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Main Challenges In The Acquisition Of Health Technologies In Southern Brazil: The Example Of Boxifarma

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Abstract:
This study explores the Brazilian context and the main challenges encountered in incorporating health technology in the private sector, using the startup Boxifarma as an example. The results obtained from the systematic review demonstrate that the majority of articles found focus on the discussion of regulations and legislation related to new technologies within the context of the Unified Health System (SUS), with restricted data for the private sector. Through Boxifarma report, it can be observed how bureaucracy and challenges in harmonizing different regulatory levels (federal, state, and municipal) delay and make the regulation of new technologies and pharmaceutical services expensive and slow.

Key Word*: Health Technologies; Acquisition of Health Technologies; Boxifarma.*

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I. Introduction

In Brazil, the acquisition of health technologies has grown in the last decades, accompanied by increasing challenges. These technologies, which include new equipment, clinical and surgical procedures, as well as systems to improve health provision and safety, have the potential to solve problems, increase safety, reduce risks, and improve the quality of services provided to patients. Despite the clear benefits, these innovations also generate jobs and demand careful regulation to ensure their effectiveness and safety.

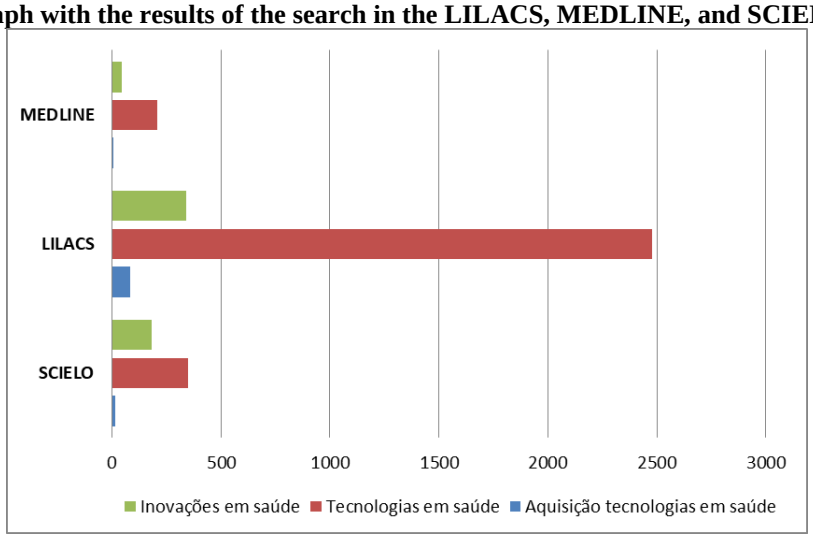
Regulation is one of the greatest challenges in the Brazilian context, involving multiple agencies such as the National Health Surveillance Agency (ANVISA) and the National Supplementary Health Agency (ANS), as well as local health surveillance and state and municipal health departments. These bodies play a crucial role in the technical and risk assessment of new technologies. However, they can also be sources of bureaucratic hurdles that result in slow and costly processes, challenging the rapid implementation of innovations in the healthcare sector.

A practical example of this dynamic is Boxifarma®, a pharmaceutical startup that introduced a personalized pharmacotherapy model for elderly patients. This model integrates medical and pharmaceutical systems for dose unitization and pharmacotherapeutic monitoring, initially focused on elderly patients in Long-Term Care Facilities (LTCFs). Boxifarma® faced significant challenges due to the lack of provision for these practices in Brazilian legislation, highlighting the need for legislative adaptations to facilitate the incorporation of new health technologies and the evolution of pharmaceutical practices in the country.

II. Material And Methods

To understand the context of the discussion on the incorporation of health technologies, a systematic review was conducted using three descriptors: health technologies, health innovations, and acquisition of health technologies. The search for the three descriptors was conducted in the LILACS (Latin American and Caribbean Health Sciences Literature), SCIELO (Scientific Electronic Library Online), and MEDLINE (Medical Literature Analysis and Retrieval System Online) databases. The following criteria were used for restriction: publications in Portuguese, the period of 10 years (2013-2023), and full articles published in journals. Theses, dissertations, monographs, or reports were not included in the search. The results found are presented in Figure 1.

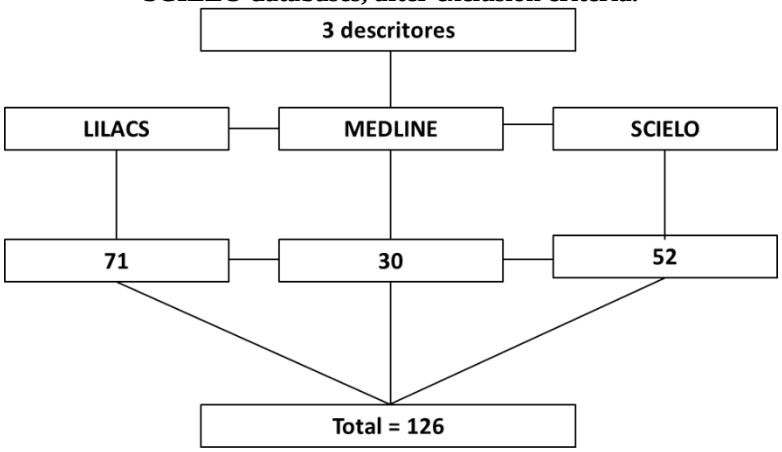
Figure 1 - Graph with the results of the search in the LILACS, MEDLINE, and SCIELO databases.



Source: The authors

From the searches in the three databases, a total of 3,707 publications were found, with 126 considered within scope (Figure 2). 16 articles were excluded due to repetition, and the bibliographic reviews found were also included in the final selection, totaling 22.2% of the results.

Figure 2 - Flowchart with the final selection of articles considering the LILACS, MEDLINE, and SCIELO databases, after exclusion criteria.



Source: The authors

III. Results and discussion

According to the obtained results, it was found that few studies brought any discussion about regulation or addressed the bureaucratic hurdles and regulatory characteristics resulting from the incorporation of health technologies. These studies correlated with the Unified Health System (SUS) and did not bring experiences related to private companies and/or startups. Alves (2021) (ALVES et al., 2021c) cited the most important regulations related to the use of technologies in Brazil, through the conduct of a documentary and exploratory research between the years 2019 and 2020. Silva and Elias (2012) addressed the topic of incorporation of health technologies by comparing the realities of Brazil and Canada and focusing on the Health Technology Assessment (HTA) system used by both countries. The theme of health technology assessment was predominant in the studies that addressed the incorporation of health technologies considering the context of SUS, which represents the majority of the articles found (ALVES et al., 2021c; NOVAES; DE SOÁREZ, 2016; SOÁREZ, 2021). HTA mainly addresses safety issues, its economic aspect, and its cost-effectiveness relationship (CAMPOLINA et al., 2017; NITA et al., 2009; NOVAES; DE SOÁREZ, 2020; TRINDADE, 2006); but it also considers aspects of equity, ethical, cultural, and environmental impacts involved in its use. Ferreira et al. (2014) also addressed the theme of the incorporation of technological innovations by the public sector and presented the awarded cases in a public health innovation competition. According to a survey conducted by Filho and Pereira (2021), the technologies incorporated by SUS were more prevalent for the drug area, representing approximately 50% of the

total 380 technologies raised, predominantly addressing infectious and parasitic diseases (RODRIGUES FILHO; PEREIRA, 2021).

Among the 126 selected studies, 28 were literature reviews addressing different topics related to health technologies used in organ transplantation (KNIHS et al., 2022), diabetes (SOUZA et al., 2019), Alzheimer's (DO CARMO; ZAZZETTA; COSTA, 2016), technology assessment in hospitals (DA SILVA GALDINO; CAMARGO; SILVA ELIAS, 2021), breast cancer (GONÇALVES et al., 2020), among other topics. According to the search, five studies also presented the theme of new technologies associated with the COVID-19 pandemic, but also linked to SUS. According to a survey conducted by Fernandes et al. (2023), there was also an increase in the deposition of patents and products under development related to the Zika and Chikungunya epidemics, which have had an increase in the number of cases in Brazil in recent years. However, as reported by the authors, few technologies were effectively launched on the market, highlighting the main reasons such as costs, the time required to finalize the development of technologies, difficulties in conducting clinical trials, and regulation (FERNANDES; MONTE; BEZERRA, 2023).

The Boxifarma Example: A Pharmaceutical Startup

Boxifarma is a pharmaceutical startup company founded in 2017 with an innovative operational model based on organizing patients' pharmacotherapy through automated dose unitization and pharmacotherapeutic monitoring, providing pharmaceutical care services to elderly residents of geriatric facilities - Long-Term Care Facilities for the Elderly (LTCFs). Unlike the example from Belo Horizonte, which proposed manual unitization, Boxifarma launched automated unitization through a robot, and the prescription analysis and identification of drug interactions digitally, through software integrated with Artificial Intelligence provided by Watson (IBM). This software needs to be fed and/or updated with the medication prescription of each patient to cross-reference the information and generate pharmacotherapy analysis, with the final interpretation by a qualified pharmacist.

The global pharmaceutical market has been undergoing a succession of innovations that are expected to reshape the sector. The shift of service provision outside and beyond physical pharmacies (consultations, online services, etc.) and the emergence of pharmacotherapy organization systems (such as Pill Pack in the USA) are expected to transform the sector. Moreover, with the COVID-19 pandemic, the need for social isolation and the impossibility of travel for a large part of the population has made the adoption of remote technologies, electronic health records, e-prescribing, telehealth services, and home deliveries even more pertinent. These trends, previously latent in society, have become urgent and essential for healthcare services.

Regardless of the aspect, it is certain that pharmaceutical services need transformation. The so-called digital transformation processes involve the incorporation of information and data technologies into work processes. The inexorable integration between pharmaceutical services and technologies constitutes what is being called technology-mediated pharmacy and will allow the development of innovative and highly customizable services for patients and caregivers. Whatever type of service is developed, its success depends on its ability to be highly individualized, customizable, integrated, and focused on the patient's and caregivers' experience. All these aspects help adherence to pharmacotherapy, especially in cases of polypharmacy, avoiding self-medication errors, and assisting in the detection of adverse events with the aid of technology.

In the case of Boxifarma, automated unitization minimizes errors since after unitization, medications are packaged individually, duly identified as required by pertinent and specific legislation for each day and time the patient needs them. Pharmacotherapy can be programmed on a weekly, biweekly, or monthly basis, according to each patient's needs. Additionally, after completion, the packaging "printing" undergoes scanning, which has a database with photos of all medications. Thus, the scanner can identify each medication present in each compartment, providing medication traceability, essential to ensure the process's safety, avoiding errors in medication administration, as any mistakes will be identified by the pharmacist during the scanning process review. Given the various benefits that the robotic technological innovation presented in performing dose unitization, combined with the scientifically based software technology signaling potential adverse events, the technological innovation of the robot's introduction also brings a pharmaceutical service innovation. Both required regulation because they were considered innovative and did not yet exist in Brazil. The regulatory trajectory of the technology and the services provided was arduous, lengthy, and costly.

In the case of Boxifarma, initially, a consultation was made to the Regional Pharmacy Council of Rio Grande do Sul to understand the organization's understanding regarding the characteristics of the service and technology being presented. Regulatory consulting was also hired to adjust and build a physical space that was consistent with the legislation and met all necessary safety requirements for the activities provided. Many months of work were required for its adaptation, until all the necessary documentation was finalized for submission to the Health Surveillance Agency (VISA) of Porto Alegre-RS. As mentioned earlier, at the time of submission of the process, there was no option that included an establishment capable of performing solid pharmaceutical form unitization and providing pharmacotherapeutic monitoring services, and thus, the opinion of the Regional Pharmacy Council and the assistance of regulatory consulting were essential.

After numerous meetings and years of discussion, even though it was a pharmacy containing the unitization service, Boxifarma® was granted the Sanitary License on 10/22/2022 with the activity of manipulation of official and magistral preparations, as established by Ordinance 19680188/2022 of the Municipal Health Secretariat of Porto Alegre (S.M. Health, 2022), also including unit dose manipulation and unitization of doses and health services; manipulation of solid pharmaceutical forms; trade in products and food; and trade in controlled products. The mentioned Ordinance was published on 07/25/2022 and brought regulation of the dispensing service of medicines through fractionalization and the preparation of unit doses and unitization of doses in the solid form, manual and/or automated, carried out by a compounding pharmacy, with exclusive supply to healthcare and healthcare interest institutions, for the city of Porto Alegre, in the state of Rio Grande do Sul. The Certificate of Regularity of the Regional Pharmacy Council of Rio Grande do Sul (CRF-RS) was issued for a compounding pharmacy type establishment, in accordance with the respective Sanitary License issued by RS. Boxifarma® also opened a branch in the state of São Paulo, where the process was faster, presenting a different Sanitary License from the one issued by Rio Grande do Sul, including retail trade of pharmaceutical products with formula manipulation. The authorized activities comprised a wider range when compared to those granted by the state of RS, including: remote marketing, special control medication dispensing - dispensing special control medications, fractionating medications, manipulating antibiotics, manipulating cephalosporin, manipulating cytostatic, medication - manipulating hormone, manipulating penicillin, special control medication - manipulating substances subject to special control, providing pharmaceutical care, providing domiciliary pharmaceutical care for formulas.

IV. Conclusion

The accelerated population aging has caused a parallel and constant increase in chronic diseases, multimorbidity, and consequently, polypharmacy; elements that are shaping the future, with a repositioning of the health market, including the pharmaceutical market. It is possible to anticipate that pharmaceutical services will need to come very close to the patients' needs, accompanying them throughout their many therapeutic journeys.

Although the incorporation of health technologies by the private sector is a crucial topic, it is still little explored by the scientific community, as revealed by a systematic review. The case of Boxifarma® vividly illustrates the coordination difficulties between municipal and state agencies, which often face challenges in harmonizing and accelerating the regulation of new technologies and services in the pharmaceutical sector. In addition to the substantial financial investments required to introduce these technologies in Brazil, the private sector also needs to invest in adapting spaces for new services, as well as regulatory consulting to organize the introduction process of these innovations.

Despite these efforts, the process of regulating technological innovations often becomes exhaustive and unfeasible due to the prolonged time for approval and the high cost of investment. This often prevents meeting the new demands of the population, harming socioeconomic development. This scenario highlights a significant gap in Brazil regarding the acquisition and incorporation of new health technologies by the private sector.

The data and discussions presented here seek to emphasize the importance of this issue and initiate a stimulus for necessary improvements. It is essential to accelerate the regulatory process to avoid missing opportunities in the acquisition and incorporation of health technologies in the country, thus ensuring a more effective response to the emerging needs of the population.

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