Empowering Access: Evaluating the Impact of Partnerships for Productive Development (PDP) on access to Rituximab in Brazil

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Introduction:

The aim of PDP is to expand access to medicines and health products considered strategic for the Unified Health System (SUS), in addition to strengthening the country's Economic-Industrial Complex.[1] As part of Brazilian public health policy, the so-called PDP is an acronym standing for Parcerias para o Desenvolvimento Produtivo (Productive Development Partnerships), which consists of a technology manufacturing transfer from a product already on the Brazilian market in order to be locally produced within the country.

To comprehend the Brazilian PDPs, it is important to understand its objectives and significant impact on public health system (Figure 1):

Figure 1 – Diagram displaying the PDP's purposes. Adapted from PDP (2024)

Partnerships are made between public institutions, private companies and the Ministry of Health (MoH).[2]

The MoH commits to purchasing a product (such as drugs, vaccines, blood products, equipment, medical-hospital items) for a specific period, while the private companies are obligated to transfer the production technology of the product to a public laboratory within the same term. By the end of the agreement, the public laboratory is expected to be fully capable of supplying the product to the MoH.[2]

At Figure 2, there are four phases that encompass the process of analysis, execution, and finalization of a PDP.[1]

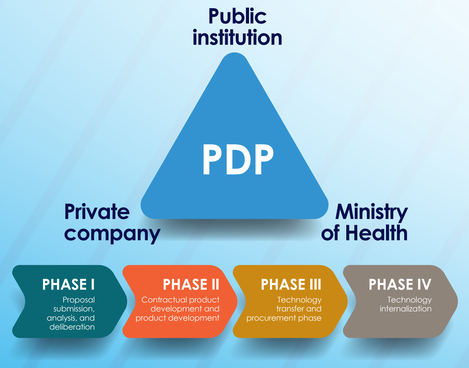

Figure 2 – Figure indicating the Phases of Technology Transfer Process. Adapted from PDP (2024).

In 2019, a partnership was established between Sandoz, Bio-Manguinhos/Fiocruz, and Bionovis. Bio-Manguinhos/Fiocruz and Bionovis are 100% Brazilian biotechnology companies that serve as the technology transfer sites, and they are pioneers in the production of highly complex biological, monoclonal antibodies. As a result of this partnership, the Brazilian Ministry of Health (MoH) has been distributing the rituximab mAbs through the Unified Health System (SUS), free of charge for patients according to guidelines developed by national health authorities. Those official protocols are named as PCDT (Clinical Protocols and Therapeutic Guidelines). Sandoz Rituximab has the same indications as the reference product in Brazil and is approved for public distribution for the treatment of non-Hodgkin's lymphomas, including large B-cell lymphoma and follicular lymphoma, as well as rheumatoid arthritis.[3]

Objectives:

This study aims to look whether the expectations of reducing public costs of rituximab resulting from the introduction of this biosimilar in Brazil's public healthcare system through the PDP has been achieved so far.

Methods:

This is a retrospective observational study.

We analyzed IQVIA Non-retail Channel report and public data from Brazil's SUS, which covers the supply of at least 50% of the public market with Rituximab Sandoz.[5] This analysis was conducted before and after the agreement to provide this biosimilar through public-private partnership involving technology transfer (PDP), aiming to improve access to essential medications and grant production autonomy to national institutions.

The agreement between MoH, Bionovis and Sandoz has started in 2019. The data collected refers to Moving Annual Total (MAT) of May 2019 and Moving Annual Total (MAT) of May 2023.[4]

All values were adjusted according to the Extended National Consumer Price Index (IPCA), a measure of Brazilian inflation.[6]

Exposure to Rituximab was calculated in number of patient doses (PD), considering 1g per patient as the maximal dose in all label indications. The calculation was based on the maximal dose recommended based on the mg/m^2 body surface area dosing, i.e., 1 g per patient, as follows: rituximab patient exposure (patient doses) = quantity of rituximab sold (g)/maximum recommended dose (g/patient) (Table1).

Results:

In May 2019 the Rituximab public market was valued at approximately BRL 182.8 million (values adjusted for inflation - IPCA rate) or approximately USD 36.6 million, just before the agreement for PDP.[4]

In May 2023, it decreased to approximately BRL 167.2 million or the equivalent to approximately USD 33.4 million.[4,7]

During the same period, the patient doses distributed increased from 30.068 to 38.970, representing a 28% increase in patient doses distributed by Brazilian MoH (Figure 3).[4]

The rational is explained in **Table 1**

28%

Rituximab	Units 2019	Units 2023	Patient doses 2019	Patient doses 2023
100mg/10mL	15.850	35.323	3.170	6.846
500mg/50mL	53.796	63.812	26.898	31.906
1400mg/11.7mL	360	277	360	277
TOTAL	**70.006**	**99.412**	**30.428**	**39.029**

Table 1 – Calculation of Patient doses based on IQVIA report. (2024)

According to the accountability of the SUS through its expenses on the acquisition of rituximab in 2019, approximately BRL 116 million or USD 23.2 million (values adjusted for inflation - IPCA rate) were spent compared to BRL 93 million or USD 18.6 million spent on the same medication in 2023, an approximate reduction of 20%.[8]

Discussion:

While the available data does not currently allow for definitive conclusions regarding whether the observed growth is attributable to an epidemiological upswing, enhanced access, or increased affordability, the following insights emerge from the analysis of the expenditure per dose distributed by the MoH:

The annual cost of rituximab for MoH decreased by 20% through PDP, which corresponds to BRL 23 million or USD 4.6 million (values adjusted for inflation - IPCA rate).[8]

The integration of biosimilar pharmaceuticals into the market, along with the implementation of the supply agreement facilitated by the PDP, resulted in price adjustments driven by the competitive dynamics among different brands, culminating in a favorable effect on overall federal expenditures.

The supply of rituximab biosimilar through PDP also indirectly resulted in approximately a 28% increase in patient doses or a 42% increase in units distributed (Figure 4), while reducing the public market value by approximately 8,5%.[4]

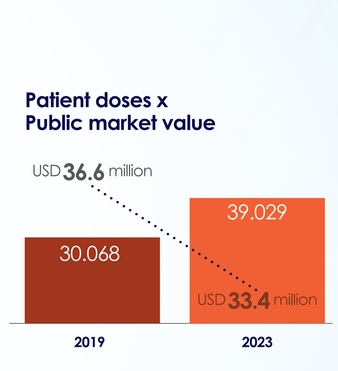

Figure 3 – Increase in PD after the introduction of PDP in the public health system of Brazil, without an equivalent cost increase. (2024)

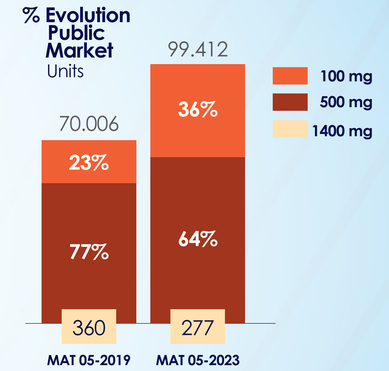

Figure 4 – Chart showing the units of rituximab distributed in the public market. Report from IQVIA NRC MAT May/2019 and May/2023 (2024).

This study has potential limitations. The SUS data only captures the values carried out by the Brazilian Ministry of Health, purchases made independently by the Brazilian States, City Halls and Public Hospitals are not included in this audit, and it was not possible categorize which government channel made the purchases.

Conclusion:

The data reveals **noteworthy cost savings** for the Brazilian government and enhanced **accessibility** to crucial medications, aligning with the **anticipated** requirements of the PDP. Moreover, this underscores that beyond technological advancements, the PDP serves as a pivotal public health initiative, augmenting **access to high-cost therapies** for the Brazilian population.

Ref.: 1. Parcerias para o Desenvolvimento Produtivo (PDP). Available at.: https://www.gov.br/saude/pt-br/composicao/sectics/pdp. Accessed: [April,2023]; **2.** Productive Development Partnerships: Rationale. Available at.: https://www.ipea.gov.br/cts/en/all-contents/articles/articles/355-productive-development-partnerships-rationale-2. Accessed: [April,2023]; **3.** Sandoz Brazil. Available at.: https://www.sandoz.com.br/news/media-releases/bio-manguinhosfiocruz-passa-fornecer-rituximabe-ao-sistema-unico-de-saude/. Accessed: [April,2023]; **4.** IQVIA data. Report RNC IQVIA May/2023.; **5.** PDP demand. Available at.: https://www.gov.br/saude/pt-br/composicao/sectics/pdp/fase-III/arquivos/fase-III-parcerias-para-o-desenvolvimento-produtivo-medicamentos. Accessed: [April,2023]; **6.** IPCA rate. Available at.: https://www.bcb.gov.br/meubc/calculadoradocidadao. Accessed: [April,2023]; **7.** Exchange rate. Available at.: https://www.bcb.gov.br/content/controleinflacao/focusdistribuicoesfrequencia/P20231204-Focus-Distribuicoes-de-frequencia.pdf . Accessed: [April,2023]; **8.** Ministério da Saúde. DATASUS. Tabnet. Brasília, DF: Ministério da Saúde, 2023.

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