

Pharmaceutical Services in Mozambique: foreign aid in public provision of medicines

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Abstract *This article examines the activities of national and international actors in Pharmaceutical Services (PS) in Mozambique from 2007 to 2012, focusing on the public provision of HIV/AIDS, malaria and tuberculosis medicines. It describes how PS functions in the country, what actors are involved in this area and the relations among them, pursuing salient issues in the modus operandi of partners in cooperation. The methodology combines literature review, document survey and analysis and interviews. The theoretical and analytical framework was given by the policy analysis approach, focusing on the role of the State and its interrelations with other actors in foreign aid in PS, and also by the networks approach. It was concluded that the interactions among the actors involved is complex and characterised by operational fragmentation and overlapping of activities between entities, centralised medicine procurement in the hands of few agents, bypassing of national structures and disregard for the strengthening needed to bolster national health system autonomy. Despite some advances in the provision and availability of medicines for these diseases, external dependence is strong, which undermines the sustainability of PS in Mozambique.*

Key words *Pharmaceutical services, Foreign aid, Medicines, Global health initiatives (GHIs), Mozambique*

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Introduction

This article examines pharmaceutical services (PS) in Mozambique from 2007 to 2012, focussing on public provision of medicines and highlighting the main national and international actors operating in this field and their *modus operandi*.

Medicines are considered essential health inputs and decisive to good outcomes in many healthcare situations. They are thus a subject of major attention and conflict nationally and internationally. On the one hand, they are classified as a public good, access to which is a basic human right connected with the right to health and, therefore, to be guaranteed by States. On the other hand, they are consumer goods produced for profit and belonging to the domain of private goods, manufactured and distributed mostly by the transnational pharmaceuticals industry and subject to the logic of the market¹. This duality accompanies the implementation of countries' pharmaceutical policies, where it is the State's duty to mediate between private economic and commercial interests and the needs of the population. That mediation between social demands and economic purposes is expressed in public policymaking and -implementation on, among other things, pharmaceutical services.

The global market in medicines represents annual revenues of around US\$ 300 billion, is steadily growing and should attain around US\$ 1,485 billion in 2021. Populations of the global North have better access to these goods and are their main consumers².

Thinking about access to medicines means looking beyond geographical availability and accessibility, to consider a multidimensional field where the State should assure the right to life and social justice. This entails addressing a much broader range of public and private actors with a diversity of – very often opposing – interests³. The State's role is thus related to its ability to regulate market dynamics and pressures and to intervene to protect its citizens and guarantee the right to health and thus local and global development⁴.

The economy is an important influence on public policy making: it can both contribute to optimising available public and private resources, but also influence regulation in its favour and obstruct the State from performing its duty.

The scenario is made even more complex by the numerous different transnational actors operating in developing countries, particularly in

Africa. As many of its States are unable to meet their care obligations for lack of budget funds⁵, foreign aid in the form of medicine donations – in kind or in funding – is a usual practice, and is present as an option though not without its problems and difficulties.

It is important to assure that medicines are available and accessible to populations severely affected by diseases and with large low-income contingents, because they are one of the determinants of health and one of the bases of social and economic development. Understanding how provision and donation processes take place and the related dynamics that are set up among national and international actors can help to reveal the strengths and weaknesses of those processes and to rethink manners of improving access to medicines and health care. The intention of this study was to contribute to the analysis of foreign aid in health to African countries.

Methodology

This article reports an exploratory case study. The theoretical and analytical framework was given by the policy analysis approach, focussing on the State's role and its interaction with national and other organisations and institutions in implementing specific policy. This meant analysing the State's role: a) as an arena where different actors operate as interest groups or economic and political coalitions⁶; and b) as a relatively autonomous organisation, irreducible to a single pressure group, but conditioned by the interrelations among various actors and other States, in a transnational context⁷. The network approach was also used, where the State should be a mediating element in the interrelations among various actors, which assumes conflicts, cooperation, negotiations and systems of shared regulations, in a complex, dynamic, multi-centric and unstable structure⁸.

The study was conducted using a qualitative approach, including literature search and review (secondary data), plus documentary survey and analysis, in addition to six key-informant interviews, three in Mozambique and three in Brazil (primary data). The documentary survey covered the period from 1975 to 2012, and the analysis, from 2007 to 2012. The interviews were designed to identify actors' perceptions of the issue, so as to complement the information retrieved and to fill gaps in the knowledge constructed⁹. The fieldwork was limited by the difficulty of the docu-

mentary survey and data collection on direct medicine procurement expenditures, as well as by several Mozambican key informants' refusing to be interviewed. The data survey was conducted remotely. The project was approved by the research ethics committee of Brazil's National School of Public Health (CEP/ENSP).

The Mozambique health system and pharmaceutical services

In Mozambique, it is the State's duty to guarantee citizens' right to health. The 1975 Constitution declares: "All citizens have the right to medical and health care, pursuant to the Law, as well as the duty to promote and defend public health" (Art.89). The 2004 constitutional review stated explicitly that: "It is the State's duty to promote, discipline and oversee the production, sale and use of chemical, biological and pharmaceutical products and other means of treatment and diagnosis" (Art.116/5). Following independence in 1975, the Socialist government made policy priorities of PS and organisation of the PS sub-sector, together with setting up a National Health Service (NHS), and specified that health was fundamental to development¹⁰.

Mozambique's NHS is organised on four levels of care. The central level – the Ministry of Health (*Ministério da Saúde*, MISAU) – coordinates the system as a whole. In 2012 it had 1,277 health clinics, 96% of them for primary care; 53 hospitals, 41 of them secondary level, as well as seven tertiary-level and five quaternary-level central hospitals. The epidemiological situation indicated that malaria, diarrheal diseases, respiratory diseases and HIV/Aids are the main causes of death¹¹.

Mozambique has received emergency donations of medicines, particularly from the United States, since the 1970s¹². In the 1980s, it adhered to the International Monetary Fund and World Bank economic rehabilitation programme; national enterprises were privatised, private participation in the service sector increased and so did the number of NGOs active in the country (rising from seven in 1980 to 70 in 1985 and 180 in 1990). The neoliberal economic reform, including reduced spending on social policies, including health policy, was conditional on adhesion to these policies, and continues so today.

Health service funding, which is essential to health sector autonomy¹³, is complex in Mozambique and interrelates with regulations in order for activities and programmes to be conducted;

and it involves the activities of a great multiplicity of national and international actors. At the central level, there are on-budget and off-budget public funds. The former are included in the Treasury Single Account, bound by State planning, execution, accounting and oversight processes and are public funds raised at the central, provincial and district levels, plus contributions from certain cooperation partners¹⁴. Off-budget funds, which do not form part of the general State budget, originate from various external donors and are destined for vertical programmes unconnected with State financial planning.

After independence, a number of bodies were also set up in relation to PS: in 1975, the Medicines and Medical Articles Centre (*Central de Medicamentose Artigos Médicos*, CMAM); in 1977, FARMAC, a public enterprise to nationalise private pharmacies dating from the colonial period; in 1977, MEDIMOC, a State import enterprise, which integrated existing private companies; and, in 1975, the Technical Commission on Therapeutics and Pharmacy (*Comissão Técnica de Terapêutica e Farmácia*). Legislation and protocols were sanctioned, prominent among them the National Medicines Formulary (*Formulário Nacional de Medicamentos*, FNM), which specifies a list of medicines to be used in public and private services, which was revised in 2007 and 2010 and is used to this day. These measures are evidence that Mozambique's public sector took the lead in PS in the 1970s, as compared with other countries of the sub-Saharan region (Mozambique's FNM was published months before the WHO Model List of Essential Medicines, a document that is a world reference)¹⁵.

Medicine provision in Mozambique takes place in stages. The FNM indicates a *selection* of products to be made available. A few (21 medicines) are produced nationally by the Mozambican Medicines Society (*Sociedade Moçambicana de Medicamentos*, SMM) – antiretrovirals, antibiotics, anti-inflammatories, and others – under a cooperation agreement with Brazil centred on technology transfer. Although enormous difficulties exist, this cooperation project continues in place with technical support from the Brazilian government and implementation by Farmanguinhos/Fiocruz¹⁶. The MISAU carries out the *registration* of each medicine that enters Mozambique; however, to this day, prequalified suppliers import medicines for donation that do not always hold national registration.

Procurement is conducted in three ways, depending on the product and the suppliers: 1) by

the “*kits route*” for essential medicines (13 of the 15 listed in the FNM) donated by international organisations, particularly by the United Nations Children’s Fund (UNICEF); 2) by the *donor route* for medicines for the vertical programmes; and 3) by the *classic route*, for medicines in general use, i.e., those not included in the groups above.

On the *kits route*, the central level uses an annual “package” of what are considered “necessary” medicines, demand for which is calculated from the number of appointments held at each health clinic and the expected use frequency. Accordingly, calculation of demand for these medicines depends on consumption as a proxy and does not contemplate the actual local epidemiological situation nor established clinical practices. Medicines for vertical programmes (*donors route*) follow their own quantification and procurement processes stipulated by the various different donors. The *classic route* depends on demand at the central level, which should be updated every four months and contemplate buffer stocks.

The procurement protocol is applied through two types of tendering: “limited competitive bidding”, which includes the pre-qualified suppliers; and “international competitive bidding”, an open process required by specific partners, such as the World Bank, to implement procurement with their funding. There is also emergency procurement, involving a faster dynamic and carried out via limited bidding¹⁷. In principle, this latter arrangement should be used only in cases of extreme medicine shortages or disasters. However, due to constant stock-outs, it is applied often, because it allows purchases to be made and services supplied quickly.

Pharmaceutical service decision-making and operationalisation processes in Mozambique

The medicine provision decision-making process in Mozambique depends on relations and coordination among a variety of national and international actors.

National actors

The main national actors in public medicine provision at the federal level are the Mozambique Ministry of Health (MISAU) and Ministry of Planning and Finances (MPF), both with their respective boards and divisions¹³ (Figure 1).

These interrelations often entail different levels of priority and lead to problems in medicine

provision. Mozambique has published norms for PS in the country, which complement existing rules (Chart 1).

In addition to State institutions and agencies, the donor-funded PROSAÚDE programme is managed in coordination with the State. Introduced in 2000, on the Sector Wide Approach (SWAp) strategy, it is intended to interrelate financing of various kinds in a single fund, so as to enable more efficient interventions, reduce transaction costs and encourage fund management alignment and coordination among donors, and transparency in MISAU operationalisation and utilization of the funding¹⁸. PROSAÚDE, financed with *on-budget funds*, began with 15 partners, including the United Nations Children’s Fund (UNICEF) and the Global Fund Against Aids, Tuberculosis and Malaria (GFATM).

In 2007 a World Health Organisation (WHO) assessment of the pharmaceutical sector in Mozambique¹⁹ recommended setting up an independent regulatory authority with administrative and financial autonomy to perform inspection, registration, clinical trials and pharmacovigilance activities, i.e., to regulate pharmaceutical products, including imported ones. This would entail a substantial administrative reform and, at the time this study ended, the authority had not yet been set up. That situation leads to difficulties in managing imports, because a number of donated medicines have no registration in Mozambique and are not included in therapeutic guidelines. However, because of extreme shortages, it is difficult for the State to refuse them.

There is also a high degree of fragmentation in the health system and, as a result, in provision of medicines (through kits, classic route and vertical programmes), which also leads to problems of management and overlapping activities, in a context of scarce human resources, which are often not properly trained to deal with this multiplicity of actors. There are also numerous structural weaknesses and slow decision-making due to the various different institutions involved. The Ministry of Health is operationally dependent on the Ministry of Planning and Finance, which regulates tendering, and this delays the medicine provision process still further, often to the detriment of the population’s needs¹⁷.

International actors

Numerous international actors play substantial roles in medicine provision in Mozambique, particularly in supplying medicines. Mozambique’s 2011 public health sector budget was

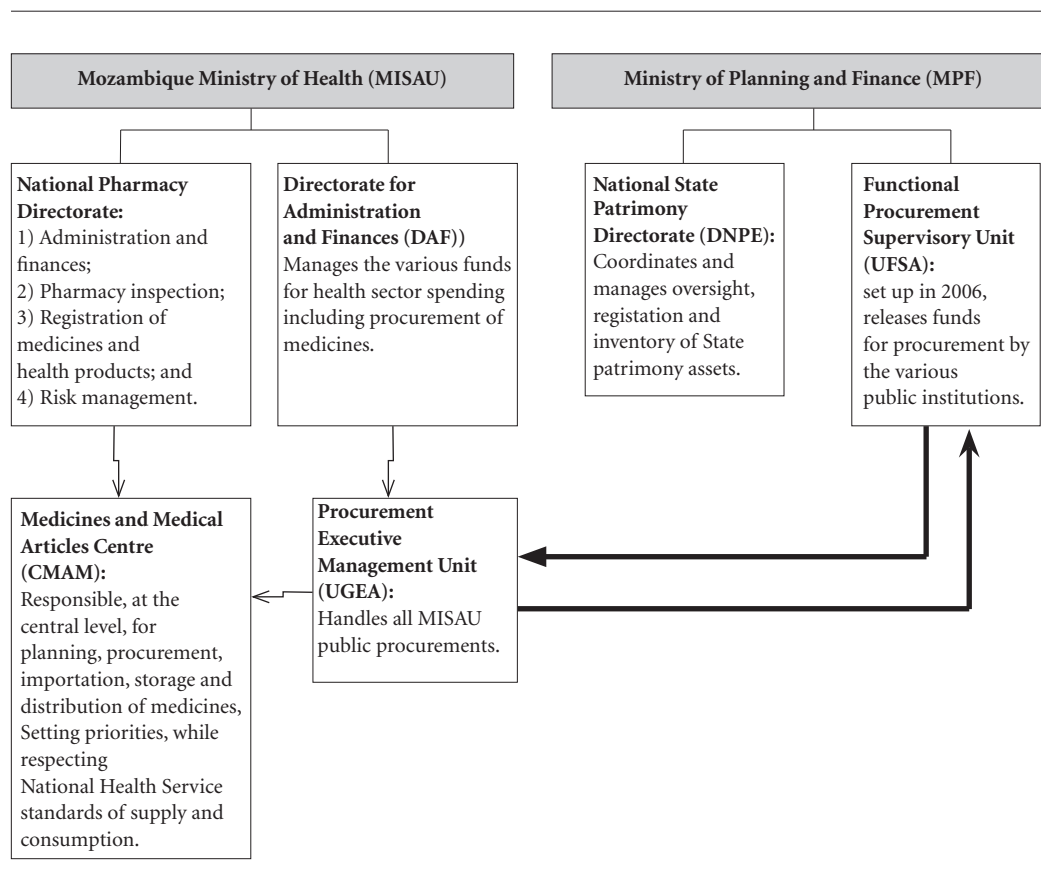


Figure 1. Federal bodies involved in medicine provision in Mozambique, 2015.

Source: the author.

about 81% financially dependent on foreign aid, approximately 60% of which was for procurement of medicines¹⁷.

These actors include the Global Health Initiatives (GHIs), a form of Public-Private Partnership (PPP), which also operate in medicine provision. PPPs emerged in the second half of the 1990s, as an international development strategy, supposedly to improve the private sector contribution to this process, and grew quickly from the 2000s onwards, allied to the neoliberal agenda of health sector reforms, backed by the UN, particularly the WHO during the mandate of Gro Brundlandt (1998-2003)¹³. They are considered by some authors to be “humanitarian actions” in provision of medical and health care and, in synergy with the global health agenda, are focussed mainly on infectious diseases and “neglected diseases”²⁰. Brugha (2008, cited in Biesma et al.²¹) defines the GHIs as “a blueprint for financing, resourcing, coordinating and/or implementing

disease control across at least several countries in more than one region of the world”.

PPPs characteristically differ from GHIs in structure, organisation, areas of intervention, project and country eligibility criteria, fund origins, operating mechanisms (forms of decision-making, management and activity evaluation) in the services and products they furnish. Both are financed, via the off-budget route, by funds earmarked for specific diseases (mainly HIV/Aids, malaria and tuberculosis) or for a particular action (e.g., immunisation and vaccine production). They operate in many countries simultaneously, mobilise large amounts of resources and use the same coordination and implementation strategies regardless of differences in local situations.

The main international actors involved in medicine provision in Mozambique are summarised in Chart 2.

Chart 1. Main norms relating to the National Health Service and Pharmaceutical Services in Mozambique, 2015.

No.	Law/Norm	Content
1	Decree-Law No. 5, 19 August 1975 (Republic of Mozambique)	Provides for the nationalisation of private clinics and the conceptualisation of the National Health Service.
2	DecreeNo.31, 28 October 1975 (Council of Ministers)	Determines the new compulsory registration of all pharmaceutical products.
3	OrderNo.27,25 January 1977 (Ministry of Health)	Publication of the National Medicines Formulary prepared by the Technical Commission on Therapeutics and Pharmacy.
4	Diploma Ministerial No.84, 28 October 1981 (Ministry of Health)	Defines the use of generic names on the National Medicines Formulary and the use of medicines.
5	People's Republic of Mozambique. Maputo, 10 May 1989	Approves the Manual of Norms and Procedures for Distribution of, and Charging for, Medicines.
6	Law No. 25, 31 December 1991 (Presidency of the Republic)	Provides for the creation of the National Health Service.
7	LawNo.4, 14 January 1998 (Presidency of the Republic)	Stipulates how to conduct the process of selection of medicines and their connection with the national register, following the international rules of the WHO, which recommends selecting medicines certified by it, and by suppliers pre-qualified to operate in the country.
8	DecreeNo.54, 13 December 2005 (Council of Ministers)	Determines the modality of State public contract, plus the modalities of tender.
9	Ministerial Diploma No.138, 24 October 2007 (Ministry of Health)	Proclaims the Pharmaceutical Department a body directly subordinate to the Ministry of Health.
10	Ministerial Diploma No.36, 29 September 2008 (Ministry of Health)	Defines the mandatory nature of registration of medicines.
11	Ministerial Instruction No.24, 30 September 2009 (Ministry of Health)	Defines the management of medicine donations.
12	DecreeNo.15, 24 May 2010 (Council of Ministers)	Regulates provision by government agencies subordinated to the central or local authorities; and creates the Functional Supervisory Unit for Procurement, in the Ministry of Planning and Finance.
13	Ministerial Diploma No.54, 23 March 2010 (Ministry of Health)	Approves Mozambique's List of Essential Medicines.
14	LawNo.15, 10 August 2011 (Presidency of the Republic)	Regulates Public-Private Partnerships (PPPs) in Mozambique (known as the PPP Law).
15	Presidential Decree No.34, 23 November 2015 (Presidency of the Republic)	Attributes the Ministry of Health's competences in relation to Pharmaceuticals.

Source: the author.

Foreign assistance for HIV/Aids, Malaria and Tuberculosis

These three diseases were included in this study both because they are considered on the global agenda of the Millennium Development Goals (MDGs) and because they are the diseases that benefit most from foreign assistance. The main international actors involved in provision of medicines for each of these diseases, and the relations among them, are summarised in Figure 2.

Eighteen international organizations are active in the fight against the HIV/Aids, with liaison

among them. In 2012, 96% of funds earmarked for the budget to combat HIV depended on donations, the most important among which were from GFATM and PEPFAR, followed by MAP and UNITAID².

In 2009, the PEPFAR²⁸ signed a document to support Mozambique's Strategic HIV/Aids Response Plan (*Plano Estratégico de Resposta ao HIV/Aids*, PEN 2005-2009). That same year, contrary to the WHO recommendation²⁹ to use Tenofovir rather than Azidothymidine (AZT) as first-line treatment, because it was "less toxic",

Chart 2. Main international actors operating in provision of medicines in Mozambique, 2015.

Institution or Organization	Type of Organization and Operation
Multilateral International Organizations	
WHO/UN	UN body responsible for health matters. Budget comprises regular contributions by Member-States and, from donors (countries and organisations), voluntary non-budget funds for specific programmes. Main donor is the USA, followed by the BMGF. Pharmaceutical companies, such as GlaxoSmithKline, also donate to the WHO. It supplies Mozambique with instruments, such as the list of pre-qualified suppliers; emergency programmes; documents to improve pharmaceutical policy and support to strengthen the pharmaceutical system ²² .
UNICEF / UN <i>United Nations Children's Emergency Fund</i>	Establishes partnerships with various organisations for provision of medicines in 190 countries, outsourcing some aspects of technical assistance. Operates in Mozambique in continuous supply of (particularly antimalarial) kits in collaboration with the PMI ²³ .
Global Initiatives and Public-Private Partnerships (PPPs)	
RBM – <i>Roll Back Malaria Partnership</i>	PPP –to raise and mobilise funding to coordination action against malaria. Set up by the World Bank, WHO, UNDP and UNICEF and its funds are donated by the GFATM, PMI, WB Malaria Booster Program, UK, BMGF ²⁴ .
Stop TB Partnership	PPP –to eradicate TB, funded by the GFATM, national agencies and NGO partnerships with the WB, WHO, UNITAID, Global Fund and UN agencies, to expand direct observation of treatment of multi-drug-resistant tuberculosis, including treatment for HIV/TB. In Mozambique, it funds the process of provision of products and supply of anti-TB drugs via a single international mechanism, the Global TB Drug Facility (GDF). It is a procurement agent set up by the IDA Foundation, and used as an implementer of the GFATM ²⁵ .
UNITAID – <i>Innovation for Global Health</i>	PPP –seeks and implements new quick, economic and effective means of prevention, treatment and diagnosis for HIV/Aids, TB and malaria. Uses a market negotiation approach and funds its operations from national taxes and air charges in some countries. Activities are implemented by local governments, cooperation partners, international and non-governmental organisations ²⁶
AMFm – <i>Q&A Affordable Medicine Facility for Malaria</i>	Initiative set up in 2010 to combat malaria, hosted and managed by the GFATM. Funded primarily by UNITAID and implemented by the GFATM to supply antimalarial drugs at more accessible prices ²⁷ .
GDF – <i>Global Drug Facility</i>	PPP –Set up in 2001 by Stop TB. Was hosted by the WHO in Geneva until 2014. Since 2015 hosted by the United Nations Office for Project Services (UNOPS). The WHO is the lead partner and member of the GDF Coordinating Board and Executive Committee. Today a unique TB drug procurement mechanism and service in the world. Funded primarily by UNITAID from 2007 to 2014. Operates via international tenders from prequalified suppliers and product delivery through to destination ²⁵ .
SWAP – <i>Sector Wide Approaches</i>	International cooperation strategy proposed by Danish development cooperation, particularly in lower-income countries. Implemented in Mozambique in 2000, prompting the creation of PROSAÚDE ¹⁸ .

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this was not implemented in Mozambique, because supply was already being met by provision of partner-donated AZT³⁰.

Figures for 2012 show increased antiretroviral therapy (ARVT) dispensing, reduced prevalence and incidence of HIV, increased coverage and treatment of children, adults and women,

increased prevention of vertical transmission in pregnant women and lower mortality²⁸. However, the MISAU Joint Evaluation (*Avaliação Conjunta*, 2012)³² noted that, in spite of the improved results of the vertical, donor-funded programmes, coverage by vertical transmission prevention and paediatric and adult ARVT were insufficient.

Chart 2. Main international actors operating in provision of medicines in Mozambique, 2015.

Institution or Organization	Type of Organization and Operation
UNITED STATES AGENCIES, INSTITUTES, PPPs AND INITIATIVES	
USAID – <i>United States Agency for International Development</i>	Bilateral cooperation agency, operates as lead implementer of projects connected with activities of United States health programmes (particularly PEPFAR and PMI), with logistics and operational support ²⁸ .
CDC – <i>Centers for Disease Control and Prevention</i>	Research centre of the United States Department of Health and Human Services; operates by supplying antiretroviral and antimalarial medicines and supporting programmes such as PEPFAR and PMI. Present in Mozambique since 2007 with a focus on the three study diseases ¹⁸ .
Deliver Project	Managed by USAID in collaboration with UNICEF, to strengthen the medicine supply system and PS logistics in Mozambique; local capacity-building for management of anti-malarial inputs and technical assistance to the MISAU provided by PMI and PEPFAR ³¹ .
JSI – <i>Research & Training Institute</i>	Non-governmental research institute connected to the company <i>John Snow, Inc.</i> (JSI Inc.), concerned with promoting technical assistance, consultancy and research to improve global health. The company has operated for thirty-five years in partnership with governments, organisations and professionals in the various countries where USAID is active. JSI partners with thirty-six organisations, involving also GHI, STOP TB and the GFATM ³¹ .
MSH - <i>Management Science for Health</i>	United States NGO conducts research and provides technical support to management of US projects at the global level. Funded by six governments (including the USA, Sweden, Kenya and Malawi); seven private actors (including the BMGF, Pfizer Inc., Rockefeller Foundation, Shell); nine multilateral agencies (including the World Bank, Global Fund and WHO); eighteen NGOs and other partners (including Save the Children) and two universities (one in the US and another in Kenya) ¹⁸ .
PEPFAR – <i>President’s Emergency Plan for Aids Relief</i>	United States PPP set up to unify operating strategies for the HIV/Aids epidemic at the global level, funded by national tax quotas. Has eight implementation groups, the most important being USAID. Performs care, treatment, prophylactic and vertical prevention activities ²⁸ .
PMI – <i>President’s Malaria Initiative – Fighting Malaria and Saving Lives</i>	Initiative designed to reduce morbi-mortality from malaria, funded from tax revenues, programmes are managed and implemented by USAID and CDC. Collects health data from other foundations, such as the Clinton Health Access Initiative (CHAI), in order to provide technical assistance to improve antimalarial drug supply ³¹ .
PFSCM – <i>Partnership for Supply Chain Management</i>	NGO set up <i>ad hoc</i> by the US research institutes, Management Science for Health (MSH) and JSI Research & Training Institute. Funded by USAID, operates in provision, offering technical and operational support to PEPFAR, PMI, UNICEF, GFATM and UNITAID ³⁸ .
PPM – <i>Pooled Procurement Mechanism</i>	Known as Voluntary Pooled Procurement (VPP), it is a mechanism used by the GFATM to improve countries’ medicines procurement and logistics. Initially used in this way in Mozambique, but since 2010 USAID has administered it through the PFSCM ¹⁸ .
SCMS - <i>Supply Chain Management System</i>	Procurement mechanism set up in 2005, which schedules and provides antiretrovirals for PEPFAR and antimalarials for PMI, administered by USAID and implemented by PFSCM ³³ . In Mozambique, it provides technical support for scheduling and supply of United States programmes.

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Malaria control activities involved 18 international organisations of various different kinds. Analysis of the data shows that the prevalence, incidence and number of cases notified declined between 2007 and 2012³⁶. In the same period, WHO recommendations led to two changes in

the national therapeutic guidelines. This affected availability of medicines, due to lack of financing for the recommended lines, scarce production at the global level and the difficulty of modifying the existing kits. The State was also found to be slow to approve and release new products when

Chart 2. Main international actors operating in provision of medicines in Mozambique, 2015.

Institution or Organization	Type of Organization and Operation
PRIVATE FOUNDATIONS	
CHAI – <i>Clinton Health Access Initiative</i>	United States private foundation, seeks local solutions for health problems. Operates in HIV/Aids, malaria and vaccines. In Mozambique, receives funding from the BMGF and UNITAID to implement specific programmes and operates as a procurement agent, identifying suppliers of raw materials for medicines ²⁸ .
BMGF – <i>Bill & Melinda Gates Foundation</i>	United States private foundation, funds biomedical research in the science and technology of infectious diseases (HIV/Aids, TB and malaria) and others. In Mozambique, funds some programmes, such as Roll Back Malaria and the GFATM ³⁴ .
IDA Foundation – <i>International Dispensary Association</i>	Dutch social enterprise concerned with supplying medicines and medical materials to health organisations worldwide. The most important of these products are the GFATM procurement contract mechanism and support for the Global Drug Facility against TB. Receives funding from the GFATM, UNITAID, World Bank and WHO ²⁶ .
GLOBAL HEALTH INITIATIVES (GHIs)	
GFATM – <i>Global Fund to Fight Aids, Tuberculosis and Malaria</i>	PPP – funds HIV/Aids, TB and malariaprevention and treatment activities. Receives 95% donated funds from 54 countries, sourced from Official Development Assistance (ODA), the other 5% comes from the private sector (BMGF) and UNITAID. The GFATM launched and approved two Rounds in Mozambique: Round 2 (US\$ 28 million) and Round 6 (US\$ 36 million), for prevention, care, support and treatment for people with malaria ²³ . The GFATM was a member of PROSAÚDE, but in 2008 began to implement an independent mechanism ¹⁸ .
MAP – <i>Multi-Country Africa Program</i>	World Bank loan mechanism for prevention, treatment, community work and health system strengthening; also offers technical support and consultancy through multi-sector and multi-agency approaches, setting up partnerships with the private sector and civil society. Implemented a project in Mozambique from 2010 to 2014 to provide medicines in partnership with UNICEF, UNAIDS and the GFATM ⁴¹ .
PRIVATE AND TRANSNATIONAL PHARMACEUTICS INDUSTRY	
Novartis	Swiss pharmaceutical multinational under contract to the GFATM as provider of medicines to treat malaria (Coartem, an Artemisia-based medicine); also supplies to UNICEF (kits donated to Mozambique) ³⁵ .
NATIONAL PRODUCTION OF MEDICINES: BRAZIL-MOZAMBIQUE BILATERAL COOPERATION	
FARMANGUINHOS/Fiocruz	Technology transfer to install the <i>Sociedade Moçambicana de Medicamentos</i> (SMM), a factory for the production of ARVs and other medicines. Has played an active role in the South-South cooperation project to encourage production of medicines in Mozambique ¹⁶ .
“Fiocruz ÁFRICA”	Fiocruz Representation Office in Africa: arranges, accompanies and evaluates Fiocruz cooperation programmes in health on the African continent, offices in Maputo, Mozambique ¹⁶ .

Source: the author from various sources cited in the table.

these became available, leading to delays in provision.

As regards tuberculosis (TB), there are 10 international organisations operating in Mozambique. The epidemiological data indicate that prevalence and incidence have increased, with no significant variation in the death rate. Coverage by the Direct Observed Treatment, Short Course

strategy has increased, helping reduce treatment dropout rates, and the recorded cure rate was 82% of diagnosed cases³⁷.

Arranging for, and operationalising, medicine provision assistance

There is liaison among the leading international actors involved in medicine provision in

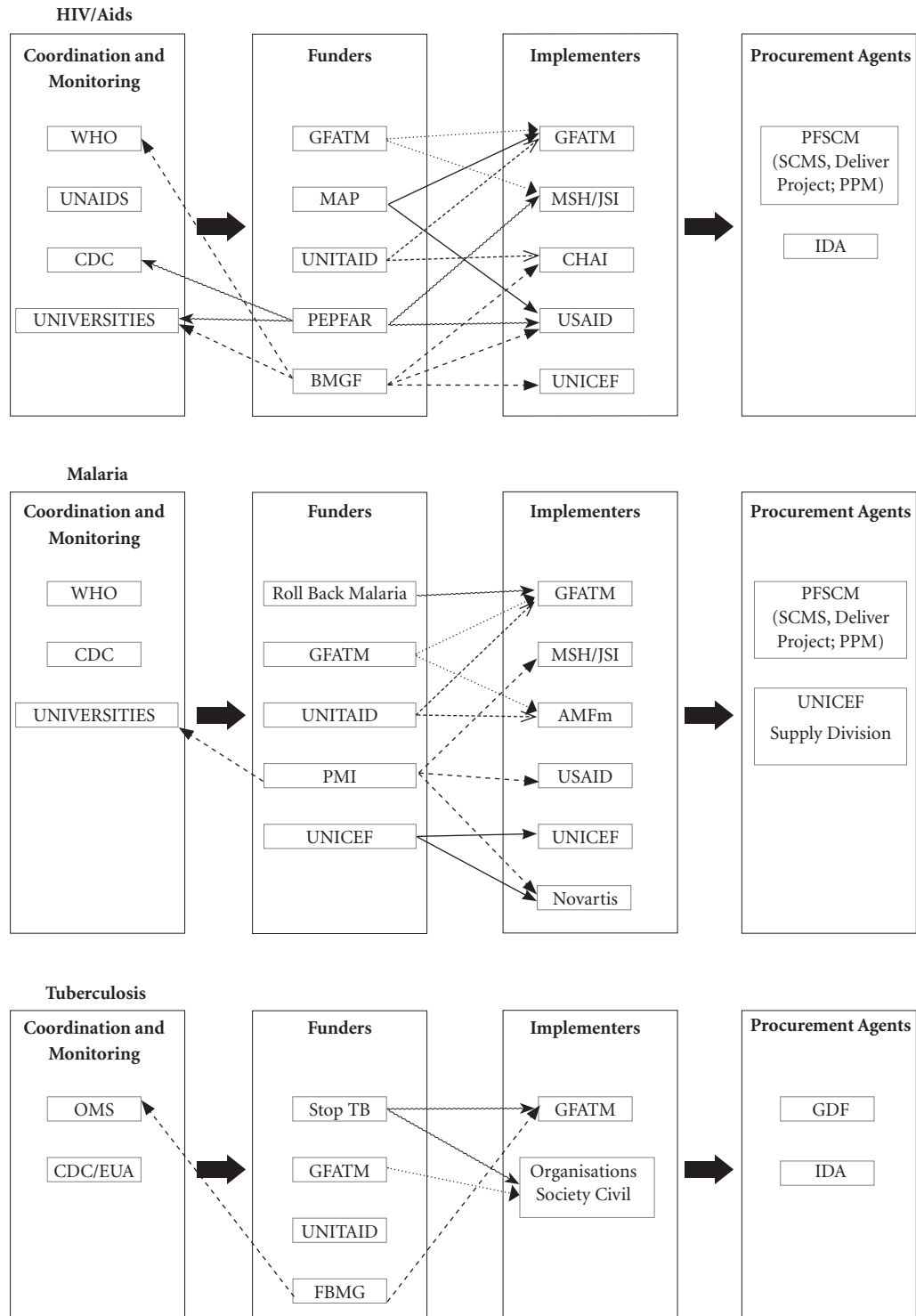


Figure 2. Relations among the main international organisations operating in provision of medicines to combat the HIV/Aids epidemic, Malaria and TB in Mozambique, 2015.

Source: the author.

Mozambique, but each of them has its own *modus operandi*, whether in financing or operationalisation, and they use different supply channels.

Many actors sit on other institutions' committees and boards or are hosted in other organisations (e.g., UNITAID is hosted in the WHO; USAID sits on the Executive Board of Stop TB; IDA is financed by the UN and the World Bank). This aspect may constitute a way of enhancing coordination among organisations and reducing their transaction costs, and equally a strategy for centralising information and hindering the formulation and implementation of national technical and policy proposals different from those prescribed by donors.

The same organisations can play the roles of funder, implementer or both, depending on their nature, the partnerships they establish and the role they occupy in a given programme. Some pharmaceutical corporations (Novartis, in particular) finance medicine providers, such as UNICEF. Private foundations, such as the Bill and Melinda Gates Foundation, also give financial support to multilateral organisations, such as the WHO, or specific funds, such as the GFATM, which can lead to significant influence on decision-making processes¹³.

There are also connections with research institutions (particularly in the United States), whose technical documents influence how GHIs operate. For instance, the Partnership for Supply Chain Management is a non profit organisation created *ad hoc*, whose lead partners – JSI Research & Training Institute, Inc. (JSI) and Management Sciences for Health (MSH) – are also both US non-profits. They all manage the Supply Chain Management System (SCMS), a programme funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development. All these organisations involve numerous partnerships with universities, including Harvard, Johns Hopkins and Columbia, just as PEPFAR and PMI have close financial relations with Seattle University²⁸.

Contrasting with the high number of actors involved in financing, coordination and monitoring, there is a paucity of "procurement agents", i.e., of intermediary organisations used for technical assistance and purchase of large quantities of medicines. Existing agents are the same for many different partners and are generally headed by United States institutions, mainly connected with the USAID-funded Partnership for Supply Chain Management (PFSCM), which manages medicine provision for PEPFAR, PMI, UNICEF,

GFATM and UNITAID. The Deliver Project, financed by UNICEF, is concerned with provision of antimalarial drugs to PMI and UNICEF and distribution of antiretrovirals to PEPFAR. The Global Drug Facility is a unique mechanism supplying medicines against TB, while the IDA Foundation procures medicines for the GFATM, which is also its funder.

The use of the same procurement agents (IDA Foundation, GDF, PFSCM) by various different programmes and GHIs leads to a concentration of management processes, which supplant existing national regulations, to impose harmonisation with the needs and wishes of donors operating off-budget³⁸, not always respecting populations' needs, nor reducing fragmentation of measures or improving coordination processes.

Vertical administration of off-budget funding is justified by the need to economise on transaction costs. It does little to strengthen the planning, management, monitoring and evaluation of medicine provision by local public authorities, while undermining administration by the State, which is disregarded in decision-making on fund allocation and receives these funds in unpredictable and unstable manners, because of the conditions imposed on disbursements, which it is unable to question³⁹.

In the study period (2007 to 2012) three stock-outs were recorded: two of antimalarials, in 2009 and 2010, due to an alteration in the therapy guidelines and failure to adjust how distribution of the medicines was being operationalised; and in 2011, when medicines were found to be expired and improperly stored and inventories out of date, due to the obsolete machines used to input data to the national health information system, compounded by the registration requirements for donated medicines¹⁴.

Under pressure from partners, the MISAU set up eight groups to devise new quantification mechanisms, with a view to preventing such stock-outs. However, nothing was done to address the lack of human resources, nor to replace the equipment that had contributed to the information systems failures. That dynamic introduced external interference into the quantification process, including reducing safety stock periods to one month, rather than the three months stipulated previously by the MISAU³⁹.

Partner disbursements are unpredictable (generally depending on donor-specific internal protocols), obliging the Mozambican State, "induced" by the lack of joint planning, to resort to emergency procurement mechanisms. This mo-

dality of procurement, on the one hand, undermines the national health authorities' planning and management structures, because it does not follow the established administrative and financial processes and, on the other, precludes building any planning history for long-term medicine provision. This also has economic sustainability implications for the whole health sector, confirming the lack of alignment between donors and recipient.

The presence of numerous GHIs operating in Mozambique for long periods, but without totally covering demand for necessary medicines, may constitute yet another obstacle to development of the national health service, because receiving supplies over a long period of time can induce a weakening of national institutions, which do not estimate the funding necessary to assure their sustainability, resulting in a "tyranny of supply"³. The donated products are accepted not because they meet national needs for the public good, but because it is unsustainable to refuse them.

Castel Branco⁴⁰ argues that aid dependence can also affect institutional culture, governance and interaction among actors, hindering the formulation of innovative proposals contrary to the dominant discourse, as well as moulding the structure of the economy and society to the priorities of cooperation partners. The actors involved are of unequal negotiating power and the day-to-day dynamics legitimates this logic, influencing national-level recipients' perceptions of their own capacities.

The "internal drain" on national human resources encouraged to work for international organisations or at least non-governmental organisations, which offer better pay and working conditions, weakens the State even more. Meanwhile, the State civil servants who remain have to meet national requirements and the continual need to formulate projects (in order to receive donations) and to render accounts to donors, on pain of suspension of their interventions. In practice, this situation prevents the Mozambican State from "appropriating" the process, in addition to posing the risk of total stock-out in the event foreign support is withdrawn.

Final remarks

The main findings point to highly complex relations among national and international actors, characterised by fragmentation, interdependence and overlapping. This limits the decision-making

power of the Mozambican State and undermines its leadership of operations, further weakening the health system, which is already fragile as a result of a lack of appropriate installed capacity and high dependence on foreign aid. Although some benefits can be seen in provision of, and access to, medicines, as the analysis proceeds, these are found to be relative, because medicine procurement and provision occur in parallel with the workings of the health system and contribute neither to strengthening it nor to increasing the State's autonomy in implementing its policies.

There have undeniably been improvements in relation to the diseases studied (HIV/Aids, malaria and TB), due to the increasing number of PS measures and greater availability of medicines, which have positively influenced treatment coverage and access, and fostered better conditions of life for many patients; these have enabled strategies to be implemented to reduce the overall price of these materials by increasing demand; they have provided mechanisms to diversify the funding directed to procurement of medicines; and have encouraged the State to develop strategic planning to meet donors' operational conditionalities. At the same time, this dynamic has encouraged the various actors in endeavouring to extend their interaction and participation (although these do not always coincide with better coordination); it has channelled external funding to non-governmental or civil society organisations; and it has caused some strengthening of technical assistance to State institutions⁴¹.

There are, however, controversial aspects that raise questions as to the validity of these interventions. United States actors predominate quite continuously: the US has been operating in Mozambique, through various different mechanisms, since the 1980s, when the International Monetary Fund entered the country. One of the adverse effects of the operations of the different PPPs and other ventures relates to the lack of a comprehensive approach to the health system²¹, which hinders attempts to strengthen it. The lack of alignment with national policies, considered by partners to be obsolete and ineffective, justifying their independent *modus operandi*, leads to operational fragmentation and negligence towards national regulations, as well as to the use of provision as defined from each intervening partner's perspective.

It was not possible in this study to explore in depth and elucidate the operational significance of concepts such as harmonisation, appropriation, inclusiveness, transparency, alignment,

mutual accountability, outcome management and sustainability, which have been discussed, formulated and reiterated at various international meetings (the Declarations of Roma in 2003, Paris in 2005, Accra in 2008 and Busan in 2011) as principles and instruments for improving the effectiveness of foreign aid for global development, and for operationalising donor actions. However, from the findings of this study, it can be inferred that compliance with the norms approved at those meeting has not led to improved

aid effectiveness in Mozambique, but rather to a major concentration of power in the hands of donors or cooperation “partners”.

While not intending to offer recommendations, it is worth stressing the importance of considering medicines as a public good, one of the inputs necessary to guaranteeing the right to health, and thus giving priority to national health care over goals and indicators specified by international actors and possibly overcoming or minimising the market logic embedded in this dynamic.

Collaborations

M Sachy, C Almeida and VL Edais Pepe participated in the conception and structure of the article and in the data analysis and interpretation; in drafting, and critically reviewing the content; and in final approval of the version for publication. They are therefore co-responsible for all aspects of the work.

References

1. World Health Organization (WHO). 2015. *Pharmaceutical Industry*. [acessado 2015 Jul 12]. Disponível em: <http://www.who.int/trade/glossary/story073/en/>
2. QuintilesIMS Institute. *Outlook for Global Use of Medicines through 2021*. 2016. [acessado 2018 Jan 6]. Disponível em: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/outlook_for_global_medicines_through_2021
3. Cassier M, Correa M. Access to Medicine in Developing Countries: Ethical Demands and Moral Economy. *Developing World Bioethics* 2014; 14(2):ii-viii.
4. Paumgarten FJ, Nascimento AC. Regulação Sanitária de Medicamentos. In: Osorio-de-Castro CGS, Luiza VL, Castilho SR, Oliveira MAO, Jaramillo NJ, organizadoras. *Assistência Farmacêutica: Gestão e Prática para Profissionais da Saúde*. Rio de Janeiro: Fiocruz; 2014. p. 207-220.
5. Bermudez JAZ, Oliveira MA, Luiza VL. Assistência Farmacêutica. In: Giovannella L, Escorel S, Lobato, LVC, Noronha JC, Carvalho AI, organizadores. *Política e Sistemas de Saúde no Brasil*. 2ª ed. revisada e atualizada. Rio de Janeiro: Fiocruz; 2012. p. 657-668.
6. Sabatier PA, Jenkins-Smith HC. The advocacy coalition framework: An assessment. Sabatier PA, editor. In: *Theories of the policy process: Theoretical lenses on public policy*. Boulder: Westview Press; 1999. p. 117-166.
7. Skocpol T. Bringing the State Backing in - Strategies of Analysis in Current Research. In: Evans PB, Rueschemeyer D, Skocpol T, editors. *Bringing The State Back*. Cambridge: Cambridge University Press; 1985. p. 4-37.
8. Zurbriggen C. La utilidad del análisis de redes de políticas públicas. *Argumentos* 2011; 24(66):181-209.

9. Reed MS, Graves A, Dandy N, Posthumus H, Hubacek K, Morris J, Prell C, Quinn CH, Stringer LC. Who's in and why? A typology of stakeholder analysis methods for natural resources management. *J Environ Manage* 2009; 90(5):1933-1949.
10. Weimer B. Saúde Para o Povo? Para Um Entendimento da Economia Política e das Dinâmicas da Descentralização no Setor da Saúde em Moçambique. In *Moçambique: Descentralizar O Centralismo, Economia Política, Recursos e Resultados*. Maputo: IESE; 2012. p. 423-488.
11. Moçambique. Ministério da Saúde (MISAU). *Inquérito de Indicadores de Imunização, Malária e HIV/SIDA em Moçambique (IMASIDA)*. Maputo: MISAU; 2015.
12. Abrahamsson H, Nilsson A. *Moçambique em transição: um estudo da história de desenvolvimento durante o período 1974-1992*. Maputo: Padrigu; 1994.
13. Almeida C. Parcerias público-privadas (PPP) no setor saúde: processos globais e dinâmicas nacionais. *Cad Saude Publica* 2017; 33(Supl. 2):1-15.
14. Moçambique. Ministério da Saúde (MISAU). *Relatório da Revisão do Sector de Saúde. 2012*. Maputo: MISAU; 2012.
15. Martins H. Uma Política Farmacêutica de Tipo Novo: Princípios Orientadores e Resultados Práticos da Experiência Moçambicana. *Rev Adm Publ* 1985; 19(1):147-157.
16. Rodrigues RD. *Cooperação internacional da Fiocruz: o caso do projeto de instalação da fábrica de medicamentos em Moçambique* [dissertação]. Rio de Janeiro: Escola Nacional de Saúde Pública; 2014.
17. Durão JR, Regúlez F. *Avaliação Rápida: Aproveitamento de Medicamentos no Setor Público*. Maputo: MISAU; 2011.
18. Global Fund. Escritório da Inspeção Geral (GFATM) Audit of Global Fund Grants to the Republic of Mozambique, *Report GF-OIG-11-018*, 28 Agosto 2012.
19. World Health Organization (WHO). *WHO External Evaluation of the Pharmaceutical Sector in Mozambique. Consolidate Report*. July 2007 [cited 2014 May 10]. Available from: <http://apps.who.int/medicinedocs/documents/s21541en/s21541en.pdf>.
20. Van Dijk DPJ, Dinant G-J, Jacobs JA. Inappropriate Drug Donations: What has Happened Since the 1999 WHO Guidelines? *Educ Health* 2011; 24(2):462-474.
21. Biesma RG, Brugha R, Harmer A, Walsh A, Spicer N, Walt G. The effects of global health initiatives on country health systems: a review of the evidence from HIV/AIDS control. *Health Policy Plan* 2009; 24(4):239-252.
22. Bujones AK. *Mozambique in Transition and the Future Role of UN*. New York: Center on international Cooperation; 2013.
23. United Nations Children's Emergency Fund (UNICEF). *Supply annual Report*. Copenhagen: UNICEF; 2016.
24. Ingabire CM, Alaii J, Hakizimana E. Community Mobilization for Malaria Elimination: Application of an open space methodology in Ruhha Sector, Rwanda. *Malaria J* 2014; 13(167):3-8.
25. Arinaminpathy N, Cordier-Lassalle T, Anant Vijay D. The Global Drug Facility and its role in the market for tuberculosis drugs. *Lancet* 2013; 382(9901):1373-1379.
26. Innovation for Global Health (UNITAID). *CHAI, UNITAID and DFID Announce Lower Prices for HIV/AIDS of the World Health Organization UNITAID*. 2011. [acessado 2015 Jun 10]. Disponível em: <https://donttradeourlivesaway.wordpress.com/2011/05/19/clinton-health-access-initiative-unitaid-and-dfid-announce-lower-prices-for-hiv-aids-medicines-in-developing-countries/>
27. Yamey G, Schäferhoof M, Montagu D. Piloting the Affordable Medicines Facility-malaria: what will success look like? *Bull World Health Organ* 2012; 90(6):452-460.
28. President's Emergency Plan For Aids Relief (PEPFAR). *Quadro de Parceria de Apoio À Implementação da Resposta Nacional de Moçambique ao HIV/Sida Entre o Governo da República de Moçambique e o Governo dos Estados Unidos de América. Estratégia Quinquenal 2009-2013*. Maputo: PEPFAR; 2009
29. Tang MW, Kanki PJ, Shafer RW. A review of the virological efficacy of the 4 world health organization-recommended tenofovir-containing regimens for initial HIV therapy. *Clin Infect Dis* 2012; 54(6):862-875.
30. Médecins Sans Frontières (MSF). Losing Ground. How Global Fund Shortage and PEPFAR cuts are jeopardising the fight against HIV and TB. *MSF Issue Brief* 2012:1-11.
31. USAID/Deliver Project. *Use of Incentives in Health Supply Chains; A Review of Results Based Financing in Mozambique's Central Medical Store*. Arlington: USAID; 2014.
32. Moçambique. Ministério da Saúde (MISAU). *Avaliação Conjunta Anual do Desempenho do Sector de Saúde (ACA XI)*. Maputo: MISAU; 2012.
33. Meny I, Thoening JC. *Las Políticas Públicas*. Barcelona: Editorial Ariel S.A.; 1992.
34. Noronha AB. Filantropocapitalismo: o que esse termo representa para a saúde no mundo. Fundação Rockefeller e Fundação Bill e Melinda Gates: a filantropia que define os rumos da saúde internacional/global. *Revista Rets* 2014; 6(21):8-16.
35. World Bank (WB). *The Multi-Country AIDS Program. Context and Objectives*. Washington: WB; 2011.
36. World Health Organization (WHO). *WHO Statistics*. Geneva: WHO; 2013.
37. Sachy M. *A Assistência Farmacêutica no Sistema de Saúde de Moçambique: um olhar sobre a provisão de medicamentos no setor público* [dissertação]. Rio de Janeiro: Escola Nacional de Saúde Pública; 2016.
38. Ott R. *System strengthening or undermining progress towards the long term goal of a sustainable supply chain: A Case Study of the Mozambican pharmaceutical sector* [essay]. Zurich: NADEL MAS- Center for Development and Cooperation; 2014.
39. Wagenaar BH, Gimbel S, Hoek R. Stock-Outs of Essential Health Products In Mozambique- Longitudinal Analyses From 2011 To 2013. *Trop Med Int Health* 2014; 19(7):791-801.
40. Castel-Branco CN. Dependência de Ajuda Externa, Acumulação e Ownership. Contribuição Para Um Debate de Economia Política. *Cadernos IESE* 2011; 7:1-59.
41. Wafula F, Agweyu A, Macintyre K. *Procurement Cost Trend for Global Fund Commodities: Analysis of Trends for Selected Commodities 2005-2012*. Nairobi: Aidsplan Working Paper; 2013.

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