

INCREASING ACCESS TO MEDICINES LEVERAGING BRAZIL'S EXPERIENCE

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Key Points

- Despite its developing country status, Brazil has successfully ensured access to essential pharmaceuticals for all citizens.
- Five unique factors underlie this success: a sustained government commitment to public health systems and an indigenous capacity to produce pharmaceuticals domestically; the emergence of a civil society coalition built around the norm of health equity; the creation of a functional and independent national regulatory authority; a willingness to leverage compulsory licensing flexibilities within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) related to the production of pharmaceuticals deemed essential to the protection of public health; and the international harmonization of quality assurance and clinical standards related to pharmaceutical research and development.
- Due to the complex historical circumstances underpinning Brazil's success in ensuring access to essential medicines, it is unlikely that other developing countries lacking indigenous manufacturing capacity can achieve similar results in the near to medium-term future.
- Instead, it is recommended that private foundations, such as the Bill & Melinda Gates Foundation, and large bilateral aid country providers, such as the United States, invest in a global funding mechanism. This funding mechanism would use pre-existing, innovative financing mechanisms to scale up production in the handful of developing countries that have achieved near self-sufficiency in pharmaceutical production, for the benefit of populations beyond their borders.

Introduction

This policy brief explores the key socio-political, economic and industrial factors that have contributed to Brazil's success in providing access to medicines to its population, and in promoting health equity both domestically and internationally. It considers how the global community can contribute to, and benefit from, Brazil's ongoing efforts to ensure populations with limited purchasing power have access to essential medicines.

Brazil is one of a small group of middle-income countries (which also includes India, China, Indonesia and Cuba) that has achieved near-total pharmaceutical self-sufficiency as a result of unique socio-political histories; strict replication of Brazil's transformation is therefore unlikely to lead other countries to similar success. However, these select countries' capacity to produce essential medicines can be scaled up to benefit global public health. This can be achieved through investments in a global funding mechanism to increase the supply of low-cost pharmaceutical production by those countries that already have near-total pharmaceutical self-sufficiency. This growth in supply will increase the access to pharmaceuticals to populations beyond their borders. This recommendation



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should be employed alongside two existing strategies: the current public-private partnership model, and the provision of funds to developing countries to enable the purchase of pharmaceuticals.

A Historical Representation of Brazil

After nearly 20 years, Brazil's military regime ended in 1985. Health was proclaimed as a citizen's right by the National Health Conference in 1986, and entrenched in the new Constitution of 1988. The right to health created the foundation for the Unified Health System (the Sistema Unico de Saude or SUS), which "aimed to guarantee free, comprehensive health care to the entire Brazilian population" (Galvão, Bastos and Nunn 2012,10). The health system was decentralized, beginning in the 1980s, which included the expansion of government decision making to more formally include social participation, and the creation of innovative institutions (Paim et al. 2011). While the relationship between social groups and the public sector was historically confrontational, it transformed into one of cooperation in the late 1980s and early 1990s (Galvão, Bastos and Nunn 2012). In particular, regarding HIV/AIDS mobilization, governments began including civil society organizations (CSOs) in government decision making by the 1990s (ibid.). Continuing throughout the 1990s, the two-tiered health system was formalized, consisting of the public SUS, and the supplementary private system, the Sistema Suplementar de Saude (ibid.; Cataife and Courtemanche 2011).

In 1990, the International Conference on Harmonization (ICH) was created to harmonize rules for drug registration among the United States, the European Union and Japan (Berman 2012, 6). Two standards were issued: the Good Manufacturing Practice (GMP), which "covers all aspects of quality assurance in the development, manufacture, and control of pharmaceutical products," and the Good Clinical Practice (GCP) which set standards for all aspects of clinical trials (ibid., 9, 19). These two standards became global guidelines "adopted in non-member emerging and developing countries," which positively impacted Brazil's pharmaceutical production capacity (ibid., 6).

In 1994, the World Trade Organization facilitated the negotiation of the TRIPS Agreement. This established "a uniform set of [intellectual property regulations] across member nations," and thus created the first comprehensive and enforceable global agreement on minimally acceptable intellectual property rights (Subhan 2006). In compliance with the TRIPS Agreement, Brazil adopted a law in 1996 that exceeded the minimum requirements in three specific areas. First, Brazil chose not to fully utilize the transition period provided to developing countries, allowing them to delay implementation until January 1, 2000. Brazil also offered pipeline protection and

adopted national exhaustion of rights when it was not required to do so (Milstien, Gaule and Kaddar 2007, 7613).

In 1999, the Brazilian Health Surveillance Agency (Anvisa), was created under Law 972 as a governmental regulatory agency connected to the Ministry of Health, with the purpose of monitoring products and services that relate to public health (Anvisa 2015).

Brazil's Unique Historical Factors

Government Commitment to Public Health and an Indigenous Production Capacity

Brazil saw health as a universal right that the state had a duty to provide, counter to the dominant trends of the time (Galvão, Bastos and Nunn 2012; Parker 2009; Paim et al. 2011). This not only helps explain Brazil's current position and capacity in public health, but also underscores the difficulty in replication in countries with vastly different histories. The inclusion of health as a right in the Constitution, as well as the inclusion of social movements into health policy more generally, is particularly impressive since Brazil was in a poor economic situation, facing economic instability and the diminishing purchasing power of workers (Paim et al. 2011).

The further maintenance of public sector capacity has been a deliberate political decision. For example, in 1989, under much pressure to the contrary, the national health congress decided not to privatize Far-Manguinhos,¹ underscoring the government's role in providing public health (Galvão, Bastos and Nunn 2012). The social mobilization surrounding HIV/AIDS had spillover effects into many other Brazilian health issues, especially due to investments in health infrastructure and the increasing formalization of the relationship between CSOs and the government (Parker 2009).

In addition to political will, Brazil was able to build upon pre-existing public health infrastructure dating back to the early 1900s (Galvão, Bastos and Nunn 2012). Under the military regime, primary private healthcare systems were greatly expanded in major urban centres, including the creation of the Central Medicines Agency in 1971 (Paim et al. 2011).

Emergence of a Civil Society Coalition

The mobilization of CSOs coincided with the re-democratization process in the 1980s, and has been pivotal to the formation of current healthcare policy in Brazil (Paim et al. 2011). The social

movements that organized around the re-democratization process brought together vastly different groups of society — including grassroots groups, middle-class populations, trade unions and some illegal left-wing political parties — all of which viewed health as a social and political issue that deserved attention and recognition by the government (ibid.). Those groups mobilizing around HIV/AIDS were in their infancy in the 1980s; however, they helped bring together disparate groups such as the Catholic Church, the sanitary reform movement and the gay liberation movement (Parker 2009; Galvão, Bastos and Nunn 2012).

Creation of a Functional and Independent Regulatory Agency

Anvisa's existence allowed Brazil to independently make pharmaceutical regulatory decisions. Regulation of the pharmaceutical industry is crucial in ensuring medicines are "safe, effective, and high quality" (Milstien and Belgharbi 2004, 128). Countries that cannot make their own regulatory decisions often import pharmaceuticals from sources that other regulatory authorities, or the World Health Organization (WHO), have deemed acceptable, increasing the cost and difficulty of accessing high-quality essential medicines in public health crises (ibid.). National regulatory authorities in developing countries are historically considered to be weak; Brazil is an exception and Anvisa is deemed to be functional "in their role as overseers of WHO-prequalified" pharmaceuticals (ibid.; Kaddar, Milstien and Schmitt 2014, 436).

Leveraging Compulsory Licensing Within TRIPS

In developing countries such as Brazil, the TRIPS Agreement limited domestic production of generic drugs that are patented elsewhere (Avert 2015). Initially, Brazilian compliance with TRIPS dramatically increased the cost of second-line treatment (Ciccio 2004). To reduce the price of medications, the Brazilian government successfully leveraged compulsory licensing, a flexibility outlined in the Doha Declaration on TRIPS, which allows for patent exceptions in the case of a public health crisis (Wilson, Kohler and Ovtcharenko 2012, 5). Specifically, Brazil repeatedly threatened to use compulsory licensing, leading to price reductions in AIDS drugs from Abbott, Merck and Roche (Avert 2015).

International Harmonization of Quality Assurance and Clinical Standards

The two ICH standards — GMP and GCP — have had major distributional effects. The first is that high standards for the approval of generic pharmaceuticals increased the cost of pharmaceuticals and clinical trials for non-commercial bodies, as commercial interests of the multinational pharmaceutical industry were promoted over patient interests (Berman 2012,

¹ Far-Manguinhos is the country's largest pharmaceutical laboratory linked to the Ministry of Health, contributing significantly to cost reductions in pharmaceuticals and increasing access among Brazilians as it acts as a regulator of market prices of antiretroviral drugs for HIV/AIDS treatment. See <http://portal.fiocruz.br/en/content/institute-drug-technology-farmanguinhos>.

6). Larger privately held, export-oriented companies and ICH member countries with the resources to comply were positively impacted (ibid., 22). Brazil's pharmaceutical industry was supported by the state and was able to absorb the cost increases, while smaller, locally oriented companies were negatively impacted.

Second, adopters of the ICH standards gained regulatory and scientific capacity because the free and easily accessible ICH guidelines "diffused technical, scientific and regulatory knowledge to the pharmaceutical industry and regulatory agencies" in areas without pre-existing regulatory guidelines (ibid., 30). As an adopter of ICH guidelines, Brazil benefitted.

Replicating Brazil's Success Is Unlikely

Most developing countries do not produce pharmaceuticals, as domestic production is plagued by a host of issues, including lower economies of scale, limited research and development, lack of access to patent-protected technologies and processes, limited experience in launching new products, managing regulatory barriers and/or conducting clinical trials, and price and quality competition from larger and more efficient production sources (Kaplan and Laing 2005; Milstien and Kaddar 2010, 2119). Achieving self-sufficiency is rare, and non-Organisation for Economic Co-operation and Development countries achieving net exporter status among pharmaceuticals is even rarer (Kaplan and Laing 2005).

Brazil, India, China, Indonesia and Cuba are some of a small group of exceptional middle-income countries that have achieved near-total pharmaceutical self-sufficiency (ibid.). These countries have all achieved this success as a result of very different socio-political histories; attempting to replicate their unique historical and industrial transformations is unlikely to lead other countries to similar success with their respective domestic pharmaceutical production systems. Thus, strict reliance on replication is unlikely to result in pharmaceutical self-sufficiency and greater health equity.

Existing Strategies

Currently, two strategies are used to expand access to high-quality, cost-effective pharmaceuticals for poor populations in developing nations.

The Public-Private Partnerships Model

Public-private partnerships (PPPs) were created to address market and state failures regarding the provision of health-related goods and services in developing countries, and thus increase access to pharmaceuticals among poor populations (Brown 2008). These partnerships are typically "based around the provision of products that are donated or heavily [price]

discounted" to populations that cannot afford the market price of these products (Caines and Lush 2004). PPPs address both health problems among populations that "have been neglected because of lack of commercial incentives" and health problems that the public sector and/or non-governmental organizations have been unable to solve independently (ibid.).

However, a key issue with PPPs is the existence of competing interests between developing countries and pharmaceutical companies. Developing countries' governments aim to maximize affordable access to medicines, while pharmaceutical companies' survival rests on maximizing profits by protecting intellectual property (ibid.). The pharmaceutical industry's involvement in PPPs contradicts its promotion of "policies that would restrict developing countries' capacity to utilize TRIPS flexibilities to assist access to medicines" from an ideological perspective (ibid.). PPPs are therefore only a valid option when profits can be guaranteed for the pharmaceutical company. Once profits subside, so too will corporate support, thus eroding the PPP model. Therefore, PPPs should continue to be part of the comprehensive strategy to increase access to medicines among poor populations, but the sole use of this model is not sufficient.

The Provision of Funds to Developing Countries to Facilitate the Purchase of Pharmaceuticals

Currently, some donor countries and organizations provide funds directly to developing countries in need of pharmaceuticals. These countries independently allocate some of these funds toward the purchase of pharmaceuticals from various producers.

However, there are two key issues with this option. The first is that it introduces the potential for inefficiency and corruption on behalf of the recipient states, including limited incentives to choose the highest quality and lowest-cost suppliers, and the potential distortion from accepting bribes (Vian 2008). Second, while this option provides recipient states with pharmaceuticals, it does not facilitate knowledge transfer and capacity support from a country of higher pharmaceutical capacity. Brazil, for example, has taken the lead in partnering with other developing countries to not only provide increased access to pharmaceuticals, but also to build local capacity by facilitate knowledge transfer (Foller 2010). Therefore, direct fund provision to developing countries should continue, but should not be relied on as the main method of increasing access to medicines among poor populations.

Recommendations

The WHO should invest in self-sufficient states through a global funding mechanism to support them in high-quality pharmaceutical production. The global funding mechanism should be created and maintained by the WHO, which would also be responsible for oversight and distribution of monies. This

fund will support a select group of exceptional middle-income countries — not just Brazil, but also countries such as India, China, Indonesia and Cuba — that have achieved total or near-total pharmaceutical self-sufficiency and produce high-quality and reliable medicines. This global funding mechanism will scale up domestic production, to increase production to a level that supports the export of excess medicines to developing countries. Investing directly in these self-sufficient countries is crucial, as this allows those states to build their production capacity, resulting in greater economies of scale. As argued above, replicating Brazil's pharmaceutical production capacity in developing countries is unlikely to be an efficient use of resources.

Furthermore, knowledge sharing among developing countries should be a condition of the funding, to ensure both medicines and pharmaceutical knowledge are exported to developing countries. Specifically, the fund would be used to support physical and human resources, subsidize technology transfer, improve the capacity of national regulatory authorities, shepherd pharmaceuticals through international regulatory processes and invest in other necessary capacities.

The global funding mechanism should invest in Brazil's pharmaceutical production capacity, expanding to support India, China, Indonesia and Cuba. Brazil is a candidate for global support as it has been active in South-South cooperation and has adopted the reputation of an “activist state” that attempts to bolster the health of other countries in the region and around the world (Foller 2010). This, in combination with the financial benefits that accompany increased exports, suggests both a desire and an ability to scale up pharmaceutical production capacity for the purpose of increasing access to medicines among poor populations.

This recommendation mitigates some of the conflict of interest that exists in the PPP model, as Brazil's pharmaceutical production capacity is state-influenced. Finally, without the competing profit motivations of the private sector, Brazil will be able to invest in pharmaceuticals related to diseases primarily plaguing developing countries.

The fund should approach existing private foundations and large bilateral aid agencies for financial support. This fund will use pre-existing innovative financing mechanisms — such as the Global Fund, UNITAID, the President's Emergency Plan for AIDS Relief, and relevant funds from the WHO, World Intellectual Property Organization, United Nations Industrial Development Organization, among others — to scale up pharmaceutical production capacity and knowledge development. The major actors that support states in achieving their health goals are private foundations — such as the Bill & Melinda Gates Foundation, the Rockefeller Foundation, the Wellcome Trust, the Ford Foundation, the UN Foundation and the Aga Khan Foundation — and large bilateral aid country

providers — such as the United States and the United Kingdom (McCoy, Chand and Sridhar 2000). The WHO should approach these donors, encouraging them to adapt their current funding to this new proposed model and support the creation of this global funding mechanism.

Conclusion

Brazil's unique socio-political, economic and industrial history has enabled it to build a strong domestic pharmaceutical production capacity. This capacity has positively impacted health outcomes within Brazil, reduced the domestic prices of pharmaceuticals, and offered a plausible challenge to international pharmaceutical companies. Brazil's unique response to these socio-political and industrial factors make it unlikely that other developing countries will be able to replicate this country's success. However, Brazil is uniquely positioned to act as a leader and supporter of other developing countries aiming to increase their own health equity within their borders, as are a handful of select other middle-income countries (such as India, China, Indonesia and Cuba). A global funding mechanism that employs a variety of international organizations, states and bilateral aid agencies should be established to scale up production capacity and knowledge-sharing functions within countries that have achieved success in domestic pharmaceutical production, thus increasing access to medicines among poor populations in developing countries.

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Acronyms

Anvisa	Brazilian Health Surveillance Agency
CSO	civil society organization
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonization
PPP	public-private partnership
SUS	Sistema Unico de Saude
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization

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