Process Modeling as a Support to Decision-Making for Productive Development Partnerships:
A Study in a Brazilian Public-Private Organization

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INTRODUCTION

Information can be seen as a condition for survival, given that it extends the communication context and rescuing and preserving social memory. Its value is intangible and resists all the mechanisms of destruction and oblivion since the collection of information. This is due, on the grounds that allows reconstructing the cognitive and knowledge assessment of a given situation in question (Lawrence & Giles, 2000).

By integrating knowledge in an interdisciplinary approach, the power of science, technology and innovation can be harnessed to leverage economic progress. However, the need to obtain full integration between the players in the national innovation system (NIS), namely academia, the private sector, and governments, may represent a hurdle for developing countries. The involvement of these three players is crucial for the success of any effort to foster knowledge integration for innovation (Lundvall, 2010; Nelson, 1993).

At the institutional level make decisions without the right information leads to inaccurate decisions and sometimes disastrous. Decisions based on facts and reliable information are more likely to generate good results thereby enabling decision maker's subsidies to meet the everyday challenges. Proper and timely information to lead developing effective strategies and acts proactively. This action can be called competitive strategy when it involves business approach, which maximizes the value of the capacity of the organization to distinguish the company from its competitors (Porter, 2008b).

The success of public policies designed to strengthen the NIS can better be understood as enhancing integration between academia, the private sector and government, because cooperation between universities, government research centers and funding agencies is so crucial. Meanwhile, it is in the interests of businesses to speed up the introduction of innovations to their production processes. Synergies of this

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kind can boost growth by developing national capabilities (Etzkowitz, 2002; Gadelha et al., 2011; J. L. de Magalhães et al., 2012).

The quality of life of the Brazilian people is on the government's agenda. Its public health programs are designed to foster the healthy ageing of the population, with economic development being linked to improved health conditions fostering a sustainable lifestyle. Brazil is seeking to reduce its health sector deficit and to boost its technology RD&I, including a variety of initiatives and investments targeting academia, the private sector and government. These include a government effort to build technological competency in the production of drugs and medications back to the relative levels seen in the mid-1980s (Magalhaes, JL et al., 2012a).

One of the key policies in this area is the Production Development Policy launched by the government in mid May 2008, which replaces the Industry, Technology and Foreign Trade Policy (PITCE, acronym in Portuguese), introduced in March 2004. The 2008 policy has a broader scope, greater depth, and focuses on increasing coordination, controls and targets. Both it and its predecessor are structured in such a way as to align the public and private sectors, with the former being responsible for facilitating business ventures through tax/fiscal incentives, credit lines, reduced bureaucracy, and regulatory adjustments.

In this sense, Productive Development Partnerships (PDP – Brazilian term) were created. The PDPs are part of these series of strategic actions, signed in the National Policy for Technological Innovation in Health, by Decree No. high cost of health care, developing strategic products with high added value (Costa et al., 2016; Gomes et al., 2015).

Consider that, in general, the management of existing knowledge in the parts holding a given technology to be transferred through a PDP is consistent, then one can think that is an architecture of information management that will lead innovations in a sector, hence, they are essential to be evaluated since from implementation to the impact on society.

This chapter shows an example of how information architecture could be applied in any field of science, in this case, through the linkage of information management and technology transfer for health products. Therefore, the focus chosen were the PDP implemented in Brazil which will provide an average savings to government spending in the order of US$ 1.7 billion upon the expiration of 103 PDP (BRASIL. MS., 2014). Thus, the macro process for PDP projects using information science will be analyzed and mapped. Subsequently, apply process modeling to propose improvements in the acquisition process via the PDP model in the Brazilian public organization.

PUBLIC PRODUCTION OF MEDICINES IN BRAZIL - OFFICIAL PHARMACEUTICAL LABORATORIES

At the end of the 19th century and the beginning of the 20th century, innovation in the pharmaceutical sector was limited and was restricted to Research Institutes, Hospitals and Universities. At this time, Boticas also began to invest in R&D and, later, in the production of vaccines, serums and synthetic medicines (Achilladelis & Antonakis, 2001).

Magalhães et al (2012) describe the pharmaceutical industry as existing in two different scenarios. The first, in the developed world, has an ageing population and therefore a greater need for medications to treat conditions such as cancer, Alzheimer's disease, Parkinson's disease and others. There is also a demand for lifestyle drugs, which include medications for hair loss, male and female sexual enhancement, cholesterol control, with a minimum of side effects, etc. (Magalhaes, JL et al., 2012b).

Meanwhile, in second scenario, there is in some developing countries a need for drugs to fight infectious and parasitic diseases, including antivirals, to meet the needs of poorer population groups. One of the most emblematic examples of this is the fight against acquired autoimmune deficiency syndrome (AIDS) in Africa, although tuberculosis, Hansen's disease, malaria, filariasis, and many other so-called neglected diseases are still awaiting more effective treatments (Magalhaes, JL et al., 2012c; Moon et al., 2012).

In Brazil, at the beginning of the 20th century, public health activities were restricted to urban centers, port areas and as an activity that guaranteed economic maintenance. Activities such as the so-called "disinfections", were commonplace activities, which consisted of depositing a certain variety of chemical products in areas of the city, ports, hotels, and slums of immigrants and as there was no national industry at the time to supply the demand for these products, imports were concentrated in countries such as the United States, Germany and England. However, during the First World War, the difficult access to some products, such as Caustic Soda for example, resulted in the local production by national companies of these products, supplying the country's demand. In the post-war period, foreign companies regained the market (Ribeiro, 2001).

The public production of medicines by Official Pharmaceutical Laboratories (OPL) is an important objective of Brazilian Policy of Medicines (1998), to ensure adequate access for the general population. Brazil has a long history of investments in the self-sufficient public production of priority medicines and vaccines for public health, and some public laboratories appeared in the 50's. Certain policies encouraged the national production of healthcare products, such as the creation of the Executive Group of the Pharmaceutical Industry in 1962, the Medicines Center (CEME – Brazilian term) in 1971 and the Medicines Master Plan of 1973 (Loyola, 2008). However, CEME was the first initiative to establish a National Medicines Policy, involving both public and private production to promote access to essential medicines. CEME had an important coordinating role with the network of OPL, controlling their production and distribution. With the end of CEME's operations in 1990 and, despite the efforts of the Ministry of Health (MoH), the OPL no longer had a central coordination that managed the purchase of medicines (Figueiredo et al., 2017).

OPL aim for the innovation, development and production of medicines, vaccines or medical devices products for Brazilian Unified Health System (SUS – Brazilian term). Therefore, they are considered strategic for Research and Development (R&D) and as price regulators in the Brazilian pharmaceutical market, as when the MoH in 2005 announced that could produce antiretroviral efavirenz, nelfinavir and lopinavir, and the prices of this medicines decreased 59%, 40% and 46%, respectively (Göttems et al., 2021; Magalhaes, JL, 2010). OPL aim to support national health policies to combat and control diseases, promote access to medicines and attempt to meet the demands of the Ministry of Health and Public Health Secretariats, especially the production of medicines for neglected diseases, that are not of interest to the private sector, and this is the particularity of OPL production (Cartaxo et al., 2014; Oliveira, 2007). PDP are partnerships that involve cooperation, through an agreement, between three institutions for guarantee the production and absorption of technology: 1) OPL for medicines and vaccines responsible for absorption and production of technology; 2) national private producer of active pharmaceutical ingredients and; 3) private entities holding the patent or that development the technology, responsible for transfer the technology. The private entities can be national or multinational. To set priorities for the PDP project proposals, a list of strategic medicines for the CIS is created and promulgated by MoH.

In general, until PDP started, OPL had a portfolio focusing in lower-cost medicines. The portfolios were similar, and they compete and with private sector for the public Market. However, with new in-

dustrial policy, the Health Industrial Economic Complex (CEIS – Brazilian term) strategy directs the composition of the OPL´s portfolios (Figueiredo et al., 2020).

Productive Development Partnerships

Partnership is considered successful not only because of the way stakeholders perceive their project's performance, but also because of the way public and private actors cooperate during the any process. In this sense, it is very important to focus on the role of trust and management in the cooperation between public and private actors in in productive development partnerships projects (Warsen et al., 2018).

Aiming at technological autonomy in the country and a developed national industry, not only related to medicines, but in other sectors, the "Innovation Law" was established, Law nº 10.973 of December 2004. Through this law, the government started to promote and carry out several "strategic partnerships" between the national public and private production sectors (Possas et al., 2015).

The policies introduced in recent decades have sparked the need to integrate the knowledge produced in alignment with the previously defined strategies. To assure success and the effective absorption of knowledge in Brazil to produce strategic medications from the SUS list, the government, through the Ministry of Health, has prepared partnership agreements under the Production Development Policy. The partnerships must include at least one foreign pharmaceutical laboratory, one official pharmaceutical laboratory, and one Brazilian pharmaceutical laboratory or pharmaceutical company.

The Production Development Policy became the government's new industrial policy under the legal provisions of the Innovation Law (10.973/2004), law 11.196/2005 (providing tax benefits for technology RD&I), the Biosecurity Law (11.105/2005), and the Biotechnology Development Policy (6.041/2007). Its main aims are to expand access to strategic technologies and to reduce the vulnerability of the public health system (SUS) by strengthening the health industry. The first PDPs were created in 2009 as part of a broad policy linking health with development for the welfare of the population and to help consolidate the national production of strategic technologies for the SUS. Its objectives (BRASIL. MS., n.d.) are:

a) to streamline the State's purchasing power by selectively centralizing health expenditures to reduce the acquisition costs of the SUS and enable the production in the country of innovative products of extreme importance to health, focusing on improving the population's access to strategic supplies;
b) to foster joint technological development and knowledge exchange for innovation;
c) to prioritize the local manufacture of products of a high cost or of public health and social impact; and
d) to reduce prices significantly and progressively as technology is transferred and developed in Brazil.

The plan for the execution of the Production Development Policy contains targets known as "systemic actions", which, once implemented, will have an impact on costs in Brazil thanks to their broad scope. The aim is to:

- increase annual fixed investments/GDP;
- increase private RD&I expenditure/GDP;
- increase the market share of Brazilian exports;
- support small and medium-sized businesses by fostering capacity building for competition in foreign markets, thereby increasing the number of such businesses which export goods.

The absorption and integration of knowledge, fostering more aligned actions and strategies, is designed to replicate in the field of health the success achieved in other sectors of the economy. Some examples worthy of note are (BRASIL. MS., n.d.):

a) World Leadership: goal achieved in mining and steel, aeronautics, and ethanol production;
b) Penetration of Markets: durable consumer goods and standardized capital goods. However, for health the aim is also to position or maintain the production system amongst the leading global exporters;
c) Specialization: to build and consolidate competitiveness in technology-intensive areas. The strategy covers not just the health industry, but also information technology and custom-made capital goods;
d) Brand differentiation or enhancement: to position Brazilian brands and businesses amongst the top five in the world;
e) Greater access by the population to goods and services: not only health services, but also broadband internet, durable and non-durable consumer goods, and civil construction.

This superstructure of broad goals and specific targets is set by the Production Development Policy where one sector, having benefitted, can interlink, and interact with others and support the health industry and other industries. The action lines of the Production Development Policy are designed to enhance competitiveness and encompass a variety of technologies, including nanotechnology and biotechnology. Another consequence of the Production Development Policy is to attract multinationals to make investments in health in the country.

In the pharmaceutical industry, the creation of Public-Private Partnerships (PPP) took place through the realization that this would be a favorable response to the difficulties related to pharmaceutical innovation in the country. To achieve a public health objective or the production of health-related products, PPPs are agreements between public sector entities and private sector entities. These agreements can be formal or informal, and do not necessarily have to be a bilateral agreement, so there can be one or more companies on both the public and private sides. Therefore, the basis for the operation of the PDP comprises the participation of a public laboratory, a national or foreign pharmaceutical laboratory that is preferably located in the country and a Brazilian API producer laboratory (Costa et al., 2016; M. de A. F. M. Magalhães & Medronho, 2017; Reithinger et al., 2009).

The PDP has four phases. Phase I is the project proposal and from the current strategic list of drugs, the OPL prepares a PDP project proposal through a standard form from the MoH. The project proposal must contain the strategic drug chosen and the institutions that are part of it (API producer and the private institution responsible for technology transfer, with priority given to a national laboratory). The OPL is responsible for contacting partners and MoH. This in turn maintains contact only with the OPL. As the acquisition of this medicine must be centralized by the MoH or the possibility of being centralized, the OPL, during the transfer, buys the medicines from the private partner and sells it to the MoH. During the transfer, the OPL executes the PDP with the profit between the purchase from the private partner and the sale to the MoH. OPL is guaranteed the purchase made by MoH and exclusively based on the lowest price in the global market. The proposal will be sent to the MoH.

Phase II comprises a contract between the Ministry of Health, OPL and other partners. This contract must contain how the technology will be developed, transferred, and absorbed, in addition to intellectual property rights and the obligations of each one. The obligations of each, the OPL and private entities must invest a minimum percentage in research, development, and innovation. The MoH must detail the conditions for purchase. In addition, the OPL must have an industrial manufacturing layout to produce

the strategic drugs selected by CEIS. Through this contract the MoH has a guide to follow the process of the first purchase after the PDP agreement. The contract will be signed, and its sanitary registration published by the National Health Surveillance Agency (ANVISA – Brazilian term) – Brazilian sanitary regulatory agency. The Sanitary registration can be granted to the private entity or to the OPL, as the official patent holder may not be the private entity that has the PDP; therefore, in this case the private entity will not have a health record before phase II. If the product does not have a patent, the preference for the development of the strategic drug for the CEIS usually goes to national private entities.

There is no period limit at this stage, but there is an internal committee created at ANVISA, especially to deal with the requirements necessary for the PDP sanitary registration (VARGAS, 2016). The private entity with the purpose of modernizing and expanding the manufacturing layout and development of strategic drugs for the CEIS, can be financed by BNDES or by the study and project financer (FINEP) linked to the Ministry of Science and Technology, Innovation and Communication (Gadelha, 2022).

Phase III is the one that, in a concrete way, begins the execution phase of product development, transfer and technological absorption. The contract signed for the acquisition of the strategic product is signed between the OPL and the MoH (DONATI, 2015). The OPL must present to the MOH the progress of technology development and transfer, technology absorption and the application of the sanitary registration in the name of the OPL. At this stage, there is a time limit of five years or ten years to complete the transfer. Usually, ten years' time is accepted for biological medicines. The evolution of the process demonstrated to the MoH must be in accordance with the schedule that appears in the approved executive project, or according to the new schedule, if it has been modified (Possas et al., 2015).

In phase IV, technology internalization begins, which means the end of the process of development, transfer, and absorption of technology for the PDP product. The OPL is already able to produce the drug on the strategic list proposed in the PDP with autonomy and technological independence. The private laboratory will have completed the development, transfer, and technological absorption and the MoH will receive the drug directly from the OPL. If, within 5 years or 10 years, the OPL has not fully absorbed the technology, the MoH will stop purchasing the medicines exclusively from it (Figueiredo et al., 2017). If the OPL is unable to meet the demand for the drug requested by the MoH, the conventional bidding process will be carried out (Bidding Law No. 8,666 of June 1993) to supply the complementary quantity of the drug.

After phase IV, the OPL and the private laboratory holding the drug registration can compete in the national pharmaceutical market.

As the PDP demonstrates a successful case in the internalization of medicine with absorption of technology, the Brazilian Ministry of Health periodically prepares a list of strategic medicines for the CEIS. Its purpose is to set priorities for PDP project proposals. This annual list of strategic medicines is coordinated by the Secretariat of Science, Technology and Strategic Inputs (SCTIE), the Secretary of Health Surveillance (SVS – Brazilian term), a government agency that is part of the GECIS, and Entities of the Competitiveness Council of the pharmaceutical sector. GECIS annually issues recommendations for the strategic drug list update process. The instruments related to a market assessment or how the selection of drugs can affect the Brazilian market are not available (Santos-Pinto et al., 2013).

The selection of these strategic products is based on three criteria: the importance of the product for SUS, depending on health promotion, prevention and recovery policies; the possibility of acquisition by the Ministry of Health in a centralized way, or aiming at a centralization; and the interest of national production of API or critical technological components that are relevant to the CEIS (Figueiredo et al., 2017). Additionally, for the selection, at least one of these factors must be considered: the high cost of the product for the SUS; dependence on the import of the product to implement the actions of promo-

tion, prevention, and recovery of health in the last three years; if it is a neglected product or if there is evidence of shortages in the SUS; the recent technological incorporation in the SUS.

Planning, Management and Process

It is necessary to understand the behavior of costs or even production cycles, sales, supplier relationships, that is, a series of activities with potential for differentiation linked to the company, using the value chain is of great help, as it fragments the company in activities with strategic relevance (Porter, 2008a). It constitutes a set of activities that in essence are value creators, from the most basic existing sources to the final product that the consumer receives. Therefore, through the value chain, a broader and more efficient focus can be given to the company (Gavirneni et al., 1999).

The elements that form the value chain are the primary activities, which normally in any industry can be identified in a generic way in five activities; internal logistics, operations, external logistics, marketing, and sales. Support activities can also be divided into other activities of different value, they are specific to each industry, but generally can be divided into four categories: Acquisition, technology development, human resources management and infrastructure. The links in the flowchart have the function of linking the activities, as they are not independent, but interdependent. Porter & Kramer (2011) suggests that value links are related to value activities. So, there is a relationship in how one activity is performed, and another has a certain performance or cost. There may be many links, but the most common are those between primary and support activities (Porter & Kramer, 2011).

Processes are activities performed in a logical and organizational way, by humans to add value to the inputs, or information (input), received by a supplier to generate a product or service for a particular customer (Output). The processes can be divided into three: Finalistic, Support or Management. The type that adds value to the customer and is a set of activities that are performed with the objective of fulfilling the mission is called the finalistic process. The support process are activities performed with the objective of providing support for the finalistic process itself. It adds value to other processes, not to the customer. The third type of process is management, whose characteristic is to measure, monitor, control and manage the present and future of the business. This type does not add value to the customer, but it is necessary to ensure that the entire organization proceeds according to plan.

The characteristics that every process has are having inputs and outputs, they are executed by men and/or machines, they transform something, they have activities and business rules. The processes start through an event (It would be a "start", a trigger). And it has the purpose of serving a customer. It can and should be measured through indicators (Ito, 2019).

When a process needs to be analyzed and planned, conceptually it is important to separate the operational, tactical, and strategic plan. An operational plan is the plan that a manager uses to fulfill his job responsibilities. "Operational planning includes all the elements and actions necessary to achieve each single objective." Operational planning can also be done generically before the event but should be adjusted accordingly. "A tactical plan is concerned with what lower-level units within each division should do, how they should do it, and who is in charge at each level. Tactics are the means needed to activate a strategy and make it work. Tactical plans are concerned with shorter timeframes and narrower scopes than strategic plans." The terms operational and tactical planning are often used interchangeably (Love et al., 2014).

In relation to Business Process Management (BPM), it is important to note that without a "process view", often the company's objective does not reach the customer's expectations, or even is not achieved. Sectors think individually, not integrated. The process view is an end-to-end view, that is, from the

"input" of inputs to the "output", that is, delivery to the customer. BPM is the management discipline that integrates the organization's strategies and objectives with customer expectations and needs with a focus on the end-to-end process (Jamil et al., 2016).

What encompasses BPM are strategies, objectives, culture, roles, policies, methods and technologies. All this with the objective of analyzing, designing, implementing, managing performance, transforming, and establishing process governance. BPM is fragmented into stages that form a cycle that seeks continuous improvement like the PDCA cycle (Jamil et al., 2015). The PDCA cycle is named after the initials of the words Plan; Do (Run/Do); Check and Act, make up the main name of the method. The use of this cycle opens a gap for the internal processes to be exemplified and subsequently improved through the component steps of the initials in the name. Planning is to make a diagnosis of the current situation of the existing processes, and soon after drawing up an action plan. Execute, as the name implies, apply what was outlined in the action plan of the previous step. Checking is ensuring that what was outlined in the action plan is in line with what was executed. Finally, acting is the step in which an overview of the entire experiment will be made, verifying that all steps have been fulfilled from the beginning. From the end, the cycle can repeat itself countless times; is infinite, as each time it is completed, another opportunity for process improvement may arise (Werkema, 1995).

Process modeling, which is part of the BPM continuous improvement cycle, is one of several other steps that are part of this management tool, including: strategic planning, process analysis, business process management, processes, process implementation, monitoring, control and process refinement. It is important to highlight that the process modeling step is a step that must be well understood by the parties involved, as it is possible that its misuse will negatively affect the proposed organization, consequently affecting the rest of the BPM cycle (Freeman, 2010).

It is important in the modeling stage, knowing the process, redesigning this process, standardizing the process, seeking to adjust documentation, training or auditing. Some methods used to gather information are interviews, research, web conferencing, practice, doing rather than observing. To model business processes in a standardized way, there are "modeling notations", and the most used is the Business Process Model and Notation (BPMN).

The BPMN enables the view both in general and at the operational level, being the most recommended for the use of this work. BPMN works as a notation that is easily understood by all business users. It must be understood by those who sketch the process, by the deftly technical developers responsible for implementing it, and by the users who will monitor the implemented processes. BPMN synthesizes the processes created in diagram form (Wang et al., 2006).

There are many standards for process modeling and that is why BPMN as a graphic notation has the facilitating feature, as it proposes to facilitate the clarification of processes in different companies, with the same depth.

Productive Development Partnerships at the Official Pharmaceutical Laboratory

A standard procedure was created to indicate the profile of drugs that the organization proposes to manufacture – to participate in a PDP. The choice of products for PDP is based on the Ordinance of the Brazilian Ministry of Health, No. 704 of March 8, 2017. It has a list of strategic products for the SUS. In view of the organization's "mission", the top management confronts the types of medicines that are part of the OPL portfolio and, through this analysis, considers the list of strategic SUS products as a practical

and priority offer for participation. The mission of the OPL is "To develop, manufacture and distribute medicines and chemical products to serve... ...the Public Health System, promoting quality of life.".

In some cases, the OPL receives product projects where high manufacturing technology is needed or at least a certain area adequacy to receive such technology via PDP. In this way, the OPL is gradually developed to improve its manufacturing plant. Given the lack of installed capacity, this can be a reason for non-approval in PDP projects.

Another criterion for failure to participate in a PDP may be the price for medicines offered in projects sent to the Brazilian Ministry of Health. For example, the laboratory is not approved by offering a price higher than the maximum regulated by the Medicines Market Regulation Chamber (CMED – Brazilian term)[1].

It is worth mentioning other criteria for the selection of private partner companies to participate in a PDP. They are: the company has authorization to operate in the country, with the activity of manufacturing medicine, the authorization to operate with the activity of importing and distributing medicines, the valid registration with the health authority of the country where the manufacturer is installed, the plant of the manufacturer installed in Brazil, have the Good Manufacturing Practices Certificate issued by ANVISA and have CBPF issued by the health authority in the country where the manufacturer is installed.

Macroprocess Mapping Involving the Productive Development Partnership

The PDP process may vary in some steps, such as the choice of drug class and the number of partners involved in the project. Therefore, it is necessary to describe and map the processes and sub-processes that are present in any project carried out by the organization, regardless of the factors mentioned above. It is important to note that the process flow used by the OPL is based exclusively on Ordinance MoH/GM nº 2.531/2014. Thus, for better understanding and visualization, the PDP phases are itemized:

- Phase I: essential to assist in the organization's decision making. The process begins with the choice of the OPL and publication in the Federal Official Gazette to choose partners. In this process, there are rules for choosing companies, such as production capacity, compliance with current health regulations, etc. Once approved, the project is forwarded to the Brazilian Ministry of Health, as an executive project. After approval of the project, a term of commitment is signed, and it is published in the Official Gazette of the Union as "Extract of the Term of Commitment". In this way, considering that the evaluation of the executive project by the Ministry of Health was mapped and approved, the Phase II Process follows.
- Phase II: at this stage, contracts are already signed with the participation of different areas of the Official Laboratory. The private company delivers its Site Master File (SMF) for evaluation of the manufacturing structure. In parallel, the manufacturer of the Active Pharmaceutical Ingredient (API) delivers its respective SMF and Drug Master File (DMF). With the favorable opinion, the stages of assessment of the industrial infrastructure and industrial and technological training begin at important points so that the transfer of the drug is carried out in its entire spectrum. It should be noted that in this phase all Human Resources training necessary for the Official Laboratory takes place. Likewise, Quality Assurance monitors the entire process of obtaining the Good Manufacturing Practices Certificate (CBPF) and Sanitary licenses from the private partner and the API manufacturer. Periodic reports are made and sent to the MoH. Once all the steps are overdue and approved, production by the PDP only takes place when the private laboratory obtains registration with ANVISA.

- Phase III is subdivided such as:
  - Phase III - step 1: carry out a technical visit to monitor the production process in the private laboratory. Request funding from the Brazilian Ministry of Health through a technical report evidencing the need for certain infrastructure or equipment to carry out the PDP. At this stage, check the GMP certification for the factory. If there is no certification yet, it is necessary to request ANVISA fulfilling all sanitary requirements. It should be noted that for technology transfer, the Quality Control and API warehouse sectors must also submit the entire dossier for regulatory submission to complete the transfer phase.
  - Phase III - step 2: refers to the survey of all documents from the production sector, such as the stages of transfer of the secondary packaging with a person responsible for the stage of the private laboratory. All documents are submitted and registered with ANVISA.
  - Phase III - stage 3: concerning the transfer of technology from the drug production stage to the OPL. The Official Laboratory is a national private laboratory that manufactures the API and/or a foreign laboratory on Brazilian soil.
  - Phase III - step 4: the transfer from the foreign API manufacturer to the national manufacturer is monitored. It should be noted that if the API manufacturer is a national producer, there is no transfer and assessment of the API DMF. It is only done after the SMF evaluation of the manufacturer's plant by the Official Laboratory. After this step, the final registration must be requested to ANVISA.
- Phase IV: this phase refers to the internalization of the technology. It is the finalization of the process of transfer and absorption of technology object of the PDP by the Official Laboratory. At this stage, the OPL becomes the holder of all the information that guarantees the mastery of the technology and is capable of technological portability to meet the demands of the SUS. In this way, the PDP is completed.

Synthesis of The PDP Model as A Support for Decision Making

In table 1, a summary of the propositions resulting from the study on PDPs carried out in this work can be seen. The critical points of the acquisition-formalization process of the Productive Development Partnership in an Official Pharmaceutical Laboratory and the private pharmaceutical company are highlighted.

FUTURE RESEARCH DIRECTIONS

Considering the potential of Productive Development Partnerships in the public-private sector, it is necessary to consider applying the mapping of processes in other sectors of the economy, in the public sector, in order to verify the same potential. The pharmaceutical sector proved to be effective, given the internalization of drugs and medications that were not yet under the control of technology in Brazilian territory.

Not only exploring the PDP model, but comparisons of other forms of partnerships between the public and private pharmaceutical sector, such as Technology Transfer, Public Private Partnerships, Value Added Reseller (VAR) and Alliances should be considered. Strategic.

However, validate the PDP carried out from the work carried out in the OPL, after a period of internalization, in order to attest to the economy of the process, cost and the improvement in access by the user population.

Table 1. Summary of proposed results

	Critical Points identified	Improvement proposals
1	Missing OPL process map	OPL will now regularly map its PDP process for updating
2	Lack of strategic planning for choosing portfolios	Strategic planning will start at the Board for case-by-case evaluation
3	Use of the MOH platform to prepare the PDP project	Synthesize projects in physical form until MOH platform issues are fixed
4	Bidding and purchase stage	Creation of an integration sector between the requesting areas and the areas responsible for purchasing
5	CBPF search during the PDP acquisition process	Certify OPL in GMP before entering complex manufacturing projects
6	Criteria for choosing private partners	Highlight partners that have the drug in a complete development and commercialization phase
7	Questionnaire for partner selection	Increase criteria for partner selection
8	Absence of a legal sector specialized in medicines and patents	Creation of a specific legal sector
9	There is no technical visit to the private laboratory prior to the partnership	Carry out a technical visit before formalizing a partnership with a private laboratory

Source: Created by the authors (2022)

FINAL CONSIDERATIONS

The pharmaceutical industry is a sector intensive in technology and innovation. As in other areas, Knowledge Management is essential in organizations. In this sense, Information Science, through information technologies, proves to be effective in helping with tools and models that favor better decision-making for managers.

PDPs are configured as an effective partnership model between public and private entities. The transfer of technology is passed on and, finally, productive, and technological self-sufficiency is ensured. The transferor, on the other hand, conquers market dominance during the execution of the PDP, as well as royalties etc.

For the management and construction of the model, process mapping is essential, to identify gaps and opportunities for improvement. This strategic planning is essential, as it measures existing risks and seeks to keep the schedule achievable. Thus, process modeling must occur for all phases. Thus, information technology should be used as an important tool in the decision-making process for effective knowledge management in organizations.

It is evident that the use of information management tools for the management of productive processes in the strategic management of public-private partnerships, bring perspectives, contributions and views on knowledge management and information technology.

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KEY TERMS AND DEFINITIONS

Brazilian Unified Health System (SUS): In Brazil, the health system is Universal, that is, it guarantees free access to all Brazilian citizens and/or with a residence permit in the country.

Business Process (BP): Also considered business process modeling or Business Process Modeling in systems engineering. It is the activity of representing a company's processes so that the current process can be analyzed and improved.

Economic-Industrial Health Complex (Complexo-Economico-Industrial da Saúde – Brazilian Term) (CEIS): Refers to the entire productive base involved in the provision of services, promotion, and health surveillance. The Complex involves both the secondary segment of the economy, such as the chemical, biotechnological, mechanical, and material based industries, and the tertiary sector, referring to the services provided in health establishments.

GECIS: Is the Executive Group of the, created within the scope of the Brazilian Ministry of Health. It aims to promote concrete measures and actions aimed at creating and implementing the Brazilian regulatory framework regarding the Federal Government's development strategy for the health area, according to the guidelines of the national policies for strengthening the productive complex and innovation in health, as well as how to propose other complementary measures.

National Health Surveillance Agency (ANVISA): It is a regulatory agency, in the form of a special regime autarchy, linked to the Ministry of Health. Its institutional purpose is to promote the protection of

the population's health, through the sanitary control of the production and consumption of products and services subject to sanitary surveillance, including the environments, processes, inputs, and technologies related to them, as well as the control ports, airports, borders and customs areas.

Official Pharmaceutical Laboratories (OPL): These are public pharmaceutical laboratories in Brazil. They belong to the Brazilian government, whether at the federal, state or municipal level, and may also belong to the military forces (army, navy or air force). They produce strategic drugs for the Brazilian government and do not compete directly with private pharmaceutical companies, since they produce drugs (in general) for diseases that perpetuate conditions of poverty (malaria, tuberculosis, leprosy, etc.). They can also act in the production of vaccines and immunobiologicals, such as Fiocruz's Bio-manguinhos Laboratory.

Productive Development Partnerships (PDP): Aim to expand access to medicines and health products considered strategic for the Brazilian Unified Health System (SUS – Brazilian term), by strengthening the country's industrial complex. These partnerships are promoted by the Brazilian State, where the partners must be, obligatorily, an Official Pharmaceutical Laboratory (public laboratory), a national private pharmaceutical laboratory and the foreign pharmaceutical laboratory (technology holder).

ENDNOTE

[1] "The Medicines Market Regulation Chamber (CMED) is the inter-ministerial body responsible for the economic regulation of the medicines market in Brazil and ANVISA plays the role of Executive Secretary of the Chamber. CMED sets limits on drug prices, adopts rules that encourage competition in the sector, monitors commercialization and applies penalties when its rules are not complied with. It is also responsible for setting and monitoring the application of the mandatory minimum discount for public purchases". (CMED, 2020)