Technical Note

PRODUCTIVE DEVELOPMENT PARTNERSHIPS: RATIONALE OF ITS FOUR PHASES

Diset

Department of Sectoral Studies and Policies, of Innovation, Regulation and Infrastructure

Nº 121

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ipea
Institute for Applied Economic Research

September 2023

Federal Government of Brazil

Ministry of Planning and Budget
Officer Simone Nassar Tebet

ipea Institute for Applied Economic Research

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How to cite:
CHIARINI, Tulio; PIMENTEL, Vitor Paiva; PARANHOS, Julia. **Productive development partnerships**: rationale of its four phases. Rio de Janeiro: Ipea, Sept. 2023. (Diset: Technical Note, 121). DOI: http://dx.doi.org/10.38116/diset121.

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Contents

1 INTRODUCTION[1]

Productive Development Partnerships (Parcerias para o Desenvolvimento Produtivo – PDPs) are a procurement tool used by the Brazilian federal government to promote the local production of health products and services, particularly drugs and vaccines.[2] Positioned within the diffusion phase of the innovation process, PDPs aim to promote the dissemination and uptake of emerging or existing products that have the potential to strengthen local production capacity and lead to incremental innovation.

The overarching objective of PDP is to stimulate the development of the Health Economic-Industrial Complex (Complexo Econômico-Industrial da Saúde – Ceis) in a systemic effort. A PDP agreement typically involves three parties: the Ministry of Health (MoH), which agrees to purchase a product (mainly drugs, vaccines and blood derivatives, but also equipment, and medical-hospital items) for the Unified Health System (Sistema Único de Saúde – SUS) for a fixed term of up to ten years. In turn, private companies agree to transfer the production technology for this product to a public laboratory[3] for the same period. During the technology transfer process private companies supply the product to SUS. At the end of the partnership, the public laboratory should be able not only to produce the product in its own country, but also to supply it independently to the MoH and to transfer the technology to other public laboratories at the request of the federal government.

Implementing a PDP is a lengthy and complicated process. The purpose of this *Technical Note* is to provide a summary of the PDP, with an emphasis on explaining the rationale behind its four phases:

- Phase I: proposal submission, analysis, and deliberation;
- Phase II: contractual and product development;
- Phase III: technology transfer and procurement phase (PDP as such); and
- Phase IV: technology internalization.

To achieve the aforementioned objective, this *Technical Note* is structured as follows: section 2 provides a concise contextualization of the Ceis. Section 3 outlines the four phases that encompass the entire process of analyzing, implementing, and finalizing a PDP. Finally, the last section presents the concluding remarks.

2 SHORT CONTEXTUALIZATION

The healthcare industry is a complex and interconnected system, which can be analyzed through the Ceis framework, as highlighted by Gadelha (2003; 2021). In Brazil, this complex accounted for 9.2% of the gross domestic product (GDP) in 2019, based on production data.[4] The Ceis consists of both the public

1. This work was funded by the Brazilian Ministry of Health (TED No. 06/2022) and it is based on Pimentel, Paranhos, and Chiarini (2022).

2. Although sharing a similar name and a common acronym, there is no relation with "Product Development Partnerships", a frequent model for vaccines and neglected diseases development under the World Health Organization (WHO) guidance. Furthermore, other acronyms, such as public-private partnership (PPP) and pre-commercial procurement (PCP), also contribute to ambiguity (refer to Box 1 for further clarification).

3. Public laboratories are state-owned entities established by the Brazilian federal government (União) or state governments (Estados).

4. Data sourced from the Brazilian Institute of Geography and Statistics (Instituto Brasileiro de Geografia e Estatística – IBGE) (Conta-Satélite de Saúde and Contas Nacionais), available at: https://www.ibge.gov.br/estatisticas/sociais/saude/9056-conta-satelite-de-saude.html; and data on GDP, available at: https://www.ibge.gov.br/estatisticas/economicas/contas-nacionais. Accessed on: Aug. 16, 2023. Note: The aggregate encompassed the following categories: "pharmaceutical product manufacturing" (fabricação de produtos farmacêuticos), "production of medical, dental, and optical instruments and materials" (fabricação de instrumentos e material medico, odontológico e ótico), "private healthcare" (saúde privada), and "public healthcare" (saúde pública).

(2.9% of GDP) and private (5.0% of GDP) healthcare delivery subsystems, as well as the pharmaceutical chain (1.0% of GDP) and the medical devices industry (0.3% of GDP) within the industrial subsystem. Understanding the composition and impact of the Health Economic-Industrial Complex is critical for policymakers and stakeholders to understand the complexity of the healthcare industry and its potential to promote economic growth and development.

In 2019, prior to the Sars-COV-2 pandemic, Brazil ranked seventh in the world in pharmaceutical market sales, with a turnover of approximately USD 26 billion, including USD 17 billion in the retail sector and USD 8.6 billion in the institutional sector (Interfarma, 2020).[5] Sales of medical, hospital, and dental equipment and supplies were estimated at USD 8.3 billion for the same year.[6] The Ceis trade deficit reached USD 9 billion[7] in 2019, with a particular concern being the dependence on imported active pharmaceutical ingredients (APIs), which account for 90% of the apparent consumption of these inputs (Mitidieri et al., 2015) . The medical, hospital, and dental equipment and materials sector is in a more critical situation, as it is heavily dependent on imported electronic components and has low competitiveness, with few niche products being produced domestically (Landim et al., 2013).

Purchases of pharmaceuticals by the federal government were estimated at USD 4.1 billion[8] in 2019 (De Negri, Mello, and Mourthe, 2023), representing 17% of the Brazilian pharmaceutical market. Between 2010 and 2019, the federal government significantly increased its participation in pharmaceutical aid financing, reversing the trend of the previous decade, which had focused on the decentralization of such actions (Pimentel, 2018). Centralizing medicine purchases by the federal government was a deliberate and negotiated move as part of health management under the federative pact.[9] Notably, the MoH's strategy to centralize strategic products through the implementation of PDPs is a key element of the Ceis development project (Fonseca and Costa, 2015) and it has been involving increasing allocation of public funds (from USD .40 billion in 2011, peak of USD 1.26 billion in 2014 and USD .42 billion in 2022, Figure 1).[10]

5. The retail channel refers to purchases made by individual consumers in pharmacies, while the institutional channel refers to purchases made by government entities and hospitals. Brazilian *reais* (BRL) were converted into USD using annually averaged exchange rates meticulously curated by Ipeadata, drawing upon data sourced from the Brazilian Central Bank (Banco Central do Brasil – Bacen). In the year 2019, the prevailing exchange rate stood at 3.95 BRL to 1 USD. Available at: http://www.ipeadata.gov.br/. Accessed on: Aug. 16, 2023.

6. Available at: https://bit.ly/3bHX7mo. Accessed on: Jan. 10, 2022.

7. It corresponds to the total trade deficit calculated by the Association of the Research Pharmaceutical Industry (Associação da Indústria Farmacêutica de Pesquisa – Interfarma) and the Brazilian Association of the Medical Device Industry (Associação Brasileira da Indústria de Dispositivos Médicos – Abimo).

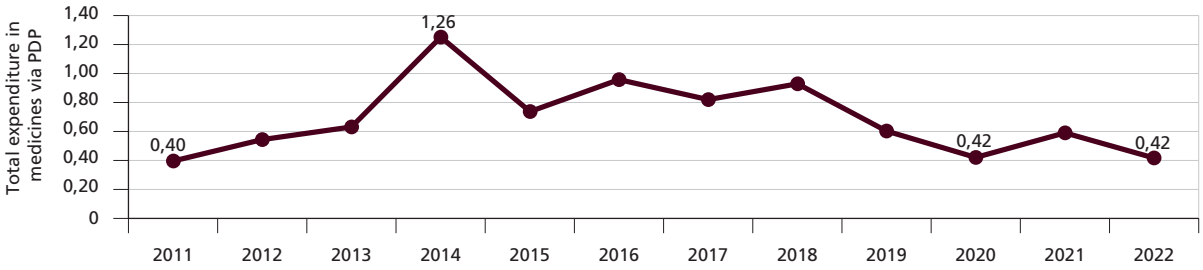
8. Brazilian *reais* (BRL) were converted into USD using annually averaged exchange rates meticulously curated by Ipeadata, drawing upon data sourced from the Bacen. In the year 2019, the prevailing exchange rate stood at 3.95 BRL to 1 USD. Available at: http://www.ipeadata.gov.br/. Accessed on: Aug. 16, 2023.

9. The pact establishes the division of competencies, revenues, and expenditures among the three levels of government, as well as the mechanisms for coordination and cooperation between them.

10. Refer to Figure A.1 (Appendix A) for BRL values.

FIGURE 1

Amounts spent in USD annually on the acquisition of medicines via PDP (2011-2022)
(In USD billion)



Source: MoH. Available at: https://www.gov.br/saude/pt-br/composicao/sectics/deceiis/pdp/fase-III.
Authors' elaboration.
Obs.: Brazilian *reais* (BRL) were converted into USD using annually averaged exchange rates meticulously curated by Ipeadata, drawing upon data sourced from the Brazilian Central Bank (Bacen).

Ensuring the availability of medicines, materials, and medical equipment at reasonable prices and with stable supplies is essential to achieving the principles of universality and integrality of SUS. However, the vulnerability of the SUS is related to the weakness of the Brazilian industrial system, its limited capacity for innovation, and the disconnection between its scientific and technology base and the health needs of the population. This weakness poses a risk to the provision of key inputs and healthcare products in Brazil, given the limited supply in the international market and a limited budget that is subject to exchange rate fluctuations (Fernandes, Gadelha, and Maldonado, 2021). The risk materialized clearly during Covid-19 pandemic, as noted by Reis and Pieroni (2021).

BOX 1

PDP, PPP and PCP

Legally, the PDP corresponds to the traditional figure of the agreement and the administrative contract (Glassman, 2020), but it is not to be confused with the PPP, as dealt in Law No. 11,079 of 2004, inspired by the Private Finance Initiative (PFI) program in the United Kingdom (UK). The main differences between PDP and PPP are presented by Glassman (2020):

- Investment responsibility: in PPPs, the private partner invests in public services and infrastructure as payment throughout the contract. In contrast, in PDPs, the private partner transfers its production technology to a public laboratory, who is responsible for the local investments (Garcia, 2019);
- Multilateralism: PDPs involve the MoH in addition to the public and private partners. The ministry has specific responsibilities, such as oversight, providing technical guidance to the partnership, and procuring the medicines produced under the contract;
- Guarantee of demand: in PDPs, there is a commitment to purchase by the MoH (SUS), while in PPPs, there is not necessarily a guarantee; and
- Formation of a legal entity: PPPs require the formation of a "specific purpose vehicle" (as per art. 9 of Law No. 11.079/2004), whereas PDPs do not require the creation of a legal entity. Instead, they involve a "temporary and limited joint venture between state administrative entities and private companies" (Justen Filho, 2018, p. 320).

According to Glassman (2020), it is inaccurate to refer to PDPs as a type of PPP, even if this is done in a general sense. This is because the two models, PDP and PPP, have opposite objectives. PPPs aim to shift the responsibility of fulfilling a constitutional mandate from the State to the private sector, while PDPs seek to involve the state structure, specifically official pharmaceutical laboratories, in the production of medicines that could otherwise be produced by private entities. In other words, PDPs attempt to bring activities within the state structure, whereas PPPs aim to take activities outside of it.

Pay attention to the difference between PDPs and PCP. The latter, which is common in the United States, involves contracting research and development (R&D) that leads to a prototype (Sampat, 2012). PCPs are similar to what is known in Brazilian legislation as a technology order, which is a special type of public purchase aimed at solving specific challenges through financing R&D activities for the development of products, services, or systems with specifications that are not yet available on the market or do not exist. In this case, the government purchases the R&D effort, but the result of the technology order may not necessarily be a useable product or service. It involves considerable technology risk and may only result in a prototype. For instance, in the US experience, technology commissioning contracts only lead to prototypes, not products ready to be used in a real environment (Rauen, 2018). In contrast, PDPs involve technology transfer of a product that has already been introduced in the market but whose production capacity is not available in the country. During a PDP, the MoH purchases a real operation product, which is actually used in healthcare. Thus, it is not appropriate to associate PDPs with the concept of PCP. PCPs (Encomenda Tecnológica) were established by art. 13 of Decree No. 9.245/2017 and are used to contract a private partner to carry out R&D activities that involve technology risk to solve specific technical problems or obtain innovative products, services, or processes in the health sector.

Authors' elaboration.

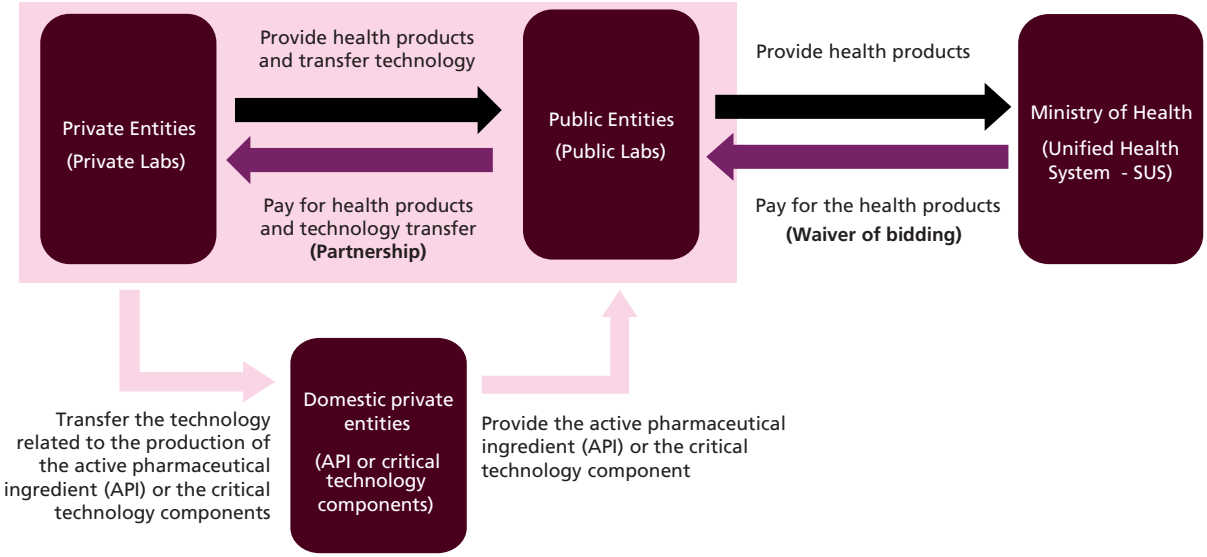
3 PDP PHASES

The PDP is an agreement signed by public laboratories in partnership with the MoH to supply key products such as drugs, vaccines, blood products, equipment, and medical-hospital items to the SUS. The MoH determines the list of strategic products of interest, which are then supplied by those public laboratories under a public-private partnership. The private entity involved in the agreement is responsible for transferring the production technology of the product to the public entity within ten years.

Thus, a PDP agreement typically involves three parties: the MoH, a public laboratory, and at least one private company. The MoH agrees to purchase a product, while the private companies agree to transfer the production technology of the product to a public laboratory within the same time frame. At the end of the partnership, the public laboratory should be able to deliver the product to the MoH, as shown in Figure 2.

The simplified diagram in Figure 2 illustrates the relationships among the key players involved in PDPs. It is important to note that, in addition to the private technology supplier (private entity), the critical technology component (API)[11] must also be manufactured locally within the national territory. This responsibility can be undertaken by the technology supplier, the public laboratory, or a third party designated by the parties, as long as local production can be demonstrated.

FIGURE 2
Simplified flow of acquisitions via PDP



Source: Office of the Comptroller General (Controladoria-Geral da União – CGU) (2019, p. 11).
Authors' elaboration.

The simplified model depicted in Figure 2 can be configured to allow for a variety of institutional arrangements. These arrangements include: i) the coexistence of a national pharmaceutical company and a multinational pharmaceutical company, with the API manufacturer being a national enterprise; ii) a national pharmaceutical company only; iii) the coexistence of a national pharmaceutical company and another national API manufacturer; iv) a national pharmaceutical company operating in tandem with a consortium of two or more national API manufacturers; v) a consortium of two or more national

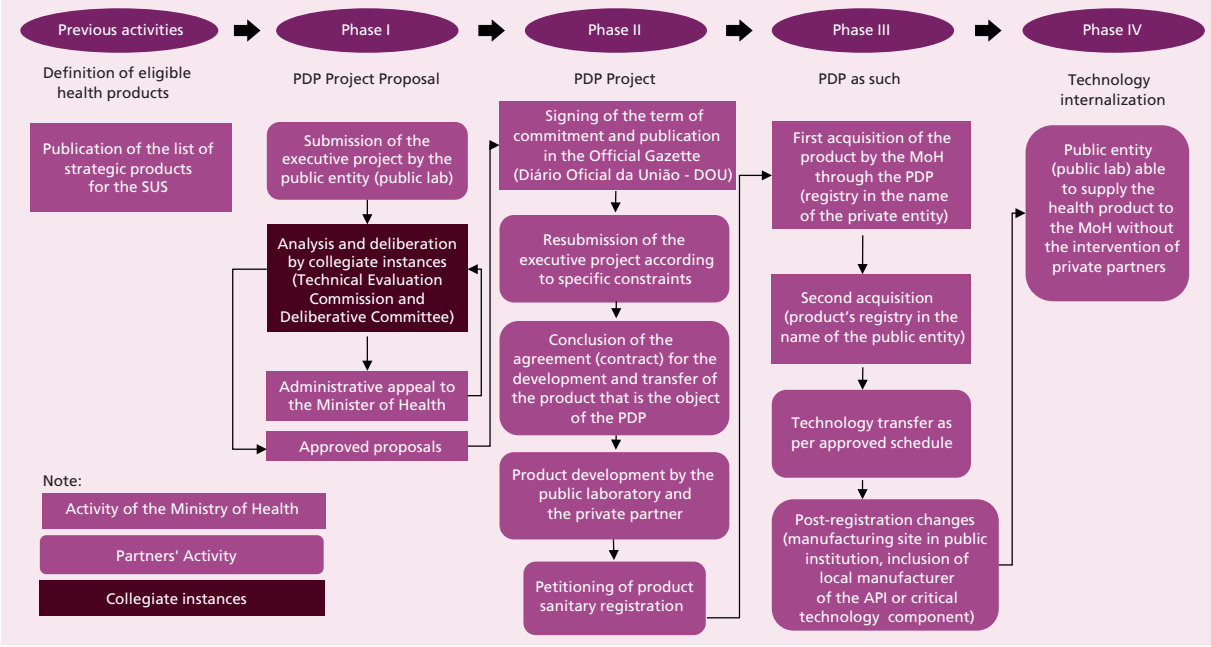
11. The definition of a critical technology component, as described in Ordinance No. 2531/2014, encompasses inputs, products, or processes that are crucial to the production chain of health product industries, and whose production is essential for the country to achieve technology independence. In this context, the master cell bank for biological products and the API for chemical synthesis products are both considered to be critical technology components.

pharmaceutical companies operating with a national API manufacturer; vi) a multinational pharmaceutical company, being the local API manufacturer the subsidiary; vii) a multinational pharmaceutical company, being the local API manufacturer another national company; and viii) solely a national API manufacturer.

The private company's interest in the PDP arrangement is the guaranteed SUS market and for the public laboratory is the benefit of the technology transfer based on a "reverse transfer model", which transfers the lower value-added productive steps, such as quality control and packaging, first. In the initial years of the partnership, the private entity performs a substantial portion of the product's production steps and is compensated accordingly. The private company also benefits from a long-term planning horizon for its investments and long-term supply of the product. As emphasized by the Federal Court of Accounts (Tribunal de Contas da União – TCU), the state benefits from the PDP arrangement by acquiring the technology, which can be used or disseminated, and by obtaining the drug ready for distribution in the SUS throughout the technology transfer process and thereafter with the availability of local production of strategic products.[12]

Figure 3 presents a systematic approach to the stages of a PDP, which are discussed in more detail in the following subsections: proposal submission, analysis, and deliberation phase (3.1); contractual and product development phase (3.2); technology transfer and procurement phase (3.3); and, finally, the technology internalization phase (3.4).

FIGURE 3
Flowchart of the complete process of analysis, execution and finalization of a PDP



Source: Pimentel (2018, p. 112).

3.1 Proposal submission, analysis and deliberation phase

To establish a PDP, the MoH must first disclose a list of strategic products that are of interest for the SUS. Once the list is published, public laboratories can submit PDP proposals, starting the "phase I" (also called "PDP project proposal phase"). Those institutions have a fixed deadline to submit their proposals to the ministry after the publication of the list.

12. Available at: https://bit.ly/3padjju.

Although a consortium of various actors may be involved, it is the public laboratory the sole responsible for providing information about the partnership to the MoH. Besides, the ministry oversees selection of private partners' technology supplies and the legal (contractual) relationships eventually formed between them and the public laboratories. In essence, the initiating public laboratory assumes the pivotal role within this model, as everything hinges upon them and starts through their efforts.

Despite the lack of legal or regulatory provision, while auditing the PDPs the TCU[13] recommended that the MoH should oversee the private partner selection and include this aspect as an additional selection criteria (Box 2).

BOX 2
Choosing the private partner

The public laboratory is responsible for selecting its private partner prior to the formalization of PDPs, as stipulated in art. 68 of Ordinance No. 2.531/2014. The rules for selecting a private partner are determined according to the legal regime applicable to the hiring of public institutions. Generally, partners are selected through competitive bidding (Glassman, 2020). However, art. 24, Section XXV of Law No. 8.666/1993 (Procurement Law), introduced by Law No. 10.973/2004 (Innovation Law), exempts public scientific and technology institutions from the need to bid for contracts related to technology transfer. Subsection XXXII of the same art. 24 (introduced by Law 12.715/2012) also confirms that there is no need for bidding for contracts for the transfer of technology of strategic products for SUS.

While the Innovation Law dismisses the need for bidding as an indispensable procedure for PDPs, some argue that this interpretation is not consensual. Glassman (2020) maintains that the dismissal hypothesis of Law No. 8.666/1993 is not related to the PDPs model, based on arguments present in a report issued by a control agency (TCU, 2016[1] *apud* Glassman, 2020).

In Judgment No. 1.730/2017, the TCU identified the lack of standardization, transparency, and criteria in the selection of private partners. While that judgment has become the reference in jurisprudence on the topic, determining "that the MoH: i) include as a criterion for approval of the PDP, the verification that the choice of the partner respected the constitutional principles; and ii) guide the public laboratories to carry out the selection and justify if it is not feasible" (Youssef, 2019, p. 48-49), the court has been applying an understanding that does not require the bidding formality for the choice of the partner. Instead, it must respect the principles of publicity and isonomy (Youssef, 2019).

Authors' elaboration.
Note: [1] TCU, Processo nº 034.611/2016-9.

The public laboratory making the request submits a PDP project proposal (executive project) that includes the private company, the strategic product, and the critical technology component to be transferred. The project is evaluated in four steps. First, the feasibility multiple PDPs for the same product is assessed based on health, technical and economic scale, and investments. Then the merit of each proposal is scored from zero to ten based on 15 predetermined criteria. If there are more approved proposals on merit than feasible PDPs for the same product, the Ministry moves to the third stage, which is the tiebreaker, consisting of 15 additional criteria scored from zero to ten. Once the recommended proposals are determined, the fourth and final stage involves dividing responsibilities based on five specific criteria. Thus, the proposals undergo evaluation based on a total of 35 criteria, making it highly complex and subjective.

Following the initial evaluation by the Technical Evaluation Commission (Comissão Técnica de Avaliação), the executive project presented by the public laboratory and the technical reports are submitted to the Deliberative Committee (Comitê Deliberativo). This committee can either validate the proposal, setting deadlines, criteria, and specific conditions, or request a new analysis by a new ad hoc Technical Evaluation Commission.

The evaluation process for PDP project proposals can be considered an adaptation of public sealed bid tendering, with the quality level of proposals measured through a scoring methodology. The merit analysis of the projects is similar to the qualification of proposals (eliminatory), while the tie-breaker analysis (classificatory) serves as the competitive judgment between qualified proposals, in line with the general public procurement procedure currently in force in Brazil. Consequently, the tie-breaker criteria are the most important, since they

13. Available at: https://bit.ly/3BTX8OG.

determine the most advantageous offer (Pimentel, 2018). These criteria are in art. 23 of the MoH's Ordinance No. 2.531/2014.

> I – adequacy of products and processes to the requirements of programs and actions of the MoH, aiming to meet the needs of SUS and the population;
>
> II – public laboratory with a production line suitable for the product subject to PDP;
>
> III – investments applied by the private partner for the execution of the PDP project;
>
> IV – shortest timeframe for technology internalization;
>
> V – price proposal with highest potential for savings to the MoH;
>
> VI – active Operating License and Active Special Operating License, when applicable, for the private partner producing the finished product;
>
> VII – active Operating License and Active Special Operating License, when applicable, for the private partner producing the active pharmaceutical ingredient (API) or critical technology component;
>
> VIII – valid GMP Certificate [Good Manufacturing Practices Certificate] for the production line of the product subject to the PDP proposal for the public laboratory, or sanitary inspection reports proving manufacturing conditions;
>
> IX – valid GMP Certificate for the production line of the product subject to PDP for the private partner producing the finished product, or sanitary inspection reports proving manufacturing conditions;
>
> X – valid GMP Certificate for the production line of the product subject to PDP for the private partner producing the API or critical technology component, or sanitary inspection reports proving manufacturing conditions;
>
> XI – additional presentation of innovation related to the product subject to PDP;
>
> XII – relative contribution of technology to the development of the Health Economic-Industrial Complex (Ceis);
>
> XIII – private entity with a production line in the country suitable for the product subject to PDP;
>
> XIV – technology development of the product subject to PDP carried out in the country; and
>
> XV – contribution to the competitive and technology balance of the market.
> (Brazil, 2014).

First, it should be noted that one of the deciding criteria is a typical qualification criterion – if a health product does not meet the requirements of the MoH's policies and programs, it is unlikely to be purchased. Criteria II to IV pertain to qualitative attributes of the project, such as the public laboratory's ability to adopt the technology, the private partners' investments, and the deadline for technology transfer. It is noteworthy that price appears in only one tie-breaker criterion (item V), which means that it has a relatively low weight

compared to the other criteria. Criteria VI to X concern regulatory requirements for production quality – special operating permits and certificates of good practice, both for the public laboratory and for the private partners. Then, there is a block of criteria that focus on the impact of the project on the productive and technology development of the country (XI to XIV), such as innovation, local private production, and autochthonous product development. Finally, criterion XV is an economic concern with the competitive balance of the market, which could be interpreted as encouraging new entrants at the expense of incumbents.

It is worth mentioning that the evaluation of PDP project proposals includes a price criterion. According to Ordinance No. 2.531/2014, the proposed price must be presented for the entire technology transfer period in a decreasing manner, adjusted for inflation.[14] Moreover, the initial prices should be in line with the prices of previous acquisitions of the same product under the SUS.[15] This ensures that, in the worst-case scenario, the PDP maintains the real prices of products acquired from SUS with a predetermined progressive decrease. Depending on the level of discount offered by the consortia, more favorable scenarios may emerge. However, it should be emphasized that the price proposal is only one of fifteen criteria for the selection of the consortium.

From this, it can be inferred that the tipping criteria establish a prioritization order for selecting PDPs, which is as follows: health quality, impact on innovation and local production, project-specific attributes, price, impact on competition, and enabling criteria. These criteria are closely related to one of the objectives of PDPs, which is to "protect the interests of the public administration and society by striving for economic viability (*economicidade*) and "advantageousness" (*vantajosidade*), considering prices, quality, technology, and social benefits" (art. 3 of Ordinance No. 2.531/2014).

3.2 Contractual and product development phase

Once approved by the Deliberative Committee, the PDP project enters the "phase II" or implementation phase (as shown in figure 2), which starts with the signing of the commitment agreement between the MoH and the public laboratory, with the agreement of the private partner entities.

During this phase, public laboratories are required to enter into a technology transfer agreement or contract with the private entities of the consortium, without any intervention from the MoH (as stipulated in art. 68 of Ordinance No. 2.531/2014). As a result, the MoH does not supervise the contractual relationship between the public laboratory and the consortium companies. In other words, the public laboratory and its private partner have the freedom to negotiate the intellectual property rights and the use of the technology to be transferred, as well as the sales potential both in the national (outside the public system) and international markets. The normative for PDPs only specifies the critical technology component to be transferred to the public laboratory. The Deliberative Committee may require that specific conditions be met, such as price discounts or schedule changes, before the partnership becomes effective, and the public laboratory must submit an adjusted executive project.

During phase II, in addition to formalizing non-contractual agreements (term of commitment) between the consortium and the MoH, there is the possibility of "co-development" of the product by the consortium to obtain health regulatory approval. It is not mandatory that the technology transferor be the owner of

14. As per Ordinance No. 2.531/2014, art 14, states that: "The formulation of the PDP project proposal shall adhere to the following guidelines: (...) VIII - regarding the proposal for sales prices and the estimation of supply capacity: (...) c) prices should be presented in a descending scale of values, in real terms, taking into account the fluctuations in the National Wide Consumer Price Index (Índice Nacional de Preços ao Consumidor Amplo – IPCA) or sector-specific price indexes, as well as the exchange rate variation rate, while complying with the regulations of Medicines Market Regulation Chamber (Câmara de Regulação do Mercado de Medicamentos – CMED).

15. According to art. 14, VIII of Ordinance No. 2.531/2014, it states that "(...) b) the proposed prices should be in line with the prices practiced by the SUS, and when necessary, with the prices observed in international markets of the countries covered by the Medicines Market Regulation Chamber (CMED), while considering the principles of advantageousness and economic viability".

the technology to be transferred; there is room, in this phase, for product development, which involves a real technology risk, as defined in Decree No. 9.283/2018. For this reason, as discussed earlier, the local development of the product that is the object of the PDP is one of the tie-breaker criteria for selecting the consortium that will develop, produce, and supply the product. However, the higher technology risk associated with co-development agreements can cause many PDPs to remain in phase II for a long time or never move on to the next phases, so they may be suspended or terminated.

If one of the partners already holds a registration for the product with the Brazilian Health Regulatory Authority (Agência Nacional de Vigilância Sanitária – Anvisa), the registration dossier of the private entity will be transferred to the public laboratory during this stage.

Once approved, any changes to the technology transfer project, such as modifications to the partners involved, the technology to be transferred, or requests for an extension of the period for acquiring the product that would also extend the timeline, must be evaluated by the Technical Evaluation Commission and Deliberative Committee (arts. 46-48 of Ordinance No. 2.531/2014).

3.3 Technology transfer and public purchases

The start of the PDP project is marked by the delivery of the first batch of the product by the public laboratory to the MoH. At this point, it is permissible for that the private entity to fully manufacture the product and register it under its own name (in accordance with art. 53 of Ordinance No. 2.531/2014). If this is the case, the public laboratory has one year to obtain health approval for the product, otherwise the second shipment cannot be made. Once the PDP has started, monitoring will be conducted according to the schedule specified in the approved executive project (as described in Box 3).

BOX 3
Generic PDP activity flow model

Based on Rezende (2013) and Pimentel (2018), a typical flow of activities in PDPs for medicines can be described in general terms. The specific activities may vary depending on the technology stage of the partners and the product and technology characteristics.

In the first step, the public laboratory submits a registration application to the Brazilian Regulatory Authority (Anvisa), using the complete product dossier of the private partner, which is known as a "clone" registration. With the registration in its name, the public laboratory begins to carry out some activities, such as quality control and secondary packaging. For regulatory purposes, the manufacturing site of the product still belongs to the private entity.

In a second stage, the primary packaging and drug formulation technologies are transferred from the private partner to the public laboratory. This transfer requires a petition for a change in the manufacturing site at Anvisa, which is called a "post-registration" change.

A third step, often performed in parallel with the first two, involves the development of API manufacturing technology by a domestic private entity. Once completed, this technology is added to the public laboratory's drug registry, which requires another "post-registration" change. At the end of these three steps, the technology is considered transferred to the public laboratory and the API production is nationalized.

Authors' elaboration.

Throughout the technology transfer process, there are four crucial points that must be addressed, as summarized below:

1) The price charged during the technology transfer period.

2) The volume of purchases by the MoH destined to PDPs.

3) The monitoring of project activities to ensure that the schedule is met and that the technology transfer proceeds as planned.

4) Mechanisms for course correction and adjustments, in the event of delays or other problems, to prevent the partnership from being suspended or terminated.

Within the executive project there is a section in which the public laboratory presents its price proposal. As already mentioned, this is also one of the criteria for the analysis of the projects. However, the prices proposed in the project are only indicative of the price to be charged in each purchase. The actual price will be negotiated in a separate administrative process, and will include a re-analysis of prices charged in the Brazilian private market and in purchases from other government entities, according to Ordinance No. 2.531/2014:

> article 55. The acquisition of the product that is the subject of the PDP will be carried out through a specific instrument between the MoH and the public laboratory, and will be made after observing and reanalyzing the following aspects:
>
> I - capacity of service:
>
> (...)
>
> II - the MoH's demand will be considered at the time of acquisition of the product that is the subject of the PDP; and
>
> III - regarding prices, economy, and advantageousness:
>
> a) the prices set for the acquisition of the product that is the subject of the PDP will consider the technology contribution associated with the nationalization of production and will decrease in real terms. Prices may vary in the periods and in the form established in the relevant legislation to take into account fluctuations in the average national and international market prices, price variation measured by the IPCA index [Índice Nacional de Preços ao Consumidor Amplo] or by official sectorial indicators, exchange rate variation when it involves imports in the transfer period, considering economies and health systems comparable to those of Brazil and, if applicable, the norms and criteria adopted by the Chamber for Drug Market Regulation [Câmara de Regulação do Mercado de Medicamentos – CMED];
>
> b) the price evaluation will consider, when applicable, the market value estimates for products that are close to the patent expiration period and the relevant reduction of market prices resulting from companies' competition strategies; and
>
> c) the economic and advantageous nature of the process must be analyzed with reference to the guidelines established in clause VIII of Article 14.
>
> § 1 The price analysis presented in the PDP project proposal shall serve as a reference for defining the acquisition price to be practiced by the MoH.
>
> § 2 The MoH department responsible for executing the specific instrument of acquisition of the product that is the subject of the PDP with the public laboratory, must jointly with the Executive Secretariat [Secretaria Executiva – SE], conduct the price analysis to be practiced with technical support from the Secretariat for Science, Technology, Innovation and Health Complex [Secretaria de Ciência, Tecnologia, Inovação e Complexo da Saúde – SCTIE], in administrative procedures separate from the PDP process (Brazil, 2014, emphasis added).

3.4 Technology internalization

The phase known as "internalization of technology" or phase IV has a confusing nomenclature, as technology internalization should occur throughout the entire technology transfer process. While Ordinance No. 2.531/2014 is quite detailed in other aspects, it is concise in its definition of this phase. It states that MoH purchases will no longer be subject to the PDP mechanism, and the public laboratory must be able to meet the demand of the SUS while proving that the technology transfer has been completed (Brazil, 2014, art. 59). Furthermore, it establishes that after this phase, the public laboratory may exercise technology portability, which refers to the technical and managerial capacity to transfer the technology to another public laboratory upon a reasoned request from the Ministry (Brazil, 2014, art. 60).

The phase referred to as "technology internalization" is better understood not as a phase but as the endpoint of the entire PDP process. Its goal is to transfer technology when its purpose has been achieved, and its objectives have been fulfilled.

4 FINAL CONSIDERATIONS

This *Technical Note* has described the four phases that comprise the entire process of proposal submission, contractual development, execution, and finalization of a PDP. In terms of PDP design, various aspects have been identified, however, the successful implementation of public procurement, requires a careful selection process that generates appropriate incentives for participants.

In general, in public procurement, the incentives are such that the duration of the contract execution is negatively correlated with the value received by suppliers. However, in the case of PDPs, the longer the technology transfer term, the higher the compensation received by the private firms supplying the technology, which may lead to opportunistic behavior such as undue delays and schedule revisions. To address this issue, PDPs use a non-contractual incentive mechanism, which allows the possibility of entering into more than one partnership for the same product. This creates competition among consortia to meet the demand of the MoH under the policy itself, reducing the risk of opportunism on the part of private companies supplying the technology or failure in the execution of the contract due to uncertainties in the technology transfer agreements. On the other hand, this may have a negative impact on economies of scale, thus hindering the feasibility of local production. This debate is not resolved and requires further consideration.

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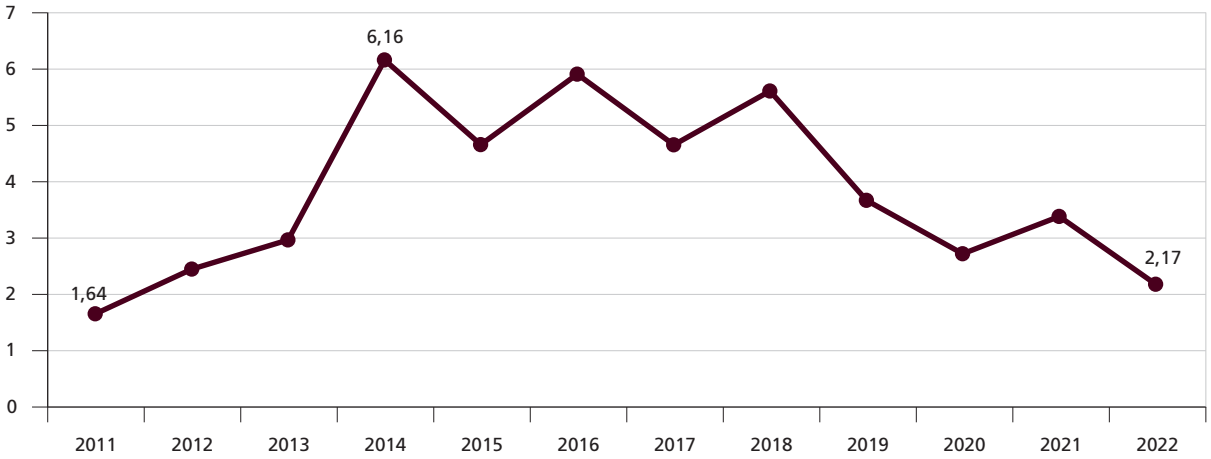
APPENDIX A

FIGURE A.1

Amounts spent in BRL annually on the acquisition of medicines via PDP (2011-2022)
(In BRL billion)



Source: Ministry of Health (MoH). Available at: https://www.gov.br/saude/pt-br/composicao/sectics/deceiis/pdp/fase-III.
Authors' elaboration.
Obs.: Brazilian reais (BRL) in nominal values were deflated using the General Price Index – Market (Índice Geral de Preços – Mercado – IGP-M) (base 2022), meticulously curated by Ipeadata, drawing upon data sourced from Getulio Vargas Foundation, Economic Situation (Fundação Getulio Vargas/Conjuntura Econômica – FGV/Conj. Eco. – IGP).

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