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Research Article



Analysis of the conditions for the creation of pharmaceutical university spin-offs within a public university in Burkina Faso

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Abstract

This study aimed to analyze the legal framework for the creation of university spinoffs, particularly those in the fields of medicine and pharmacy in Burkina Faso. This was carried out through a literature review, supplemented by interviews with resource persons from the sectors in charge of commerce, industry, finance, scientific research and innovation, health, and youth.

In Burkina Faso, there are no specific provisions for promoting university spinoffs. A Simplified Joint Stock Company is the most appropriate legal form for these types of companies. Moreover, these laws do not favor the mobility of researchers in entrepreneurship. In addition, university spinoffs are subject to the same tax pressure as conventional companies. Nevertheless, the University of Joseph KI-ZERBO supported project leaders through its incubator. However, its lack of status, insufficient material, and financial resources limit its actions

Keywords: Spin-off, economic development, research, innovation, university.

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1. Introduction

Scientific research is the set of actions taken to produce and develop scientific knowledge. (1) Research activities in universities, institutes, and research centers cover several fields including food, health, energy, modern technologies and culture. Scientific research is a strategic sector for the socio-economic progress of countries. (2-4)

In developed countries, public authorities have increasingly focused on the commercial exploitation of the research results over the last 15 years. (4-7) Spin-offs, which are the prerogative of large groups such as universities and research centers, are used as a lever of innovation. (4) A university spin-off is a new company established by the university to exploit knowledge through commercial activities. (8-10) In many countries such as the United States, France, Belgium, and Italy, university spinoffs are considered vectors of economic growth for

which multiple public policies are deployed. (11-12) For instance, the 1999 law known as the "Allegre law" in France has encouraged the creation and development of spin-offs from universities and research centers. (13-14) In developing countries, such as Tunisia, a quasi-similar law has been adopted, encouraging researchers to set up businesses. This has facilitated the development and marketing of products through university research. (15)

Burkina Faso, a developing country, is characterized by a scarcity of natural resources and a weak industrial sector. Furthermore, education in general, and university education in particular, is a national priority. Joseph KIZERBO University (UJKZ), the largest university in Burkina Faso, has approximately 42 research laboratories, centers, and institutes, (16) where research is conducted in various fields, including medicine and pharmacy. In the pharmaceutical field, drug development occupies an

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important place in the laboratories and research institutes of Burkina Faso. (17) However, many inventions and innovations of therapeutic interest fail to reach the drug market. (18-20) Indeed, the inadequacy of policies for the valorization of results generated through medical research constitutes a major difficulty that hinders the valorization of African inventions and innovations in the field of medicine and pharmacy. (21) Additionally, the lack of pharmaceutical industries in Burkina Faso to appropriately exploit the results of university research exacerbates this situation. Indeed, a study on the valorization of traditional medicine products in Burkina Faso and Benin by DORI et al. (2019) indicated that spin-offs, just as it is by universities in the American, European, and Maghreb countries, could be a relevant and interesting alternative for the commercial valorization of phytomedicine developed by Abomey Calavi University (Benin), Joseph Ki-Zerbo University (Burkina Faso), Liege University (Belgium), and the Catholic University of Louvain (Belgium). (22)

Unlike countries such as France, Belgium, Canada, and the United States, where the legal framework for university spinoffs is well established, understood, and exploited in favor of their emergence, the situation in Burkina Faso, to our knowledge, has not yet been studied and, therefore, deserves further examination, given that spinoffs have proven to be a potential driver of economic growth in other countries. Specifically, this study analyzes the legal framework for the creation of university spinoffs in the fields of medicine and pharmacy in Burkina Faso. Key prospects for the valorization of university research results in the country.

2. Material and methods

This work consisted of a cross-sectional descriptive study was conducted between August and October, 2020. The UJKZ of Ouagadougou and the public structures in charge of trade, industry, finance, scientific research and innovation, health, and youth served as a framework for this study.

The participating structures were selected based on a reasoned choice, particularly those considered to be capable of providing maximum information on the industrialization of research results from universities. For all these structures, the responsible parties or their designated representatives were interviewed using a survey grid comprising open and closed questions. The interviews were coupled with a documentary review conducted through a collection of legislative and regulatory texts from all participating structures in the study. The obtained documents were analyzed according to the specific field of university spin-offs to identify the fields covered by legal provisions as well as any existing legal gaps.

Data entry, text processing, and table design were performed using the Word 2016 software. Data were collected after obtaining an agreement between the participating structures and the consent of the respondents.

3. Results and discussion

Eight public structures were included in this study. Fourteen individual interviews were conducted, including six at the UJKZ, two at the Ministry in charge of Higher Education and Research, three at the Ministry in charge of industry, one at the Ministry in charge of finance, one at the Ministry in charge of youth, and one at the Ministry of Health. Nineteen legislative and regulatory documents were recorded. The results of the analysis of the legal framework for promoting the exploitation of university research results and the accompanying measures preceded the proposal for a functional organizational model and institutional anchoring of a pharmaceutical university spin-off from UJKZ.

3.1. Legal framework for promoting the exploitation of research results

The collected legal texts were analyzed in relation to several areas of research result exploitation, such as the conditions for creation, legal form of the spin-off, intellectual property rights, and management of human resources from the research.

Creation of research results in exploitation company by or with the UJKZ

UJKZ is a public State University Institution (SUI) belonging to the category of Public Institutions of a Scientific, Cultural, and Technical nature (PISCT). (23) Its fundamental mission is the development of knowledge and know-how, and it has several objectives, including the valorisation of research results. (23) Burkina Faso's PISCTs were governed mainly by Law No. 038-2013/AN on November 26, 2013, the Orientation of Scientific Research and Innovation, Law No. 010-2013/AN on April 30, 2013, the creation of state public establishments, Text No. 2014-612/PRES/PM/MEF on July 24, 2014, the general status of PISCTs as well as the statutes specific to each PISCT. These texts do not provide specific provisions for the creation of valuation structures for commercial purposes resulting from SUIs such as university spin-offs. In addition, certain provisions of these texts allow the state and its branches to create companies and/or hold shares in whole or in part within private companies or companies belonging to the UJKZ. These companies are subject to the provisions of legislation applicable to commercial companies and Law No. 025/99/AN. They were created by a decree taken by the Council of Ministers. (24)

Furthermore, Law No. 010-2013/AN of April 30, 2013, on the rules for the creation of categories of public establishments provides, in its article 4, that "a Public Cooperation Institution (PCI) is created by one or more legal persons governed by public law." Any creation of a PCI is subject to the production of a reasoned file, indicating the necessity, relevance, and viability of the corporation to be created. On the one hand, the creation file includes an organizational study highlighting the intended mission of public services, and on the other hand, an economic and financial study demonstrating the usefulness and viability of the corporation. Competent authorities create public corporations through regulations. (25) Article 31 of Law No. 038-2013/AN on November 26, 2013, on the orientation of scientific research and innovation provides that "scientific and technological interest groups, endowed with legal personality and financial autonomy may be set up between public and/or private companies to carry out research or technological

development activities together for a fixed period, or to manage the equipment of common interest necessary for these activities". Although these groupings can be made using an agreement approved by the administrative authority, they do not relate to commercial activity as required by the economic valorization of innovations resulting from research. (26)

provisions relating to shareholdings require authorization by a decree issued by the Council of Ministers. Indeed, Decree No. 2014-612/PRES/PM/MEF on July 24, 2014, on the general statutes of the PISCTs indicates in Article 10 that the deliberations of the board of directors relating to the issuance of borrowings and the placement of available funds can only become enforceable after the express approval of the minister in charge of finance. (25) This provision is supplemented by Article 35, which stipulates that the board of directors of the PISCT is strictly prohibited from equity investments in any form, whether in existing companies or in the process of creation. These provisions were also provided for Decree No. 2017 of July 3, 2017, approving the statutes of the University Joseph KI-ZERBO, particularly in Articles 31 and 37. (23)

In the pharmaceutical field, industrial preparation units, distribution, and wholesale establishments are governed by national and community legislations.

Indeed, according to the Burkina Faso public health code, a pharmaceutical preparation establishment is defined as a company engaged in the manufacture, storage, and wholesale of drugs, products, and objects subject to pharmaceutical monopoly. (27) Thus, the establishment is a commercial enterprise subject to all the obligations of commercial law. The Public Health Code was supplemented by statutory instruments, such as Order No. 00-069/MS/MCAB on February 22, 2000, at the opening and operation of a pharmaceutical preparation establishment. (28)

According to the regulations in force, the creation of an industrial pharmaceutical production unit is subject in particular to i) the creation of the company that allows it to register in the trade and personal property credit register and a unique tax identifier number; ii) obtaining an environmental feasibility opinion and carrying out an environmental impact audit; iii) obtaining authorization to operate; iv) the appointment of a chief pharmacist; v) compliance with specifications defined by the Ministry of Health; and vii) compliance with the requirements of the annex to Decision No. 08/2010/CM/WAEMU on Good Manufacturing Practices for Pharmaceutical Products for Human Use in the Member States of the West African Economic and Monetary Union (WAEMU). (28-30)

In France, PISCTs are responsible for the development and progress of research, the dissemination of scientific knowledge, the promotion of research results, and training. Unlike Burkina Faso, a specific legal framework is in place in the context of innovation and exploitation of research results. To this end, law no. 99-587 of July 12, 1999, on innovation also called the "Allegre law" repealed by order no. 2004-545 of June 11, 2004, relating to the legislative part of the research code, enabled PISCTs to create spinoffs in the form of commercial subsidiaries. (31)

Furthermore, the French education code of August 3, 2020, and the 2020 research code also provide equity investments and the creation of subsidiaries. (32,33)As such, when a public research establishment holds more than half of the shares or capital contributions of a company, the latter becomes a subsidiary of this public establishment. Public research establishments may also be authorized to make shares or capital contributions in companies or groups governed by private law after approval by the board of directors. On the contrary, in Burkina Faso, the law prohibits the deliberation of the board of directors of public institutions on the acquisition of shareholdings and requires the express authorization of the minister in charge of finance. (23) Moreover, PISCTs in France can also provide services by agreement, manage research contracts, exploit patents and licenses, and market the products of their activities. (31)Institutions may also establish public interest groups, foundations, and industrial technical centers within the framework of the exploitation of research results. (32)

Relationship between research staff and companies resulting from research results

In Burkina Faso, the teaching and research staff of the UJKZ are subject to the legal regime applicable to the profession of agents from public establishments, including university hospital teachers and researchers. (34-36)

According to the research actors interviewed during data collection, these legal texts do not encourage researchers to create or develop their own companies. Indeed, the current provisions are unfavorable, restrictive, and inflexible vis-à-vis a project leader who would like to commit to the creation of a university spin-off without having to suspend his professional contract with the public administration. Article 30 of Law No. 033-2008/AN on May 28, 2008, on the legal regime applicable to the profession and employees of SUIs provides for obligations and incompatibilities. (34) Thus, concerned officials are required to devote all their professional activity to the accomplishment of their assigned job, to be present at their service during legal working hours, and to carry out tasks entrusted to them by themselves. (34) According to this rule, agents may not, on a professional basis, engage in any gainful private activity of any kind whatsoever, nor may they have, by themselves or by proxy, under any name whatsoever, interests in a company of which they may have, the administration, the management, or the control. (34) However, agents may be authorized to conduct consultations, give classes related to their competence, or produce scientific, literary, or artistic works. (34)

In addition, Law No. 036-2016/AN on November 24, 2016, amending the Law No. 025-2010/AN of May 18, 2010, on the legal regime is applies to the employment of university hospital teachers and research employees in Burkina Faso, states in its article 60 that "research is part of the activities of the teacher". In this respect, he may carry out the following actions: the development of fundamental, applied, and educational research as well as the exploitation of results; the development of research programs; supervision; the conduct of scientific research; the dissemination of the culture of scientific and technical information; and so on. (35)

[42]

Law No. 025-2010/AN on May 18, 2010, on the legal regime is applicable to the employment of university hospital teachers and researchers in Burkina Faso in its unmodified provisions; in particular, its title III defines the classic statutory positions offered to university and university hospital teachers and researchers who wish to undertake mobility. Three classic forms of mobility are foreseen (36): secondment (Articles 22–50), layoffs, and provision (delegation). Contrary to the context of Burkina Faso, in France, the law n° 99-587 on July 12, 1999, and thereafter the ordinance n° 2004-545 of June 11, 2004, relate to the legislative part of the amended code of research on innovation and research, derived from the principle of prohibiting research personnel from setting up a business as an associate or manager. However, this exception is limited to research exploitation. (31-33) Articles 531-4-531-6 of the French Research Code of 2021 indicate that research staff can benefit either from a secondment or from being made available to the company (33) while still claiming advancement or appointment in the original public service. article 531-8 of the same code of research allow research staff to establish two further links with a company that promotes research work. Indeed, he can lend his scientific assistance to the company (consultancy, expertise, etc.) and/or hold shares in the share capital. (33)

Apart from the possibility granted to civil servants to carry out expert appraisals or consultations relating to their competence and authorized by Law No. 081-2015/CNT on the general status of the State Civil Service, no other regulatory facilities exist in Burkina Faso to date. Fortunately, this constringent and restrictive law expressly excludes Article 2 teachers and researchers, including hospital and university employees. (37) Thus, apart from teaching, this category of workers may carry out gainful activities, assuming that these are linked to their skills and compatible with the exercise of their function. (36) However, a regulatory text to define the type of lucrative activities and set the terms for implementation of this provision has not yet been adopted. This could be an opportunity to include mobility facilities as in France.

It is worth noting that, in addition to all the already mentioned legal facilities, the 2021 research code in France also allows research staff to be members of the board of directors of a commercial company and participate in share capital, (33) unlike in Burkina Faso.

Legal form and taxation of university spin-offs

The university spin-off as a commercial enterprise is governed at the national level by the revised Organization for the Harmonization of Business Law (OHBL) Uniform Act of May 5, 2014, relating to the law of commercial companies and economic interest groups, the law n° 058-2017/ AN on December 20, 2017, the General Tax Code of Burkina Faso, the law N°015-2017/AN on April 27, 2017, the guidance and promotion of small and medium-sized enterprises in Burkina Faso, and the law n°038–2018/AN on October 30, 2018, the investment code of Burkina Faso.

The revised OHBL Uniform Act of May 5, 2014, provides for an SJC, a more appropriate legal form for public university spin-offs, as in the case of the UJKZ. It differs

from other legal forms in the flexibility of its organization and its operation through its statutes, the abolition of the compulsory minimum share capital, the possible issue of contributions in industry, the openness to any type of partner (legal person or physical), the abolition of the nominal amount of the share, and above all, the possibility offered to any state employee to be associated. (38)

Furthermore, the interviewed actors underlined the inadequacy of specific fiscal incentives for the creation of innovative companies such as pharmaceutical university spin-offs. These planned exemptions would not benefit young small businesses. Indeed, the Investment Code provides exemptions from customs duties, value-added taxes, and direct taxes. However, it requires that the company has a minimum investment of 100 -500 million (~\$200 000 - 1 million), and it might also provide at least 20 permanent jobs with at least 5 years contract. (39) Moreover, current customs tax regulations do not favor local production. Raw materials for pharmaceutical products, packaging materials, and reagents are not exempt from import customs duties.

Nevertheless, upon request, a new company can benefit from tax exemption (patent, installments, corporation tax) but only for its first year of operation. (40-42)

Contrary to these Burkinabe provisions, which are less favorable to start-ups, the French legal framework provides for tax and legal arrangements for the benefit of young innovative companies, whether or not they result from public research. This is rendered possible through the attribution of "an innovative start-up" status. This status confers tax exemptions over 24 months, abolition of property taxes for seven years, and exemptions from social taxes for small and medium-sized enterprises that incur research and development expenses representing at least 15% of the expenses. (43)

3.2. Supporting measures

3.2.1. State support

Burkina Faso implemented non-fiscal measures to support the creation of young innovative companies, including university spinoffs. Indeed, a program named "Burkina Start-up" is dedicated to this type of business and is funded by the "Burkina Faso Fund for Economic and Social Development". (44) In addition, several funds are available, the main ones being: the Agency for Financing Small and Medium-sized Enterprises (45) and the National Agency for the Promotion of Research. (46)

However, these measures remain inadequate. For instance, at the fiscal level, there are no specific taxes or social exemptions for this type of business. Start-up businesses are subject to the same constraints as conventional companies, even though they differ from small and medium-sized enterprises and other businesses in that they do not have solid financial bases and develop in an environment of uncertainty where the risk is difficult to assess. Therefore, the company's founder lands in the market with a new idea or technology that has strong growth potential but also with a significant need for financing.

3.2.2. Support from Joseph KI ZERBO University

UJKZ has an incubator to support leaders of new innovative projects, such as spin-offs. The university incubator proposed providing a package of services for the benefit of spin-off projects. However, these proposed aid packages are not yet available for diverse reasons. Indeed, the UJKZ incubator encounters major difficulties in the execution of its missions, particularly because of the absence of texts that govern its operations, the insufficiency of material and financial resources, and the absence of funds dedicated to business support.

Comparatively, in the French or Belgian system, the university supports the creation of spinoffs through two distinct modules of support and aid. First, university spinoffs can receive support from a set of facilities comprising the incubators, the offices for technology transfer, the provision of guides and rules that govern access to resources material of the university, the participation of the university in the boards of directors, the participation of the personnel of the universities in the capital, and the protection of the intellectual property. Second, spin-offs

are supported by the provision of laboratory equipment and equipment through conventions. (47-49) As an indication, nearly one-third of universities in Europe participate as shareholders in the capital of spinoffs. (50) This mode of operation is also effective in the African country of Benin through the Foundation of the University of Abomey Calavi (FUAC). (51) Furthermore, Berbegal-Mirabent et al. (2015) showed that the presence of specific infrastructures and professional staff plays a key role in the creation of university spin-offs. Thus, a favorable regulatory framework along with specific programs that help academic entrepreneurs prove to be a great asset for the creation of spin-offs for universities. (52)

3.3. Model of functional organization and institutional anchoring of a pharmaceutical university spin-off from Joseph KI-ZERBO University

Despite the existing constraints and insufficiencies, the current national legal framework of Burkina Faso offers possibilities for creating a pharmaceutical university spinoff. Table 1 summarizes the possible options.

Table 1. Summary of possible options for creating a pharmaceutical spin-off

Creation options	Legal basis
Public establishment of cooperation (SUI)	Law No. 010-2013/AN of April 30, 2013, on the rules for the creation of
	categories of public establishments (Article 4)
State company or public capital company	Law No. 025/99/AN on the general regulation of public capital
	companies (Article 4)
Commercial company (PLC, LLC, SJC) 'and	Decree No. 2014 612/PRES/PM/MEF of 24 July 2014 on the general
participation of the university in the capital of	status of public state establishments of a scientific, cultural, and technical
the said company with the express agreement	nature (PISCT) (Article 10)
of the supervisory ministry or signature of an	
agreement	
A scientific and technological interest group	Law No. 038-2013/AN on the orientation law of scientific research and
in partnership with the private sector.	innovation (Article 31)
Project company within the framework of a	Law No. 020-2013/AN of May 23, 2013, on the legal regime of Public-
public-private partnership.	Private Partnership in Burkina Faso (Article 4)

PLC: Public-limited company; LLCL: Limited liability company; SJC: Simplified joint stock company

The creation of a public cooperation establishment is subject to a long administrative procedure because the viability of the project must be demonstrated. One of the limitations of this option is the mobilization of financial resources centered on the budget of the public institution in charge. In addition, the main constraint of state companies is the government's reluctance to create new state companies in a context where existing companies are already struggling to ensure their self-support. (53,54) The option of creating a commercial company with the participation of the PISCT in the capital is also strictly binding because of the regulations, as it prohibits the Board of Directors of the PISCT alone from approving such a proposal and requires express approval from the supervising ministries. The main advantage of this type of company is the wide range of legal forms offered by the uniform act of commercial company law and economic interest grouping, involving better options for raising funds, particularly from the private sector, as well as autonomy in administrative and financial management.

If a university spin-off takes the form of a scientific and technological interest group, it will have a wide variety of possible partnerships with the private sector, including the mobilization of funds and expertise from the private sector. However, the limited duration of this type of partnership is a constraint for research and development, which is generally part of a long-term perspective. In any case, a spin-off in the form of a project company within the framework of a public-private partnership is strictly regulated and subjected to lengthy procedures. The main advantage is the realization of a turnkey project by a private partner and risk sharing. However, in this case, the university has little control over the company.

Given its commercial nature and specific pharmaceutical regulations, the national legal framework offers limited leeway for the creation of a pharmaceutical university spin-off. Moreover, regarding the support possibilities offered by the program "Burkina Start-up" and the UJKZ university itself, the options that seem to emerge are either the creation of a state company or a commercial company carried by one of the researchers with the participation of the university in the capital of the company, or the signing of a collaboration agreement between the UJKZ and the company created. In this case, the PISCT could focus on

research and development, and the company on the commercial aspect. In one scenario, the project leader, as a public servant, will have to choose his administrative position.

The SJC company seems to be the appropriate legal form because of its advantages. Indeed, its mode of operation is free with a board that can be chaired by a legal person, its minimum capital is not compulsory, and the amounts of capital and the share are freely chosen and can involve any kind of partner.

Thus, by the SJC's mode of organization, the pharmaceutical spin-off that the UJKZ might consider

should be organized as follows: a board of directors, which is the governing body with a president who could be the UJKZ itself. The university will thus have the right to scrutinize the company, with general management as the executive body, and a responsible chief pharmacist as required by the regulations in pharmacy, an Industrial Development and Production Department (IDPD), a Supply and Logistics Department (SLD), a Department for Regulatory Affairs (DRA), a Quality Assurance Department (QAD), a Marketing and Sales Department (MSD), as well as an Administration and Finance Department (AFD). This scenario is illustrated in Figure 1.

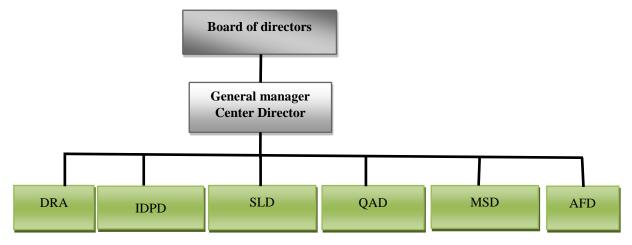


Figure 1. Proposed organizational chart for a pharmaceutical university spin-off

Legende: IDPD: Industrial Development and Production Department, SLD: Supply and Logistics Department, DRA: Department for Regulatory Affairs, QAD: Quality Assurance Department, MSD: Marketing and Sales Department, AFD: Administration and Finance Department.

To circumvent the legal and institutional constraints related, in particular, to the acquisition of a stake and the mobility of personnel, the spin-off created should operate as a private company with the university as an incubator. An agreement should formalize the collaboration between the UJKZ and the spin-off with academic, scientific, and economic benefits for the university.

Before this was achieved, the surveyed research personnel identified a lack of awareness of valuation mechanisms, such as spin-offs, as a major difficulty. Others, on the other hand, believe that shortcomings are more related to the binding provisions of legal texts and the weak entrepreneurial culture of researchers. The suggestions put forward are more in line with the improvement of the legal and institutional framework by reviewing the texts to give a certain autonomy to the PISCT to create spin-offs and offer tax relief to these types of companies. The suggested improvement could also be made by taking specific texts in favor of the valorization of research results, which could arouse more interest and enthusiasm among the researchers.

Indeed, current legal texts do not facilitate the emergence of companies through the promotion of public research. Consequently, it is necessary to improve these legal texts to facilitate the participation of PISCTs in private structures created based on the research results. It will also be necessary to elaborate on a more specialized legal status for the UJKZ incubator by giving it a legal personality and financial autonomy with the possibility of participation in the social capital of innovative companies. The development of university spin-offs could be boosted by i) establishing a framework agreement defining the specific conditions of access to or rental of materials, premises, and equipment from the university to the spin-offs, and ii) promoting the mobility of research personnel who wish to engage in the creation of companies from the valorization of their research work, or those who wish to provide scientific assistance to such companies without compromising their scientific careers. The granting of tax benefits innovative companies, particularly to pharmaceutical companies, such as exemptions from customs taxes on imported production inputs, could boost local production. Finally, the establishment of an investment fund dedicated to financing companies created from the valorization of research results will strengthen the direct or indirect contribution of UJKZ to the economic growth of Burkina Faso. The granting of tax exemptions to companies, particularly pharmaceutical innovative companies, such as exemptions from customs taxes on imported production inputs, could boost local production.

4. Conclusion

The UJKZ has the potential for innovation and economic and industrial development in several areas, including the pharmaceutical sector. However, Burkina Faso currently does not have favorable regulations for the creation of university spin-offs, even pharmaceutical ones. Current legal texts have several shortcomings, and their

improvement, in addition to the strengthening of cooperation between public research and the economic world, should significantly contribute to promoting the emergence of university spin-offs, including pharmaceutical spin-offs, and therefore promote local pharmaceutical production. This perspective is particularly interesting for a developing country such as Burkina Faso since the emergence of university spin-offs, especially in the areas of pharmacy and medicine, constitutes a significant factor for national economic growth.

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Conflict of Interest

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