

# Productive Development Partnerships: an essay on the construction of strategic product lists

*Parcerias para o Desenvolvimento Produtivo: um ensaio sobre a construção das listas de produtos estratégicos*

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**ABSTRACT** This is an essay on the construction of strategic product lists for the Brazilian Unified Health System (SUS) eligible for the submission of proposals for Productive Development Partnerships (PDP). The objective of this study was to critically analyze the process of constructing these lists, reviewing the criteria used, the interaction currently existing with the evaluation of health technologies, the collaboration between decision makers and researchers or reference institutions, and the influence of the composition of the list on the outcome of the projects and reach of the objectives of the initiative. It was found that the use of scientific evidence and collaborative actions of researchers are reduced in decision making, and that the composition of the list has a great influence on the outcome of the PDP, and its construction is a key factor for the success of this initiative and the internalization of technologies. A suggestion for organizing the list-making work is the regimental definition of the use of an independent rapid response program organized between the government, the academy, and institutions involved in PDP approvals, so that the best scientific evidence is available to policy decision makers in the short term.

**KEYWORDS** Public-private sector partnerships. Technology assessment, biomedical. Evidence-informed policy.

**RESUMO** Trata-se de um ensaio sobre a construção das listas de produtos estratégicos para o Sistema Único de Saúde brasileiro elegíveis para a apresentação de propostas de projetos de Parcerias para o Desenvolvimento Produtivo (PDP). O objetivo deste estudo foi analisar, de modo crítico, o processo de construção dessas listas, revendo os critérios utilizados, a interação existente atualmente com a avaliação de tecnologias em saúde, a colaboração entre tomadores de decisão e pesquisadores ou instituições de referência e a influência da composição da lista no desfecho dos projetos e alcance dos objetivos da iniciativa. Verificou-se que o uso de evidências científicas e as ações de colaboração de pesquisadores são reduzidos na tomada de decisão, e que a composição da lista apresenta grande influência no desfecho das PDP, sendo a sua construção fator primordial para o sucesso dessa iniciativa e internalização das tecnologias. Apresenta-se, como sugestão para organização dos trabalhos de elaboração da lista, a definição regimental de uso de um programa de respostas rápidas independentes organizado entre o governo, academia e instituições envolvidas nas aprovações das PDP para que a melhor evidência científica esteja disponível para os tomadores de decisão em um curto prazo.

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**PALAVRAS-CHAVE** Parcerias público-privadas. Avaliação da tecnologia biomédica. Política informada por evidências.



## Introduction

Productive Development Partnerships (PDP) are partnerships that involve cooperation between public producers and between them and private companies for development, technology transfer, production, productive and technological training of Brazil in strategic products for the Unified Health System (SUS)<sup>1</sup>. These partnerships aim to:

- I. increase population access to strategic products and reduce the vulnerability of SUS;
- II. reduce productive and technological dependencies to meet the health needs of the Brazilian population in the short, medium and long term;
- III. rationalize the purchasing power of the State, through selective centralization of health spending, with a view to SUS sustainability and the expansion of production of strategic products in the Country;
- IV. protect the interests of the Public Administration and society by seeking economicity and advantage, considering prices, quality, technology and social benefits;
- V. encourage technological development and the exchange of knowledge for innovation within public institutions and private entities, contributing to the development of the Health Industrial Economic Complex (Ceis) and to make them competitive and capable;
- VI. promote the development and manufacture in Brazil of strategic products for SUS;
- VII. seek the technological and economic sustainability of the SUS in the short, medium and long term, with the promotion of structural conditions to increase the productive capacity and innovation of the Country, contribute to reduce trade deficit of the Ceis and ensure access to health; and
- VIII. stimulate the development of the public production network in the Country and its strategic role for SUS<sup>1(4)</sup>.

The strategic products for SUS that may be the object of PDP project proposals are

listed in an annual list published by the Ministry of Health (MH) according to the recommendations of the Executive Group of the Health Industrial Complex (Gecis)<sup>1</sup>. The Minister of State for Health, therefore, is responsible for decision-making in the prior stage of establishing PDP supported by an intergovernmental group<sup>2</sup>.

Decision making in the context of health systems becomes a complex activity due to the amount of information involved, institutional constraints, interests, ideas, values, limited time and external factors such as recessions. Implementing evidence-based interventions in healthcare practices requires organizational changes related to motivation, leadership, content changes, and organizational climate (organizational maturity). The translation of scientific knowledge to real life is also associated with challenges<sup>3</sup>. Furthermore, in organizational implementation, there is a growing need to adapt the use of evidence to local reality and of the countries, using standardized procedures, organizational policies and local data in different forms of evidence interconnection to simplify scientific knowledge and make them applicable to the local context<sup>4</sup>.

For the PDP, which involve projects with high technological risk and a large volume of public resources, the complexity and relevance is no different. It should be increasingly supported by scientific evidence and well-established relationships between decision makers and researchers to achieve public objectives and, this way, to remove the conflicts of interest involved in this arena<sup>5</sup>. In addition, it should be characterized by transparent, systematic and agile access in evaluating inputs of the policy-making process<sup>6</sup>.

From the analysis of the article by Oxman et al.<sup>6</sup>, it is possible to evaluate the dimensions of research evidence, its role in providing input for health policy decisions and policy making. The authors ratify the position that policy decisions should be based

on scientific evidence to prevent poorly informed decision-making from contributing to problems related to the ineffectiveness, inefficiency, and inequity of health systems.

Varrichio<sup>7</sup>, in a preliminary study on PDP whose objective was to understand their functioning, their management and their scope in the promotion of technological innovations in the light of demand-side public innovation policies, observed that in the period after 2014, the government has been sending contradictory signals to the agents about the policy, because, while trying to speed up the mechanism for submitting PDP project proposals, there were postponements in the disclosure of the list of strategic products for SUS, and there was non-compliance with the provisions of the normative.

With this study, the objective is to critically analyze the process of constructing the lists of strategic products for SUS eligible for submission of project proposals for PDP, reviewing the criteria used, the existing interaction with the rite of use of best practices in health technology evaluation, the collaborative actions with researchers and institutions of reference and the influence of the composition of the list on the outcome of the projects and the achievement of the objectives of the initiative. This analysis aims to demonstrate the extent to which political decisions in the field of defining strategic products and promoting the Health Industrial Economic Complex (Ceis) in the health sector have been based on scientific evidence, contributing to the evaluation of the PDP initiatives and implementation of process improvements.

## Material and methods

This is an essay developed through documentary research, in an exploratory manner, of normatives related to the PDP and lists of strategic products for SUS in the website of the MH, in the domain <http://portalms.saude.gov.br>, and searching the literature related to these topics and the evaluation of health technologies.

The qualitative approach was adopted in this study from the critical analysis of the literature content and norms, corroborating the practical experience of the authors in the support processes for the construction of strategic product lists for SUS during the exercise of activities in the MH.

This study was guided by the strategy of promoting interaction between researchers and decision makers by Dias et al.<sup>8</sup>. From seven systematic reviews, these authors presented this and three other strategies to assist in decision making and action, namely: a) produce and disseminate evidence syntheses with language adapted to different audiences; b) encourage the use of journalism and other forms of communication to broaden the dissemination of scientific knowledge; and c) use an online virtual platform for the dissemination of scientific knowledge. The four strategies, the authors point out, can be used synergistically, and should, therefore, assess the more general impact on the health system<sup>8</sup>. The choice of this strategy is due to the fact that PDP involve public and private interaction in actions to carry out technology transfer projects of strategic inputs to SUS.

## Results and discussions

In Brazil, the strategic product list is of particular importance, as it has guided important policies in the context of Ceis, such as the PDP. This list is a guiding instrument for the national and international producer market, public and private, because, from their products, technology transfer projects may be presented, the results and products of which are supported by the State in public procurement, through the use of the purchasing power of the MH of high value-added centralized products<sup>9</sup>. This

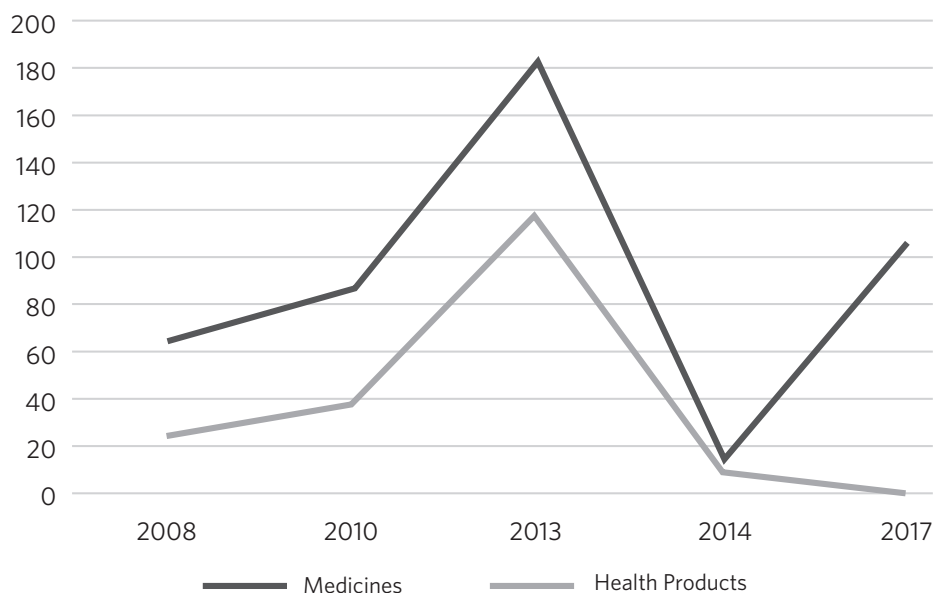
list includes the products defined in the normative act of the Ministry of Health as:

[...] products necessary to SUS for health promotion, prevention and recovery actions, with centralized acquisitions or subject to centralization by the Ministry of Health and whose national production and its active pharmaceutical inputs or critical technological components are relevant to the Ceis<sup>1(3)</sup>.

The first list of strategic products for SUS was published in 2008 and had 64 medicines and 25 health products<sup>10</sup>. The updates to this

list occurred in the following years<sup>11-14</sup>, with the increase in the number of items included in 2010 and 2013, subsequent decrease in 2014 and further increase in 2017 (*graph 1*). In 2017, the list no longer includes health products and was divided into two, namely: list of strategic products for SUS eligible to submit PDP project proposals in 2017 and list of products not eligible for submission of new PDP project proposals because they are already included in PDP established with MH in previous years or other forms of technology transfer<sup>17</sup>.

Graph 1. Evolution in the number of strategic products for the Unified Health System by year of list update



Source: Own elaboration (2019).

Note: The number of items of 2017 considers the sum of products from the lists of strategic products for SUS eligible and not eligible for submission of proposals for PDP projects.

Initially, the publication of strategic product lists was every two years and aimed to collaborate to the development of Ceis<sup>10-12</sup>; From 2014 on, it became annual and

focused on PDP<sup>13,14</sup>. These lists guide the productive sector, government agencies responsible for financing and product research that will be eligible for the submission of

new PDP project proposals, annually, by laboratories and public institutions<sup>15</sup>. These projects rely, above all, on the use of the State's purchasing power in direct public acquisitions carried out by the exemption from technology transfer-based bidding in accordance with article 24, item XXXII of Law n° 8.666/932.

The normative also foresees that strategic products for SUS may be the object of measures and initiatives aimed at research, development, technology transfer,

innovation and national production, with the purpose of contributing to the strengthening of Ceis and to expanding its access by the population.

The criteria used in the definition of the annual list are presented in *chart 1*, which necessary criteria are verified, those indispensable to all products in the list of strategic products for SUS, and the additional ones. For the latter, at least one of the conditions of election of a new product to the strategic product list must be met.

Chart 1. Criteria groups used for the construction of the list of strategic products for the Unified Health System

Criteria groups	Detailing
Necessary criteria	<ul style="list-style-type: none"> <li>a) importance of the product for SUS, according to policies and programs for health promotion, prevention and recovery;</li> <li>b) centralized acquisition of the product by the Ministry of Health or subject to centralization;</li> <li>c) national production interest of the product and its active pharmaceutical ingredients or critical technological components relevant to Ceis;</li> </ul>
Additional criteria (at least one of the criteria is required)	<ul style="list-style-type: none"> <li>a) high acquisition value for SUS;</li> <li>b) expressive dependence on the import of the product for the programs and actions of promotion, prevention and health care in the scope of SUS in the last three years;</li> <li>c) recent technological incorporation into SUS;</li> <li>d) product neglected or potentially at risk of shortage.</li> </ul>

Source: Own elaboration, through article 6 of Ordinance n° 2.531/2014\* (2017).

It is verified that there are criteria that use information from the MH databases themselves and their strategic programs, such as recent technological incorporations in SUS, updated values of centralized acquisitions, the expressive dependence on product importations for the programs and health promotion, prevention and care actions in the last three years.

However, there are criteria that denote the clear need to use informed opinions from researchers or reference centers, use of published studies and statistical data for the best decision to include in the annual list of strategic products. The following criteria

may be listed under this condition: a) importance of the product to the SUS, according to policies and programs for health promotion, prevention and recovery; b) national production interest of the product and its active pharmaceutical ingredients or critical technological components relevant to Ceis; and c) product neglected or with a potential risk of shortage.

For these three criteria, there is a need to use scientific evidence, best practices and strategic collaborations, and not only to make use of data from the Secretariats involved of the MH, due to the topics involved. These are matters that involve the

importance of the product for SUS, related policies and programs, evaluation of critical technological components for the health production complex and its technological horizon, the shortage of neglected products and available or developing technologies for the diseases involved.

In addition, it is necessary to avoid spending on wrong choices in project development strategies that will not result in significant gains for the increase of access or for the contribution to the national production of inputs in the productive complex. In this sense, it is important the position of Oxman et al.<sup>6</sup> that, due to limited resources and substantial burden with health services, countries with low and middle income per capita should apply their health budgets intelligently.

In the context of PDPs, the choice of products that make up the strategic product list should be based on scientific evidence to dispel biases related to market interests overlapping public interests in the conduct of projects aimed at strengthening the national productive base of active pharmaceutical ingredients, medicines and health products.

As stated by Oxman et al. <sup>6</sup>,

[...] it is assumed that the overall policy-making process is not systematic and transparent. However, within the overall policy-making process, systematic processes are used to ensure that relevant research is identified, evaluated and used appropriately<sup>6(17)</sup>.

Thus, the processes used in policy making should be transparent to ensure that others can examine the rationale used, the research evidence that formed the concepts, and decisions based on resulting judgments.

In this regard, the importance of creating a common ground among high-level policy makers and others involved in critical and urgent decisions is emphasized, the concepts of 'evidence', the role of evidence in health policy formulation and informed 'evidence-based health policy-making' that

supports changes applicable to a variety of contexts within health systems for better use of pharmaceuticals and health, and procedures that helps the health of patients and support sustainable health systems<sup>16</sup>.

Evidence-based policy formulation helps policy makers understand building processes. As from the decision-making act on the list of strategic products, provided for in the legislative act, there is a need to encourage the approximation of decision-makers when drawing up each annual publication list, with researchers more involved in the areas of interest of the products that will be part of the new list. The works must be structured, registered and processed in the administrative records of the MH, for each product decided by the entry in the list.

Dias et al.<sup>8</sup> suggest actions for better use of evidence in decision-making, which is associated with the responsibility of the MH, notably the Minister of State for Health, to draw up the annual list of strategic products. As a suggestion, from the analysis of the work of these authors<sup>8</sup>, the contact between researchers and decision makers should be promoted when preparing and elaborating the new annual list. As foreseen in the normative<sup>1</sup>, the MH may make specific consultations with subject matter experts, public and private bodies and entities, and public consultations before defining the list, in addition to considering recommendations of the Gecis.

One can also make use of virtual platforms and institutionally define the names of those that will be used when drawing up the annual list. The Evidence-Informed Policy Network (EVIPNet), under the coordination of the MH is cited, which aims to promote the use of scientific evidence in health decision-making and has been synthesizing evidence for health policy in its Evidence Centers (NEVs).

In addition, the building process of the list of strategic products meets demands from all secretariats of the MH and public



producers and already counts on deliberative spaces in which the main actors involved in its elaboration are grouped. It is, therefore, necessary to make use of these spaces to include researchers at the necessary times and to consider a set of assumptions and analysis, sometimes intangible for better decision making.

It should be borne in mind that this is a complex system involving the pharmaceutical market and that all evidence is context sensitive, as all observations are necessarily related to a specific context, and the applicability of the evidence must always be evaluated in addition to its original setting or context<sup>6</sup>.

It is also worth mentioning the position of Oxman et al.<sup>6</sup> that a specialized opinion, also inferring the collegiate opinions, involves more than mere evidence, as it is also the combination of facts, their interpretation and conclusions. Moreover, it also impacts on the observation of the opinions that not all evidence is equally convincing and reliable, as they depend on the types of associated observations and their quality respectively.

It is, therefore, necessary to assist in the decision making and evidence building process for the best choice of each product for the strategic product list; therefore, the idea of using fast response programs, as defined by Haby and Clark<sup>17</sup>, may be a solution. This instrument aims to promote greater interaction between managers and researchers and helps to reduce barriers to facilitate the use of scientific evidence in a short period. It is known that the times that managers have for decision making are generally influenced by other times: as the time of the population needs, the implementation of a certain policy or even the political time.

The know-how gap, as cited by Toma and Barreto<sup>18</sup>, in this case, may have consequences and negative impacts on the national pharmaceutical market and with international reflection because the participating and operating companies come

from both markets when it comes to PDP.

In the daily practices of the MH, in the annual elaboration of the list of strategic products, one must take into account the need for better management of the use of research evidence itself, as suggested by Oxman et al.<sup>6</sup>, who also recalled that the “evidence by itself does not make decisions”<sup>6(20)</sup>.

Thus, evidence-based approaches allow policy makers to ask critical questions about the evidence of research available to support advocated policies; demonstrate that they are using good information to inform their decisions, and ensure that the evaluations of their initiatives are appropriate with the expected outcome measurement.

The biggest negative impact for the construction of the strategic product list is the inclusion of non-strategic inputs for the purposes proposed by the normative, such as the national production of strategic inputs for the development of Ceis and pharmaceutical assistance policies of the SUS. There is a political risk, as mentioned by Oxman et al.<sup>6</sup>, in the conduct of policies, as they may be based on imperfect information.

Recognizing this risk and using the best evidence can protect decision makers in course changes if policies do not work as expected.

There is a much greater political risk when policies are defended without recognizing the limitations of available evidence and then, when it adheres to policies, regardless of the results<sup>6(19)</sup>.

There is also the risk of causing an erroneous movement of the pharmaceutical sector towards mobilization of efforts, resources, people, in the incorrect understanding that SUS will make use of its purchasing power for its use as is characteristic of this policy. It further aggravates the fact that partners who have made these efforts will put pressure on managers to make purchases that were entitled to approve a PDP project years earlier.

Another negative impact is the inclusion in the list of strategic products of products that have not yet been incorporated by the National Commission for incorporation of Health Technologies in SUS (Conitec), to the detriment of the additional criteria of the current regulation. This impacts the sense that the projects presented, and then conducted and executed, may not have a positive outcome for the public and private partners involved in the project if, at the time of purchase by MH, the product is not incorporated into SUS.

It is worth remembering that the processes of incorporation of the product in the Brazilian health system are consolidated by Conitec and count on processes based on scientific evidence and proper rite for the definition of new technologies for SUS. The process of execution of PDP should not interfere and cannot change the logic of incorporation of products in SUS, thus, the products to be evaluated as possible PDP must be incorporated into SUS as the

current regulation already advocates.

On this topic, it is important to analyze the PDP projects that were extinguished in the course of their implementation by identifying that their transfer objects were not really strategic for SUS, either because they were replaced by a more modern pharmaceutical form, such as the PDP of ritonavir soft gelatin capsule, replaced by thermostable formulation; either because they were not even included in the clinical protocols and therapeutic guidelines of the MS, such as cetuximab and simeprevir; or by reducing demand for SUS such as lopinavir and ritonavir; or by the already national manufacture by public producers as in PDP of chloroquine; or because the purchasing power tool, which would be the way to make the project viable, could not be implemented, as in the PDP of raloxifene, formoterol and budesonide, salbutamol, budesonide, entacapone, selegiline, tolcapone, hearing aid, allergenic extract and docetaxel<sup>19,20</sup> (chart 2).

Chart 2. Productive Development Partnership Projects extinguished for reasons related to technology

Commitment Term	Year of extinction	Medicine	Public partners	Private partners	Year of establishment of the PDP	Reason for the extinction - Deliberation of the Deliberative Committee
Nº 02/2009	2018	Raloxifene	LFM	Blanver Farmoquímica e Farmacêutica S.A, Nortec Química S.A.	2009	Lack of perspective for medicine centralization.
Nº 03/2009	2018	Formoterol + Budesonide	Farman- guinhos	Chemo Iberica S.A. Nortec Química S.A.	2009	Absence of a centralization perspective, and the fact that the partnership does not present evolution.
Nº 04/2012	2017	Lopinavir + Ritonavir	FURP, Farman- guinhos, IQUEGO	Cristália Produ- tos Químicos Farmacêuticos Ltda.	2012	Medicine does not meet the definition of 'strategic for SUS, and national production is no longer relevant for the Industrial Health Complex due to the reduction of demand for the financial area' (Health Surveillance Secretariat).
Nº 06/2012	2014	Budesonide + Formoterol, Salbutamol, Budesonide	Farman- guinhos	Chron Epigen	2012	Failure to comply with the requirements and constraints set out in the signed Commitment Term and the regulations in force during the extinction period.



Chart 2. (cont.)

Nº 07/2012	2015	Ritonavir (Soft capsule)	LAFEPE	Cristália Produtos Químicos Farmacêuticos Ltda.	2012	Public Institution reported, through Letter, the withdrawal of the PDP project, because Ritonavir presents lower storage and transport costs and for internalization it would be necessary high investment to adapt the manufacturing area to the need of equipment acquisition.
Nº 08/2012	2017	Entacapone	FURP, Lifal, IQUEGO	EMS S.A. Nortec	2012	Impossibility to centralize the purchase of this medicine at the time of the evaluation of the committee.
Nº 11/2012	2017	Tolcapone	Lifal	Cristália Produtos Químicos Farmacêuticos Ltda.	2012	Non-absorption of technology by the Public Institution, low added value of the product and non-centralized acquisition by the Ministry of Health, considering also that there are other therapeutic options available in the market.
Nº 17/2012	2017	Selegiline	Lifal	Cristália Produtos Químicos Farmacêuticos Ltda.	2012	Non-absorption of technology by the Public Institution, low added value of the product and non-centralized acquisition by the Ministry of Health, considering also that there are other therapeutic options available in the market.
Nº 19/2012	2014	Docetaxel	Farman-guinhos	Libbs, Quiral	2012	Failure to comply with the requirements and constraints set out in the signed Commitment Term and the regulations in force during the extinction period.
Nº 03/2013	2015	Chloroquine phosphate	LAFERGS	Cristália Produtos Químicos Farmacêuticos Ltda.	2013	The Public Institution did not have a manufacturing plant (needed investments in the production line) and the existence of chloroquine production in two other public institutions.
Nº 08/2013	2018	Hearing aid	FURP	Politec Importações e Comércio Ltda	2013	Non-evolution of the process of transfer and absorption of product technology; Manifestation of the public institution regarding the lack of interest of the private partner for the continuity of the PDP; Manifestation by Conjur/MS regarding the impracticability of direct acquisition of the product in the forms presented for this PDP.
Nº 11/2013	2015	Cetuximab	IVB, Bio-Manguinhos	Bionovis, Merck Serono	2013	The product was not incorporated by Conitec for the treatment of metastatic colorectal cancer.
Nº 12/2013	2015	Cetuximab	Butantan	Libbs, Mabxience	2013	The product was not incorporated by Conitec for the treatment of metastatic colorectal cancer.
Nº 29/2013	2017	Allergenic Extracts	Bahiafarma	BioCen	2013	Impossibility to centralize the purchase of this drug at the time of the evaluation of the committee.
-	2016	Docetaxel	Farman-guinhos, LAQFA	Cristália Produtos Químicos Farmacêuticos Ltda, Quiral Química do Brasil S.A.	2015	It is impossible to centralize the purchase of this medicine.
Nº 10/2018	2018	Simeprevir	Farman-guinhos	Blanver Farmoquímica e Farmacêutica S.A., Microbiológica Química e Farmacêutica Ltda.	2018	The Health Surveillance Secretariat (SVS) reported that there are no expectations that Simeprevir will be presented as a therapeutic option in the next Clinical Protocol and Therapeutic Guidelines (PCDT).

Source: Extracted from the web portal of the Ministry of Health<sup>19,20</sup>.

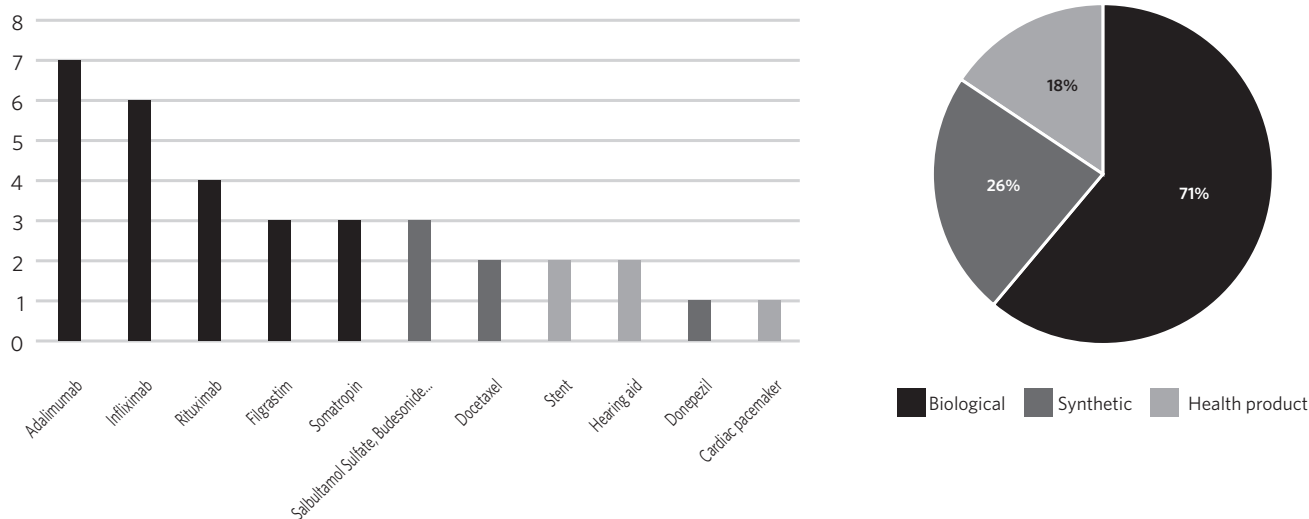
Although the above-mentioned PDP did not involve the purchase of the products by the MH because they were extinguished in the PDP design phase, public resources were spent for the assembly of the executive project and implementation attempts, especially those whose extinction occurred after a long time period of its establishment.

Thus, it appears that there is a need to reduce the gap between scientific knowledge and decision-making in political and management practices of health systems on relevant health issues and topics, technological horizon and economic aspects. It is important to consider that decision-making in policy formulation and implementation is much more complex, partly because of its nonlinear nature and the need to consider

a variety of factors such as context, acceptability of interested parties and feasibility of implementation<sup>17</sup>.

Taking as an example the 34 project proposals of PDP submitted to the MH in 2015<sup>21</sup> with products from the SUS strategic product list published in 2014, it is observed that they were related to 11 list items and that there was a great competitiveness in proposals for biological medicines (*graph 2*). Nine products from the list<sup>13</sup> (39%) were not the object of PDP proposals in 2015, namely: mycophenolate mofetil, L-asparaginase, dactinomycin, arterial stent, surgical stapler, multiparametric monitor, defibrillator and cardioverter, ophthalmology equipment set, hemodialysis machine and platinum spirals.

Graph 2. Number of proposals for Productive Development Partnerships projects presented in 2015 according to items on the list of strategic products published in 2014 and percentage of proposals according to product class



Source: Own elaboration (2019) from data of the Ministry of Health<sup>21</sup>.

Note: For the item salbutamol sulfate, the list included two other antiasthmatic products (budesonide and formoterol and associated budesonide), but only one of the proposals included the three products<sup>21</sup>.

It is also considered that the greatest adherence of the pharmaceutical production sector is associated with products of greater

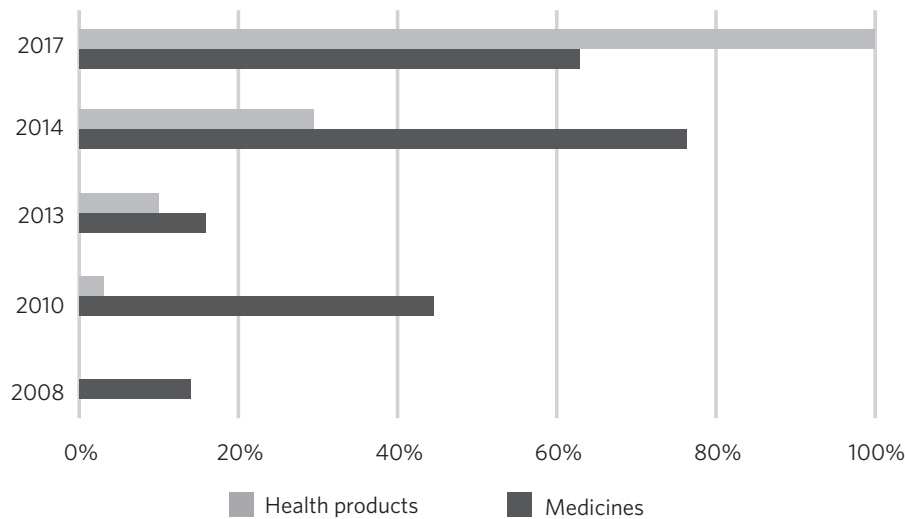
commercial value and with a larger market in recent years, leaving aside products whose manufacture has been discontinued by its

sole producers, such as L-asparaginase.

Also analyzing the percentage of items on the lists of strategic products for SUS explored by PDP per year of publication of

the list (*graph 3*), there is a need for other strategies to be associated with PDP in order to expand the coverage of products required by SUS.

Graph 3. Percentage of items on the lists of strategic products for the National Health System explored by the Productive Development Partnerships by year of publication of the list



Source: Own elaboration (2019).

Note: The percentage of 2017 considers only the items on the list of strategic products for SUS eligible to submit proposals for PDP projects.

In a PDP evaluability study, Silva and Elias<sup>22</sup> analyzed the vulnerability of this initiative and identified three possible invalidation conditions related to the list of strategic products for SUS with high impact on PDP. For these conditions, the authors proposed control actions that are linked to changes in the process of building this list: reformulation of the analysis to identify future strategic products; use of multicriteria matrix, considering magnitude, injury transcendence, and other relevance criteria; inclusion of technology horizon assessment; and prioritization of distinct proposals for PDP projects, presented by the

same partners, involving high value products and products for diseases and neglected populations<sup>22</sup>.

In a situational diagnosis of PDP<sup>23</sup>, the actors involved with the partnerships also pointed to the need to review the criteria used to elaborate the list of strategic products, keeping existing ones and including others, such as disease impact – burden, prevalence and severity of the disease, therapeutic need and variation of clinical practice – characteristics of product use, its implementation and its platform and analysis of the time horizon of technology.

## Final considerations

The building process of the lists of strategic products for SUS follows the criteria provided for in regulations of the MH, which currently have little interaction with the evaluation of health technologies and collaboration between decision makers and researchers, listed as best practices for developing countries like Brazil. Although one of the criteria is the recent incorporation into the SUS, the other criteria do not include elements of the evaluation of health technologies and the use of evidence.

Although the normatives indicate the annual publication of the list of strategic products, in practice, in recent years, this has not occurred, which has generated distrust and fear on the part of the productive sector regarding the continuity of actions to promote Ceis<sup>24</sup>. The last list was published in January 2017, already late, since the previous one was published in December 2015<sup>25</sup>. Such facts put in question the predictability of the process.

The composition of the list has a major influence on project outcomes and achievement of the initiative's objectives, and this preliminary phase is a key factor for the success of the PDP and the internalization of technologies.

A suggestion for the problem faced annually by the MH in organizing work and drawing up the strategic product list for better orientation and continuity of PDP policy is the regimental definition of the use of an independent rapid response program organized between government, academia and the public institutions involved in PDP approvals, such as Gecis, to make the best scientific evidence available to decision makers in the short term.

The analysis shows the need to develop lists appropriate to the desired objectives with the PDP policies, exempt from presenting products that are really necessary in the context of strengthening the national Ceis and that consistently drive the efforts and investments made by the partners involved, especially in a developing country.

## Collaborators

Rezende KS (0000-0002-5183-2291)\*, Silva GO (0000-0003-1809-3789)\* and Albuquerque FC (0000-0002-1512-9531)\* contributed to the conception, planning, analysis and interpretation of the data; critical review of the content; and approval of the final version of the manuscript. ■

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