CENTER FOR GLOBAL DEVELOPMENT

CGD BRIEF | JUNE 2023

Leveraging Brazilian Leadership and Procurement Arrangements in the Fight Against Antimicrobial Resistance

MORGAN PINCOMBE, ANTHONY MCDONNELL, AND JAVIER GUZMAN

Building on research and analysis led by INCAE Business School[1]

Summary

Facing the high—and rising—burden of antimicrobial resistance (AMR), Brazil has an opportunity to improve access, stewardship, and innovation for critical antimicrobials at the national, regional, and/or global level(s) by modifying procurement arrangements. Brazil is positioned for significant domestic benefit and further regional leadership in Latin America and the Caribbean (LAC) by leveraging a version of the existing Partnerships for Productive Development (PDP) model for antimicrobials: the annual fee PDP. Products manufactured through annual fee PDPs could be procured across LAC through the Pan American Health Organization's (PAHO) Revolving Funds or through a global procurement platform.

Background

Almost 140,000 people die with a drug-resistant bacterial infection in Brazil every year.[2] Antimicrobial sensitivity tests in Brazil in 2021 found that less than 14 percent of acinetobacter baumannii bacterias examined were susceptible to Carbapenems antibiotics[3]—a resistance rate more than 17 percentage points higher than the worldwide rate estimated by the World Health Organization.[4] Brazil is also the least prepared G20 country to combat AMR, according to a study conducted by the Global Coalition on Aging and the Infectious Diseases Society of America.[5]

Despite this large AMR burden, many critical antimicrobials are not available through the publicly funded Unified Health System (SUS)—the main source of health care in the country, which provides a package of health products and services to all citizens. This reality is partly explained by a stringent market entry system with price caps designed to reward innovation and therapeutic benefit while keeping the cost of publicly funded medicines low. For example, Posaconazole—a drug used against fungal infections—is not sold through SUS, in large part due to the disputedly low assigned price cap.

Despite these challenges, Brazil has several assets in the fight against AMR: Brazil is the most populous country in the LAC region and the eighth largest economy in the world, making it one of the largest pharmaceutical markets in the world and the largest in LAC.[6] Brazil's network of official public laboratories has substantial manufacturing capacity to supply medicines and other health technologies to SUS and Brazil's private market and, more broadly, to other countries in the region and the world. These public laboratories have also successfully received technology transfer from multinational pharmaceutical companies in the past through several mechanisms, including the PDP model.

Partnerships for Productive Development Model

The PDP model, launched in 2009, has a successful track record of bringing new medicines to Brazil, stimulating local production, and decreasing treatment costs, though results vary by partnership.[7] Under a PDP, a Brazilian public laboratory enters an agreement with a pharmaceutical company, which gradually transfers the technology and production of a health product over the course of ten years. The Ministry of Health, which must approve the PDP, then purchases the product from the public laboratory on behalf of SUS at an agreed price and volume. At the end of the PDP, the public laboratory fully supplies the product to SUS, while the pharmaceutical company may still supply the private market.

As of December 2022, there were 66 active PDPs, mainly related to antivirals, anticancer, and immunosuppressant medicines. PDPs generated estimated savings for SUS of more than $500 million between 2011-2018, mostly due to a decline in price of over 50 percent charged for drugs subject to PDPs.[8] The PDP model is a largely untapped opportunity for the antimicrobial market, as there is only one PDP for an antimicrobial—a tuberculosis treatment.

The Annual Fee PDP: Delinking Profit from Sales Volume in the PDP Model to serve LAC

Payment within the traditional PDP can be modified to secure steady, predictable revenue while disincentivizing overuse and inappropriate use of antimicrobials. This modified payment system would help make the market for these drugs financially viable while protecting the effectiveness of the drugs.

Traditional PDPs link the volume of sales to revenue—i.e., the procurement entity pays both pharmaceutical companies and public laboratories more for each additional unit. Annual fee models can help protect against incentives to oversell by setting a fixed payment independent of the volume purchased. Similar interventions have been piloted in settings like the UK and proposed in the US.[9]

In the proposed model, the annual fee PDP, PAHO's Revolving Funds would pay a fixed annual sum to the pharmaceutical company and the official lab, independent of the number of units purchased on behalf of LAC countries. Several elements would be factored into the calculation of the annual fee, including adherence to stewardship standards and countries' ability to pay, to ensure equity among LAC countries, among others.

The annual fee PDP model would offer several benefits:

- Strengthen and expand domestic antimicrobial production capacity through technology transfer;
- Improve access to new high-cost antibiotics that might otherwise not be economically attractive to bring to LAC, while providing support to strengthen stewardship efforts; and
- Decrease incentives to oversell drugs through the annual fee-style payment.

Key Considerations and Options for Implementing the Annual Fee PDP in LAC

The first step to implement the annual fee PDP for antimicrobials in LAC will be to conduct horizon scanning to determine the molecules that should be considered for this PDP model. The annual fee PDP model could initially be applied to recently developed synthetic antimicrobials that are available in the private market, but not through public procurement channels in LAC, and/or high-cost antimicrobials or ones available from a single supplier.

Selected molecules must then be listed as "strategic products" within SUS. PDPs can only apply to products with this distinction, which typically indicates that the products are costly, mainly imported, technologically complex, and/or at risk of shortage.[10]

PAHO's Revolving Funds would also need to include the selected antimicrobials in their portfolio of services, and voluntary licenses would have to be granted for the LAC region, not just Brazil's domestic market. Prior voluntary licensing deals—such as the licensing agreement signed between Shionogi, GARDP, and CHAI for cefiderocol that covered 135 countries, including all 33 from LAC[11]—lay the groundwork for similar future deals and could be well suited to a regional manufacturer in LAC.

This regional hub, with Brazil as the supplier and PAHO's Revolving Funds as the procurer, could be integrated into a global procurement framework, in line with the arrangement that a CGD working group is considering,[12] to facilitate access to a portfolio of medically important antimicrobials and diagnostics facing access issues in low- and middle-income countries.

Selecting the antimicrobials to prioritize, advancing the conversation with the pharmaceutical industry on voluntary licensing, developing the methodology to calculate the annual fee payments, and garnering support among key stakeholders in the region are critical next steps in implementing the annual access fee model in LAC. CGD is conducting several briefings with regional institutions that could help advance this proposal, including PAHO and the Inter-American Development Bank.

Endnotes

1 https://www.cgdev.org/publication/facing-pandemic-antimicrobial-resistance-current-actions-and-future-challenges
2 https://vizhub.healthdata.org/microbe/
3 https://app.powerbi.com/view?r=eyJrIjoiZDIwZjYyMzUtMmYxZS00MTRjLTk0NWMtZWE2ZDUzOGRjOTVjIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9
4 https://worldhealthorg.shinyapps.io/glass-dashboard/
5 https://globalcoalitiononaging.com/wp-content/uploads/2021/06/GCOA-AMR-Preparedness-Index_FINAL.pdf
6 https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicines-2022/global-use-of-medicines-2022-outlook-to-2026-12-21-forweb.pdf
7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6178857/
8 CGU. 2019. "Relatório de Avaliação. Secretaria de Ciência, Tecnologia e Insumos Estratégicos." Controladoria-Geral da União.
9 https://www.gov.uk/government/news/world-first-scheme-underway-to-tackle-amr-and-protect-uk-patients; https://www.congress.gov/bill/117th-congress/senate-bill/2076/text
10 https://www.scielo.br/j/csp/a/63L4VL6b4mkVZVJdw6SPXVn/?lang=en; https://doi.org/10.1590/1413-81232018236.06482018
11 https://gardp.org/wp-content/uploads/2022/06/License-and-Technology-Transfer-Agreement-1.pdf
12 https://www.cgdev.org/working-group/new-grand-bargain-antimicrobial-resistance-amr

MORGAN PINCOMBE is a program coordinator at the Center for Global Development.
ANTHONY MCDONNELL is a senior policy analyst at the Center for Global Development.
JAVIER GUZMAN is the director of Global Health Policy and a senior policy fellow at the Center for Global Development.

CENTER FOR GLOBAL DEVELOPMENT
www.cgdev.org