

# **CAFÉ WORKING PAPER NO.19**

Centre for Applied Finance and Economics (CAFÉ)

# How does public support influence the Large Brazilian Pharmaceutical Companies' decisions to internationalise?

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June 2022

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# How does public support influence the Large Brazilian Pharmaceutical Companies' decisions to internationalise?

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### Abstract

The study explores how public policies have supported the internationalisation of the Large Brazilian Pharmaceutical Companies and analyse the influence of two types of support (financial or non-financial) in the decision to go abroad based on the companies' point of view. The methodology consists of a multiple case study through document analysis and interviews with eight Large Brazilian Pharmaceutical Companies (making up 30% of the Brazilian pharmaceutical market share), five policymakers, and three sector experts. Regarding the findings, the non-financial support was more critical for companies at the beginning of going international by compensating the latecomer disadvantages. Nevertheless, financial resources for internationalisation were previously generated and leveraged, partly, by policy incentives to strengthen local production. This paper presents a pioneering case study research for Brazil on different policies to support the internationalisation of companies. So far, the studies on the Brazilian government backing companies' internationalisation have focused on the general policies and financial support or the natural resource-based companies. This paper contributes to the literature of International Business by focusing on a science-based sector and contrasting the effects of two types of support for the internationalisation of companies. The study provides policy recommendations to support the internationalisation of pharmaceutical companies. Supporting companies from developing countries, such as Brazil, is necessary to compensate for the lack of advantages of being a latecomer and to reduce the knowledge gap between the different institutional environments.

**Keywords:** public policy; internationalisation; pharmaceutical companies; Brazil; emerging countries multinationals.

#### 1 Introduction

Several studies (Kumar et al., 2013; Lorenzen, 2005) have pointed out the importance of internationalisation to strengthen and increase companies' competitiveness from developing countries. Internationalisation can be used as a springboard by companies from developing countries to shorten the technological gap related to companies from developed countries (Luo and Tung, 2007). By going abroad, companies can access resources that are not available in their home markets, representing gains to their innovative capabilities (Li, 2003; Mathews, 2006). The international expansion also benefits the home country by reducing external vulnerability through export growth, diversifying the knowledge base, and creating technological spillovers from abroad to the domestic market (Cyrino et al., 2017; Esteban-Jardim and Urraca-Ruiz, 2018, 2017; Lipsey, 1999). In this sense, internationalisation can be a technological catching-up mechanism when designed for that purpose (Jayanthi et al., 2016; Kothari et al., 2013; Lee, 2016).

The investment in foreign markets is a strategic decision of the companies. Still, the public policies have the role of creating instruments that facilitate and stimulate their external expansion, following their industrial development goals. The international business literature has pointed out that the policies to support internationalisation have different effects between countries. The governments from developing countries tend to exert more influence over their firms' investment decisions than their counterparts in developed countries because they are more constrained by economic policies and the content and quality of national institutions (Dunning et al., 2008). As companies from developing countries have entered the international market later than those from developed countries, public policies are decisive in building its competitive advantages and directly impacting their performance in the international environment (Kale, 2007; Pradhan, 2004).

The governments can create various policies' instruments to support internationalisation, such as loans, tax breaks, risk insurance, bilateral/regional agreements, foreign markets information assistance, and others. These instruments fall into two categories: financial and non-financial. The importance of policies to support internationalisation, mainly in developing countries, is well established in the international business literature (Cuervo-Cazurra and Ramamurti, 2014; Liu and Giroud, 2015; Luo et al., 2010; Pinto et al., 2017; Sauvant and Mallampally, 2015; Wang et al., 2012). However, there is a lack of studies investigating how financial and non-financial supports influence the companies' decision to go abroad. Therefore, taking the Large Brazilian Pharmaceutical Companies (LBPCs) as the object of this study, we aim to explore how public policies have supported their internationalisation and analyse the influence of two types of support – financial or non-financial – in the decision to go abroad based on the companies' point of view.

So far, the studies on the Brazilian government backing companies' internationalisation have focused on the general policies and financial support offered by the Brazilian National Bank (BNDES) (Acioly and Schatzmann, 2009; Alem and Cavalcanti, 2005; Fleury and Fleury, 2014; Musacchio and Lazzarini, 2014; Pinto et al., 2017; Sennes and Mendes, 2009). Also, some context-specific studies on the natural resource-based companies, so-called national champions (Casanova and Kassum, 2013; Caseiro and Masiero, 2014; Finchelstein, 2017; Fleury and Fleury, 2011; Santos, 2015). This paper contributes to the literature by focusing on a science-based sector and analysing two types of supports backing the companies' internationalisation.

This paper presents a pioneering case study research for Brazil on different policies to support the internationalisation of companies. We bring first-hand evidence of the eight largest LBPCs, acting in the Brazilian market for 40 years, on average, entirely owned by Brazilian shareholders and family-controlled companies. These companies are manufacturing generic and low value-added drugs and are highly dependent on imported inputs – about 90% of the Active Pharmaceutical Ingredient (API) are from China and India (Mitidieri et al., 2015). The changes in the Brazilian institutional environment over the past 20 years have contributed to the Brazilian pharmaceutical industry' strengthening concerning the LBPCs' expansion and the increase of their innovation efforts (Hasenclever et al., 2018).

The paper is organised as follows. In the second section, we present the theoretical framework on which the study is based. In the third section, we describe the methodological procedures for the research. We introduce the characteristics of the institutional environment for LBPCs in section four. The results and their discussion are presented in sections five and six. Finally, we give our conclusion and policy recommendations.

#### 2 Theoretical framework

Prior research has pointed out the relevance of the institutional context in the decisionmaking of TNCs, and, within this spectrum, the role of policies to support the companies' internationalisation (Cantwell et al., 2009; Hoskisson et al., 2000; Peng et al., 2008). Several authors are focusing on home or host policies to stimulate internationalisation or the differences between developed and developing countries (Gaur and Kumar, 2009; Hong et al., 2015; Khanna and Rivkin, 2001; Luo et al., 2010; Peng et al., 2008; Sauvant and Mallampally, 2015; Wang et al., 2012). However, understanding how the different policy instruments support companies' internationalisation is less present in the international business literature.

The institutional environment represents a set of rules and behaviour patterns such as habits, routines, and laws that regulate the interaction between individuals, groups, and organisations in society (Edquist and Johnson, 2006). The institutional structure modifies its companies' competitive advantages as it interferes with its resources, capabilities, and competitiveness – mainly the innovation capabilities resulting from the interactive learning process (Lundvall & Johnson, 1994). Thus, the institutional structure influences internationalisation strategies (Dunning, 2006). Countries with more institutional similarities facilitate the technology transfer between subsidiaries and headquarters (Eriksson et al., 1997; Johanson and Vahlne, 2009; Teece, 2014).

The policies to support companies' internationalisation is part of the institutional environment. The relevance of this kind of policy remains of the benefits reaches with internationalisation. The establishment of international activities provides companies better access to resources, such as know-how, technology, management experience, which increase their competitiveness (Sauvant and Mallampally, 2015). The engagement in the Global Value Chains through outward FDI enhances growth and productivity, although the upgrading process is often conditioned by domestic policies (Kummritz et al., 2017; OECD, 2013). In addition, the most crucial benefit for developing countries is to accelerate the catching-up process at the microeconomic level. In many developing countries, the weak national innovation systems explain why the technological strategies through internationalisation have become such an essential channel for technological catching-up (Fan, 2011; Kim, 1997; Lee and Lim, 2001; Lee and Malerba, 2017; Luo and Tung, 2007).

As well as other policy instruments for promoting companies, the support for internationalisation is not an isolation measure of the governments. It needs to be included in the industrial policies and seeks long-term goals. The governments need to be clear about what they intend to achieve with international insertion and to design instruments for this purpose (Perez, 2008).

In developing countries' environment, the institutions can be obstacles or incentives for internationalisation (Cuervo-Cazurra, 2008; Cuervo-Cazurra, 2012; Cuervo-Cazurra and Genc, 2008; Hoskisson et al., 2013; Luo and Wang, 2012; Meyer et al., 2011; Teece, 2014). Narula & Dunning (2010) set that companies' internationalisation in a country is linked to its economic development stage. A company starts going abroad as the country improves its economic, political, and institutional structure. Because of this, companies from developing countries are latecomers to international business.

The companies from developing countries start going abroad while their institutional structure was still underdeveloped seek to improve their competitive advantages from the internationalisation process, else companies from developed countries that internationalise to exploit their capacities in the foreign market (Ramamurti, 2009). So, the government backing is especially critical for companies from developing countries that internationalise under the influence of their home governments' policies and regulations (Cuervo-Cazurra and Ramamurti, 2014; Luo et al., 2010). Moreover, the policies can help to compensate for the lack of managerial skills (Liu and Giroud, 2015) and technological capabilities (Wang et al., 2012), moderating the negative influence of institutional distance on the internationalisation process (Pinto et al., 2017). In this perspective, governments of Asian developing countries, such as South Korea, China, India, Taiwan, and Singapore, have engaged with public policies to promote the internationalisation of their local companies as a mechanism for achieve national strategic objectives and improve economic competitiveness (Lau, 2003, Buckley et al., 2008, Liu et al., 2013).

In terms of instruments, Unctad (2006) presents seven categories of promotional policies for outward FDI: information provision, match-making services, incentives, feasibility studies, legal support, support for training, investment guarantees. According to Luo et al. (2010), governments from developing countries are able to offer a range of institutional support for local firms to be global, such as (i) financial incentives, for instance, tax breaks and low-interest loans; (ii) political risk insurance; (iii) agencies focused on the international expansion of private companies; (iv) double taxation avoidance agreements; (v) articulation of bilateral and regional foreign investment protection treaties; (vi) organisation of a bilateral or multilateral framework to liberalise investment conditions in host countries; (vii) assistance the TNCs in dealing with governmental or legislative institutions in the host country. Sauvant et al.(2014) contribute to distinguishing the types of instruments offered to companies in (a) direct or indirect, (b) provided by the government and non-government actors, (c) grouped into broad categories of support and the types of institutional actors that often offer them, (d) different in terms of their objectives and (e) different in their level of development, coherence, and integration.

The policies and instruments' effects vary across companies and sectors. In order to assess the influence of a range of institutions on companies' behaviour, it is necessary to know which specific institutions apply to particular companies/sectors (Allen, 2013). The policies would select some factors to determine whether an investor qualifies for support regarding the industry in which an investment is made, the size of the investing firm, country of destination of foreign activities, and others (Sauvant and Mallampally, 2015). In this sense, it is worth considering that some sectors have more significant potential to influence industrial development. Companies from technological/knowledge-intensive industries and the science-based sector as pharmaceutical (Lall, 2000; Pavitt, 1984) have a more dynamic effect on economy and capacity for growth/diversification, close interaction between firms, universities/research institutes, and propensity for technology spillovers to other sectors (Mazzucato, 2013). The internationalisation strategies carried out by pharmaceutical companies are influenced by national governments' policies and the characteristics, orientation, and nature of technological changes (Dicken, 2003). The experiences of developing countries are examples of government support for pharmaceutical companies' internationalisation. The internationalisation of Chinese and Indian pharmaceutical companies was heavily determined by the government (Dunning & Narula, 1996). Studies such as Kale's (2007) and Pradhan's (2004) evidence the relationship between the Indian pharmaceutical industry's success in recent decades and government policies shaping corporate strategies towards internationalisation. The government policies have enabled Indian pharmaceutical companies to overcome the disadvantage of late external insertion by enhancing their domestic productive capacities through technological catching up completed in the internationalisation (Jayanthi, Sivakumar & Haldar, 2016).

The importance of non-financial incentives to support internationalisation is highlighted in studies on developing countries. Sauvant and Mallampally (2015) propose that the information services to inform on available opportunities and host country conditions are likely to be more important to companies from developing countries to reduce the knowledge gap related to the institutional environment. Hoskisson et al. (2013) and Luo et al. (2010) also pointed out the importance of government provide privileged access to information on host countries and networks, including foreign public agencies. UNCTAD (2006, 1995) defined that the most straightforward and earliest form of outward FDI promotion in developing countries is providing information and technical assistance, especially for smaller and inexperienced investors. However, there is no differentiation between financial and non-financial incentives to support internationalisation applied to a context-specific.

# 3 Methodological procedures

The study presented in this paper consists of a multiple case study to understand a contemporary phenomenon with a high degree of complexity, which is the case of the policies and instruments to support companies' internationalisation. The techniques we used are literature review and field research, with interviews and document analysis. By applying the triangulation, we test the validity of converging information from different sources (Patton, 2015). Although this method allows a deepening understanding of the phenomenon, it is not subject to generalisations (Yin, 2017).

The literature review aimed to understand the research problem. We covered the main topics: the influence of the institutional environment on companies' strategies; the role of policies to support the internationalisation of companies from developing countries; types of instruments to support internationalisation; and the Brazilian policies to support internationalisation.

The field research was carried out to gather first-hand empirical evidence. Adopting this technique facilitates understanding what is behind a scantly researched phenomenon, evincing details that could not be captured by other means, such as aggregated analyses elaborated from purely quantitative methods (Miles and Huberman, 1994). We carried out field research conducted by 19 semi-structured and focused interviews with 16 actors: eight companies, five

public institutions/representative bodies of the sector, and three experts in the Brazilian pharmaceutical sector. The interviews were carried out from July 2017 to February 2018 and were conducted in person (16) and by call (3). The field research was carried out in six stages: (i) goal determination; (ii) selection of interviewees; (iii) preparation of reports about the companies; (iv) preparation of the questionnaire; (v) initial contact and interviews; and (vi) transcription, consolidation, and data analysis. The topics covered in the interviews of this research<sup>1</sup> refer to the actors' evaluation of policies, use of instruments by companies, factors that helped to go abroad, and the institutional obstacles to internationalise.

The criteria for companies' selection consist of (a) to belong to the pharmaceutical industry (classified in the National Classification of Economic Activity – CNAE<sup>2</sup>, division 21); (b) to be a large size (at least 500 employees); (c) to be Brazilian controlling capital; and (d) to have internationalisation strategy, previously identified in the companies' report and news about them. The eight companies that meet the criteria – Achè, Biolab, Blanver, Cristália, EMS, Eurofarma, Hebron, and Libbs – represented more than 30%<sup>3</sup> of the Brazilian pharmaceutical market turnover in 2018. The institutions selected are in charge of policies and instruments to support internationalisation: the Ministry of Economy, responsible for the industrial policies; the Brazilian Development Bank (BNDES), accountable for the financial incentives; the Brazilian Agency for Export and Investment Promotion (Apex-Brasil), in charge for non-financial incentives; and the National Sanitary Surveillance Agency (ANVISA), which is responsible for the regulatory issues. The experts' selection is based on their work as consultants or representative associations for the pharmaceutical sector.

We performed the data analysis from interviews and documents using Atlas.ti software. The coding process was carried out in three rounds – open, axial, and selective coding (Gray, 2017). First, we conduct a top-down analysis, and then we worked on open coding on the data to reduce the amount of information. The data phenomena were named and categorised through close examination (Corbin and Strauss, 2015). During this process, the codes were constantly compared to categorise the phenomena with fitting names. Second, the codes were connected, depending on their relatedness, into subcategories by axial coding (Gray, 2017). Third, the subcategories created during the axial coding were grouped into major categories using selective coding. To increase the reliability of the coding, several moments of discussion took place to revise the codes (Gray, 2017). The process was completed when data saturation was reached to answer the research questions.

The method we applied allows the compilation of different actors' perspectives on policies and the instruments to support the LBPCs' internationalisation. Furthermore, the use of multiple methods (interviews and documental analysis) and the sample diversity (three groups of respondents) sought to broaden the analysis spectrum and identify similarities and differences in the understanding of each group according to their positions. In the following

<sup>&</sup>lt;sup>1</sup> The field research conducted in this paper was part of a broader research project, which aimed to identify and analyze the competitive advantages, strategies, entry modes, and obstacles of the LBPCs in their internationalization process.

<sup>&</sup>lt;sup>2</sup> The National Classification of Economic Activities (CNAE) have its structure based on the International Standard Industrial Classification of All Economic Activities (ISIC), from United Nations Industrial Development Organization (UNIDO). The manufacture of pharmaceuticals is classified in section C, division 21 of ISIC, Rev.4.

<sup>&</sup>lt;sup>3</sup> It does not comprise revenue from two of the sample companies because of confidentiality reasons.

sections, we analyse the field research results supported by secondary data (reports from companies and institutions, documents received by companies) to understand the research problem.

# 4 The institutional environment and international strategies of the LBPCs

Brazil had a late industrial development process based on import substitution industrialisation. In this model, selected sectors, such as chemical and pharmaceutical, received public incentives for industrial development and domestic market protection, mainly by tariff and non-tariff barriers (Special Import Programmes and the Similar National Law). So, the pharmaceutical companies developed with a market reserve and little incentive for international insertion.

This type of industrialisation model also stimulated the entry of large pharmaceutical TNCs in the Brazilian market, without requiring counterparts from them, such as applying innovative efforts in the Brazilian market to promote technological spillovers or transfer technology to local companies. Therefore, the technological capacity divergences have always been significant between TNCs and Brazilian companies and have intensified since the economic opening of the 90s. The economic opening and liberalising reforms – inflationary pressure, currency devaluation, and closure of developmental policies – and the technological backwardness to TNCs led to the loss of pharmaceutical companies' competitiveness. Consequently, a large part of the domestic production was replaced by imports, mainly APIs and finished products (drugs) (Strucker and Cytrynowicz, 2007). So far, pharmaceuticals TNCs deliver new and innovative medicines to the Brazilian market; however, the innovation and manufacturing activities are not a priority for them, which import finished/semi-finished products and perform R&D at their headquarters (Carlsson, 2006).

The institutional environment for the pharmaceutical sector has undergone several changes since the 90s. Brazil's adhesion to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), due to its entry into the WTO in 1994, led to the sanction of the Industrial Property Law (No. 9279) in 1996. The early harmonisation process rapidly increased industrial protection and entry barriers into the sector, especially for non-patent-owned domestic firms<sup>4</sup> (Hasenclever et al., 2010).

The National Health Surveillance Agency (Anvisa) was created in 1999 (Law No. 9782) to inspect pharmaceutical production plants designed and operated following Good Manufacturing Practice standards. The Brazilian government implemented the Generics Drugs Law (No. 9787/1999), establishing generic drugs in Brazil and requiring tests to prove their certification. The production of generic drugs required significant national pharmaceutical companies' tremendous efforts to meet bioequivalence and bioavailability demands. The Anvisa requirements follow high standards of quality control, which have made it internationally recognised. On the other hand, many national companies were unable to develop the necessary technological capacities to meet the new legislation requirements in time and eventually shut their operations down (Strucker and Cytrynowicz, 2007).

The resumption of the explicit industrial and STI policies in the Brazilian government agenda, since 2003, placed the pharmaceutical/health sector as a priority and was the target of

<sup>&</sup>lt;sup>4</sup> For further information on the TRIPS Agreement and its effects on the Brazilian pharmaceutical industry, see Hasenclever *et. al.* (2010) and Urraca-Ruiz and Paranhos (2012).

measures and policy instruments to support the productive and innovative capabilities of companies. As a result, the MDIC implemented three industrial policies: Technology and Foreign Trade Policy (PITCE, in Portuguese), 2003-2007, Productive Development Policy (PDP), 2008-2010, and Greater Brazil Plan (PBM, in Portuguese), 2011-2016<sup>5</sup>. In addition, for the first time in Brazilian industrial development, companies' internationalisation was a goal of the industrial policies (Perin and Cario, 2020).

In the last 20 years, LBPCs have reached capabilities that enabled them to internationalise. These companies had an accelerated international insertion, which means that they did not follow gradual steps – some of them started with FDI and then licensing or installed commercial representative offices abroad. This process was made possible by adapting the capabilities developed to survive and succeed in the Brazilian competitive environment to competitive advantages to internationalise. The companies able to adjust to the new regulations imposed by the implementation of the Generics Law and the creation of Anvisa reached capabilities that allowed the rapid growth and accumulation of financial resources to invest in internationalisation.

LBPCs mainly follow two internationalisation patterns: exploitation or exploration of the companies' assets and capabilities in the international market. The first pattern is the market-seeking strategy, complemented by a resource-seeking strategy (such as APIs and other inputs). This companies' main competitive advantage is specific ownership advantages related to the portfolio, which comprise diversity and good drug quality. The destination of most of their international operations (FDI, licensing, and exports) is to Latin American and African countries. Also, there are some exports to developed countries (USA, Canada, Europe). Since they have strategies to conquer markets, companies face institutional and regulatory divergences between countries as the main obstacles to going abroad.

In the second pattern, companies' motivation for internationalisation is their assets and capabilities exploration. The LBPCs adopt strategic innovation-seeking and strategic-asset-seeking related to technological expertise. The main objective of this international expansion is to seeking niche markets with radical innovation. Companies want to accelerate their innovative capabilities, reaching resources in developed countries, such as sophisticated knowledge and technologies, which are not available in the Brazilian environment. For this purpose, companies are installing R&D centres, investing in biotech firms, and acquiring other firms. The main obstacle to these companies' pattern is to create absorption capacity to capture technological spillovers in host countries.

We discuss the policy instruments which have supported the internationalisation of LBPCs in the next section.

#### 5 Policy to support the internationalisation of the LBPCs

One of the transversal goals of the industrial policies during the 2000s was increasing the internationalisation of Brazilian companies. In this sense, the Brazilian government created instruments to stimulate companies' international insertion, some of them specific for pharmaceutical companies, offering financial and non-financial support. The non-financial incentives are direct – i.e., explicitly designed to support companies' internationalisation – or

<sup>&</sup>lt;sup>5</sup> For further information on the industrial and STI policies for the pharmaceutical/health sector between 2003-2014, see Hasenclever *et al.* (2016).

indirect – created for a different objective but influence foreign operations. **Table 1** displays the supports to internationalisation of Brazilian pharmaceutical companies.

Type of support	Title	Validity Period	Institution in charge	Support offered
Financial	BNDES-Exin	1990-now	BNDES	Credit
	Internationalization Programme	2004-2016	BNDES	Loan
	Profarma	2004-2016	BNDES	Loan
Non- Financial	Brazilian Pharma Solutions	2008-now	Apex- Brasil; Abiquifi	Buyers' projects; business roundtables; market intelligence; assistance for international technology transfer; forming partnerships for drugs co-development; identifying target countries for potential insertion
	Regulatory rules	2016-now	Anvisa	High regulatory standard International harmonisation of regulatory rules
	Productive Development Partnerships (PDPs)	2008-now	Ministry of Health	Public Procurement

**Table 1.** Types of support to internationalisation of Brazilian pharmaceutical companies

Source: Own elaboration.

# 5.1 Financial support

In the financial support group are the support offered by the BNDES, two of which are available for all sectors, and one instrument specific for pharmaceutical companies. The BNDES-Exim is a financing modality created in 1990 to support the manufacture of goods forwarded to exports. There are two types of support – pre-shipment credit and post-shipment credit –, preferably made available for products with high added value and at least 60% of manufacturing/inputs made in the Brazilian market. In 2005, BNDES created the Internationalization Programme as a financing modality to FDI through loans or companies' minority interests (BNDES-Par). Besides financing, BNDES formed an International Area to monitor and offer institutional support to the Brazilian companies' investments abroad. This support system had offices in Montevideo (Uruguay), London (UK), and Johannesburg (South Africa). The BNDES had plans to set the London office to prospect international funding, mitigating the currency risk embedded in international investment, as reported by BNDES' respondent.

BNDES also established a programme specific for pharmaceutical companies: Programme to Support the Development of the Pharmaceutical Productive Chain (Profarma)<sup>6</sup>, launched in 2004. Profarma aims to stimulate the manufacturing of drugs and APIs and innovation efforts, strengthening companies. The financing was offered by loans applying a low-interest rate (1.5% to 4.5% per year) and a high amortisation period (10 years). Profarma had three phases and different subprogrammes, such as Production, Innovation, Exports, and

 $<sup>^{6}</sup>$  In 2007, Profarma became the Programme to Support the Development of the Health Industrial Complex, under the same acronyms.

Biotech. The internationalisation of companies is one of the many projects eligible in Profarma. However, the financing modalities for export or FDI fall under the BNDES-Exim or the Internationalization Programme, respectively.

Only one company of the survey accessed BNDES financing to invest abroad. This financing represented less than 1% of the Internationalisation Programme modality. None of the companies surveyed had requested funding for the BNDES-Exim or Profarma-Exports programmes. Even considering all Profarma participants, Paranhos et al. (2020)found that only four companies obtained financing from the Profarma-Exports, representing 0.5% of the total Profarma resources. The BNDES respondent stated that the financing resources to internationalisation are meagre to influence the outward investment movement.

On the other hand, they are committed to financing only large projects (US\$ 50 to 80 million), excluding small projects, such as creating a distribution centre/office abroad. From the companies' point of view, none was interested in accessing the BNDES-Exim, since they do not need support to manufacture products. The main obstacle to exports is bureaucratic issues, and the incentives available did not act in this sense. Seven of the eight companies stated that they had financial resources to start the internationalisation process independently. One company had tried to obtain financing from BNDES to maintain investments abroad due to a strong exchange rate depreciation. This company argued that it did not have access to financial support because it failed to meet the BNDES' requirements. After all, the lack of financial resources led it to withdraw from the internationalisation process.

#### 5.2 Non-financial support

The non-financial support group consists of one direct programme (Brazilian Pharma Solutions), which is a specific incentive for the pharmaceutical sector, and two indirect supports (regulatory rules and Productive Development Partnerships). The Brazilian Pharma Solutions<sup>7</sup>, launched in 2011, is in charge of Apex-Brasil and Abiquifi<sup>8</sup>. In 2008, Apex-Brazil started a sectoral project to support Brazilian pharmaceutical companies' participation in the CPhI Worldwide, the leading international business forum of the pharmaceutical sector. Then, in 2011, Abiquifi joined the programme as a partner, and they created the Brazilian Pharma Solutions to promote the Brazilian pharmaceutical sector abroad. The segments supported by the programme are human and veterinary medicines, APIs, and biotechnology.

The programme has a more outstanding adhesion of the pharmaceutical companies (seven of eight companies surveyed). It offers many types of support, such as buyers' projects (bringing potential customers to Brazil to know the Brazilian factories), business roundtables, investment missions, and market intelligence. The programme also offers international business strategies support through international technology transfer, forming partnerships between

<sup>&</sup>lt;sup>7</sup> In 2019, Brazilian Pharma Solutions became Brazilian Pharma & Health.

<sup>&</sup>lt;sup>8</sup> Brazilian Export and Investment Promotion Agency (Apex-Brasil), created in 2003, is an autonomous social service, an entity under private law, whose mission is to promote exports of products and services from Brazil, contribute to the internationalization of Brazilian companies and attract foreign investments to the country. Brazilian Pharmaceutical Industry Association (Abiquifi), founded in 1983, is a class association of the pharmaceutical sector that brings together pharmaceutical companies and producers of pharmaceutical raw materials (e.g. API).

Brazilian and international companies for drug co-development, and identifying target countries for potential insertion.

All companies' respondents stated that Brazilian Pharma Solutions is an essential support to internationalisation. Six companies' respondents highlighted the Sanitary Image Project, promoting Brazilian regulation, products, and companies' quality. Two companies had emphasised the assistance of the customised solution in terms of legal and regulatory aspects and providing a course on internationalisation strategies. Two experts pointed out the programme's efforts to promote innovation strategies, seeking to insert companies into technological frontier environments. One company reported that Brazilian Pharma Solutions offers essential tools and resources to take the foreign market's first step through exports. Also, offering different internationalisation support types, Brazilian Pharma Solutions has the most effective programme to reduce the pharmaceutical trade deficit, as reported by one institution's respondent.

Regarding the regulation, Anvisa imposes a high regulatory standard regarding drug registration requirements and industrial operations' quality and safety requirements. Anvisa's Good Manufacturing Practice guide is similar to the European Union's guide, which provides greater security and predictability than Asian competitors. Due to its participation in several international forums, Anvisa is recognised as a world reference, mainly in Latin America, making the region's countries accept the Brazilian dossiers without many changes (Pimentel et al., 2014). Despite not being direct support, Anvisa's efforts to reach international standards change the local market's regulatory rules and become an internationalisation incentive. So, LBPCs following Anvisa's requirements have a competitive advantage to internationalise.

In 2016, Anvisa became a member of the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH). The Conference is composed of the world's leading regulatory authorities, such as the Food and Drug Administration (FDA), USA, the European Medicines Agency (EMA), European Union, and the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. Anvisa has committed to harmonising its guides to the five ICH guides in five yearsas an ICH member. Furthermore, Brazilian Pharma Solutions has assisted the standardisation process by promoting discussions among the actors and translating the dossiers into analyses.

On the one hand, all companies' respondents appreciate standardisation because it can increase access to international markets since the regulatory aspect is usually a non-tariff barrier in the pharmaceutical sector. But, on the other hand, institutions and experts worry that all Brazilian companies will be forced to adopt a standardisation set at developed countries level.

There are also other regulatory issues, which companies respondents highlighted as obstacles to internationalise, such as (i) Anvisa's delay in liberalising cargoes at ports and airports led companies to face additional costs and time than other sectors to export, impacting on the international competitiveness of Brazilian drugs; (ii) Anvisa's delay in drug registration, which decrease the agility to deliver new drugs in the international market<sup>9</sup>; (iii) the lack of communication among the actors of the pharmaceutical sector (companies, policymakers, and

<sup>&</sup>lt;sup>9</sup> Anvisa's Resolution No. 27/2008, which deals with products for health (except for drugs) that are manufactured in Brazil and destined exclusively for export, do not need to be registered, unless registration is required by the target country.

Anvisa). In addition, all companies claimed difficulty having open access with Anvisa to discuss the sector's main issues, as the international regulatory standardisation.

The Productive Development Partnerships (PDPs) is also an indirect support to companies' internationalisation. The Brazilian Ministry of Health implemented the PDP in 2008 to support public-private partnership projects for the technology transfer of a range of strategic products. The partnerships consist of the technology transfer from TNCs or Brazilian pharmaceutical companies to public laboratories to reduce the Unified Health System (SUS) vulnerability by developing high value-added strategic technologies. In some cases, a TNC transfers technology to a Brazilian pharmaceutical company, then the latter transfers to a public laboratory. Private companies receive institutional support in the technology transfer process and guarantee being exclusive suppliers (of a given product) to the Ministry of Health during this process (Pimentel, 2018). However, after public laboratories become able to produce that given product, companies lose their share in the home market. Therefore, PDPs enable Brazilian companies to manufacture a higher added value drug, increasing their foreign market competitiveness. One company's respondent, which had a PDP contract, reported that the exports were a solution to maintain the product's manufacturing after the losses of home market share.

All companies' respondents also reported the lack of communication among the actors. None of the companies in the survey stated knowing the industrial and STI policies being implemented in recent years, nor that internationalisation was their goal. When asked to assess public support for internationalisation, no company argued that the existing instruments were sufficient.

# 6 Discussion of results

An important aspect of the latest Brazilian industrial policies is supporting companies' internationalisation in the government agenda. For the first time, the Brazilian government seemed to be seeing the international market as an opportunity for companies to improve their innovative capabilities and competitiveness. Another positive aspect of the policies was prioritising the pharmaceutical sector and supporting internationalisation in the supports, incentives, and programmes created for the sector.

However, the period in which the policies and supports were in force was not enough to incorporate them into the institutional environment. Since 2016, several institutional and political restructuring have been taking place in Brazil. The industrial and STI policies have left the government agenda, replaced by a neoliberal agenda of fiscal constraint. This restructuring marked a change in the course of Brazilian science, technology and health policies, which maintained a certain alignment between them until then (Fonseca et al., 2019).Consequently, backing the companies' internationalisation is no longer a goal for the government. The current MDIC agenda focuses on trade agreements, especially in tariff negotiations between countries. The restructuring also discouraged the programmes implemented by BNDES and Apex-Brasil. The BNDES Internationalization Programme suffered a significant reduction in resources, and its offices abroad were closed. Profarma was closed, and the BNDES incentives for the pharmaceutical sector rely on general support for the health sector. The PDP instrument has lost strength as no partnership has been signed since 2018. The only programme to support the internationalisation of companies still in force are Brazilian Pharma Solutions (Brazilian Pharma & Health) from Apex-Brasil and Abiquifi and the actions of Anvisa.

The lack of a long-term policy makes it harder for companies to maintain internationalisation and innovation strategies. However, as seen in the literature on Asian developing countries (Lau, 2003, Buckley et al., 2008, Liu et al., 2013, Jayanthi, Sivakumar & Haldar, 2016), internationalisation can be a mechanism for companies to catch up when designed as part of public policy strategies, carried out continuously for several years with well-defined goals. This is the most significant difference between companies' internationalisation from Asia and Latin America. While the local government supports the former, the latter suffers from economic and political instability, which hinders the continuity of the policy and the maintenance of support instruments (Cuervo-Cazurra, 2008; Cuervo-Cazurra & Genc, 2008;).

Regarding the supports, there was no articulation between them in order to align the different types of incentives to the pharmaceutical industry – productive, innovation, regulatory, and internationalisation. In this sense, we argue that the Brazilian government's support for internationalisation did not compensate for the lack of advantages present in latecomer firms, as did the governments of Asian developing countries (Liu and Giroud, 2015; Wang et al., 2012). Although the industrial policies aimed to stimulate internationalisation, there were only a few instruments acting individually. The support to LBPCs' internationalisation were restricted to a few institutions and there was no variety of incentives, in contrast to the wide range of instruments mentioned in the literature(Luo et al., 2010; Sauvant and Mallampally, 2015; UNCTAD, 2006). So, Alcaraz and Zamilpa's (2017) interpretation that Brazil has adopted an active policy of promoting international investments and plans to maintain it in the upcoming years are no longer valid.

The financial support are very restricted in terms of financing modalities and offered by only one institution – BNDES. The only type of support provided was for financing M&A or greenfield projects. The modality does not include the various stages of a gradual internationalisation process, such as installing distribution centres. Also, the BNDES programme for internationalisation was not specific to pharmaceutical companies. As much as the incentive was part of the sectorial programme (Profarma), it was not designed exclusively for pharmaceutical companies' needs. The BNDES's focus on internationalisation was on national champions, whose pharmaceutical companies were not chosen to be part of, even though they are market leaders in the generics segment, have a high potential for technological spillovers have great socio-economic relevance.

Thus, BNDES designed internationalisation support for large companies to carry out large projects. The companies in this research are large. They assessed the financial support as nonessential for two reasons: either the companies had their resources to invest independently, or the type of investment they made does not fit within the financing modalities offered. We assume that smaller companies would give more importance to financial incentives, although they probably want to invest in smaller projects. In this sense, the internationalisation loan for SMEs must be explicitly designed for their characteristics, with financing conditions that they can fulfil (Lloyd-Reason and Mughan, 2002). Yet, BNDES has been offering loans to pharmaceutical companies with special requirements (e.g., low interest rate) since the beginning of the 2000s. The pharmaceutical companies had accessed these loans to improve their manufacturing plants and adapt to the new regulations, which helped them increase their size and market share (Paranhos et al., 2020). Thus, the resources generated in the domestic market have become competitive advantages for going abroad.

Respondents better evaluated the non-financial supports, are more used by companies, and make a difference in deciding to go abroad. The findings match other studies (Hoskisson et al., 2013; Luo et al., 2010; Sauvant and Mallampally, 2015; UNCTAD, 2006, 1995), which

state the importance of non-financial incentives for companies from developing countries. Regulatory issues are the most critical in the internationalisation of pharmaceutical companies, as they become substantial entry barriers (Rugman and Brain, 2004). Anvisa's regulatory harmonisation with ICH is a factor that will facilitate the entry of companies in developed countries, as highlighted by the companies' respondents. However, in general, these companies already adopt (or are in the process of) international standards.

On the other hand, the harmonisation can have a perverse effect on companies that fail to adapt over time, impacting their internationalisation and survival in the home market. A similar situation occurred with the Generic Law's implementation, on which many companies could not adapt to the new legislation. It should be noted that Anvisa and the regulatory rules are not specifics supports to internationalisation. For this reason, actions in this sense should be aligned with the objectives of industrial policy. However, there is a lack of interaction by Anvisa to address relevant issues that impact companies' strategies. The support most appreciated by companies in the Brazilian Pharma Solutions, mainly because the programme meets the companies' interests. The programme was designed with the active participation of companies' association and, therefore, it has greater adhesion and impact on their internationalisation.

These results show that non-financial supports were most critical to supporting the eight surveyed companies at the beginning of going abroad. They helped LBPCs close the knowledge gap related to the institutional environment by providing access to host countries and technical assistance. Nevertheless, companies had financial resources to invest abroad generated, partly, by the policy instruments to support the strengthening of local production.

#### 7 Conclusion and policies recommendations

As already shown by the international business literature, the governments of developing countries have a fundamental role in formulating policies and instruments that stimulate the companies' international insertion, compensating for the lack of advantages of being a latecomer firm and reducing the knowledge gap in different institutional environments. In this paper, we observed that the Brazilian government still does not understand this orientation since the supports were punctual, scarce, without alignment with each other, and limited to changes in government. Hence, the Brazilian government designed isolated incentives to support the internationalisation of pharmaceutical companies, not addressing the long-term goals for companies to catch up. However, during the 2000s, the Brazilian government began to put in place incentives for the internationalisation of companies. Now, the main challenge is probably to get the policies and instruments back.

In general terms, our results found that the instruments to support the internationalisation of LBPCs during the 2000s were limited in financial terms based on the point of view of the eight LBPCs. Still, the availability of financial incentives did not make a difference in the decision of companies. At the same time, companies are relatively satisfied with non-financial incentives, influencing companies' decisions. Therefore, we conclude that non-financial supports have more importance on companies' decision to going abroad when they have already built competitive advantages in the home market. Thus, these findings contribute to the international business literature by pointing out that different types of support have different effects on companies' decisions to go abroad, depending on the stage of internationalization, the sector and the time of operation in the market.

It is worth considering that the results are related to the characteristics of LBPCs, which have a significant share in the Brazilian market but little experience in the international market.

Although we cannot generalise the results to all sectors, these are the characteristics of a wide range of Latin American companies. Based on international business literature and survey respondents, we propose some policy recommendations to promote Brazilian pharmaceutical companies' internationalisation.

The first step is implementing a continuous industrial policy aligning all incentives for developing the Brazilian pharmaceutical industry: productive, innovative, regulation, and internationalisation. The support for companies' internationalisation could not be an isolated measure. Instead, it should be part of an industrial strategy. Furthermore, in order to have broad adhesion of companies, the programmes must be built with the participation of companies. **Table 2** synthesises the recommendations for financial and non-financial supports.

 Table 2. Policy recommendations to support the Brazilian pharmaceutical companies' internationalisation

Туре	Recommendations				
	Create loans internationalisation modalities according to the companies' size				
Financial	Reset the international area for institutional support and global resources attraction				
support	Set up investment insurance, mainly against political risk (coverage for currency transfer				
	restrictions, expropriation, war and civil disturbance, and breach of contract).				
	Expand training services to actual and potential investors				
	Increase the offer of technical services (investment missions, provision of legal assistance,				
Non-	consultancy services and feasibility studies)				
financial	Create "comfort zones" in host countries (offer a one-stop point of access to various governmen				
support	ministries as well as local education, health, and recreation facilities).Implement the regulatory standardisation in a suitable way for companiesCreate mechanisms for prioritising Anvisa's customs clearance for the exports				

Source: Own elaboration.

Regarding the financial supports, we suggest creating different loan modalities, according to the firms' size, since large and SME diverge on their capacity to invest abroad and expectations on international activities. Also, the loan categories should address the different internationalisation stages and firms' strategies (exports, central distribution, manufacturing plants, R&D centre). Besides loans, other types of financial resources are also necessary, as many developing countries use them to promote internationalisation. For example, offering investment insurance, mainly against political risk (coverage for currency transfer restrictions, expropriation, war and civil disturbance, and breach of contract). The diversification of the sources of the financial resources – national and international – should be taken in mind. The international areas, such as those formed by BNDES, allow set mechanisms for attracting international resources. Such tools would reduce the probability of interruption in domestic economic crises and decrease the exchange risk embedded in foreign operations with the national currency. The financial resources should demand a company's counterpart, such as export growth, productivity increase, and innovative Brazilian matrix outcomes.

For the non-financial supports, our recommendation is to improve the existent efforts. For example, enhance the training services to current and potential investors and the technical services (investment missions, legal assistance, consultancy services, and feasibility studies). Also, it is important to create new ones, such as set "comfort zones" in host countries, offering a one-stop point of access to various government ministries and local education, health, and recreation facilities. Furthermore, particular attention should be given to the form and speed of the regulatory standardisation implementation to prevent the same effect obtained in the Generic Law implementation. The last one is creating mechanisms for prioritising Anvisa's customs clearance for the export of drugs since the agility with which the products are placed on the market is also a decisive factor for the international competitiveness of Brazilian companies. Based on these results, we suggest that at least non-financial supports could remain active on the government's agenda, even in times of fiscal constraint, as they are the least costly.

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