staff recruited locally had to be sent for training abroad, some of those employed have been poached by competing businesses in wholesaling and retailing, and highly specialized positions in the factory are still covered by expatriate staff. Although personnel with middle-management skills should be already supplied by the local labour market, experienced executives with a track record of management in comparable industries are acutely lacking in Mozambique, given the country's relatively recent history of industrial development.

Mozambique's particular industrial environment was recognized as another factor hampering the development of the pharmaceutical factory. In comparison to other African countries with a more established industry, Mozambique seems to be lacking a critical mass of suppliers, products and services needed for the development of a competitive pharmaceutical business. All the primary products needed for Maputo factory's manufacturing are, up to now, imported from Brazil; all the basic maintenance and technical services are contracted to South African firms, and resorting to lower cost Indian and Chinese equipment has not been an option, given the limited equipment maintenance services provided by such suppliers in Mozambique.

Strengthening the government's current quality control of pharmaceutical manufacturing processes and final products is needed, as this was also reported to be a hurdle for the long-term development of pharmaceutical manufacturing in Mozambique. A lack of quality regulation *de facto* allows competitors to employ cheaper substandard machinery in pharmaceutical production and produce substandard – and, crucially, cheaper – generic products. The factory's case study shows that lack of effective quality regulation ends up benefitting those importers of non-branded generics for whom an ability to cut costs and offer wildly discounted generics represents the core of their market strategy in Mozambique.

This experience, however, also identifies a path to local industry development based on foreign assistance but also on national governments' willingness to support local procurement of drugs (Russo and Banda, forthcoming). As is already well known in those African countries with a more established pharmaceutical industry, this case study reaffirms that only through preferential pricing and reduced profit margins can local medicine production be competitive in Mozambique, but that the spill-over information-related benefits from local production can be substantial for epidemiological surveillance as well as for governments' price negotiations (Russo et al., 2014). However, a number of points of discussion are raised by this case study on the



feasibility, sustainability and opportunity of local pharmaceutical production in Africa.

At the time of writing, the factory's sustainability after the likely end of Brazil's support in 2017 remains an issue. Brazil's original objective was to provide MISAU with enough production capacity to carry out its medicine policies; however, the GoM's appointment of IGEPE, together with the conspicuous absence of references to the factory in MISAU's policy documents, seem to signal a more pronounced interest in the factory's contribution to the country's industrial assets rather than to its public health goals. To this respect, the GoM will have to decide whether it is still in its interest to keep the factory as a public enterprise, or to attempt a privatization with a degree of public sector involvement, in the way similar experiences developed in Uganda and South Africa (Rajagopal, 2013; World News, 2013).

Finally, this case study raises questions about the suitability of foreign health policy and production models to the African context. If Brazil's original plan was to help Mozambique to replicate its own domestic experience in the AIDS fight and in pharmaceutical production, the implementation of this factory project exposed Brazil's limited familiarity with the development cooperation conundrum, but also the relevance of the differences between the two contexts (Russo et al., 2014). If some of the holdups in the project could be attributed to the relative lack of experience of Brazilian civil servants borrowed from their domestic duties to implement a cooperation project in the African continent, this case study probably shows that solutions that have proved effective elsewhere are hard to replicate in Mozambique for more than just one reason.

First, there is evidence from this experience that MISAU's engagement with the project and enthusiasm for using the factory as an implementation tool for its own national drug policy has not been the same as that which motivated the creation of public pharmaceutical laboratories in Brazil in the past decades (Russo et al., 2014; Flynn, 2010). Second, in stark contrast to what happens in the Brazilian pharmaceutical market, the majority of medicines in Mozambique are imported and paid for by the international community, so it is easy to understand why the government of Mozambique failed to see short-term gains in acquiring national production capacity and paying for something – ARV drugs – already provided for free. Finally, the human capital and manufacturing environment fundamentals that made possible the development of the pharmaceutical industry in Brazil are, in all likelihood, not yet in place in Mozambique. As a result, setting up a factory project already tested

back home became highly cumbersome in a context where lack of skills, funds and services is the norm rather than the exception (Cabral, Russo and Weinstock, 2014).

## Conclusion

Contrasting with other chapters in Part I that discuss very different experiences in African countries with a more established pharmaceutical industry, the present chapter has presented an original experience of developing local manufacturing from scratch through collaboration between two national governments. By describing the decade-long process through which Brazil and Mozambique cooperated to set up *Sociedade Moçambicana de Medicamentos* in Maputo, we aimed to illustrate the complexity of shoring up such an ambitious development cooperation project. Our analysis suggests that national and regional demand may justify SMM's production of ARVs and other generic drugs, but that public purchase of drugs remains essential to guarantee the sustainability of the business. We have also highlighted the differences between the two settings, Mozambique and Brazil, and have drawn attention to the possible risks involved in putting emphasis on the development of an enterprise without linking up adequately with local pharmaceutical markets. We believe that such an experience offers an insight into the complexities of developing pharmaceutical manufacturing operations in Sub-Saharan Africa, and into the options that the international community has to support it. The hope is that this will contribute to advancing the debate on local pharmaceutical manufacturing and on paths to its development.



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