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IMPACT OF INNOVATIVE STRATEGIES ON LONG-TERM SUSTAINABILITY AND GROWTH: EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY IN THE MIDDLE EAST

Walid SLAIBY, Ph.D.[1], Rola Noun[2], Giovanna BEJJANI[3], Sara CHAITO[4]

[1]Assistant Professor, Higher Colleges of Technology, Faculty of Business, Abu Dhabi, United Arab Emirates, https://orcid.org/0000-0002-4278-3432
[2]Lecturer, Higher Colleges of Technology, Faculty of Business, Abu Dhabi, United Arab Emirates, https://orcid.org/0009-0006-0212-7760
[3]Senior Lecturer, Higher Colleges of Technology, Faculty of Business, Dubai, United Arab Emirates. , https://orcid.org/0000-0002-3207-2207
[4]MBA, Pharmacist, La Sagesse University, Faculty of Economics & Business Administration Beirut, Lebanon

Corresponding Author: Walid SLAIBY, Ph.D.

wslaiby@gmail.com[1]
wslaiby@hct.ac.ae[1]
rnoun@hct.ac.ae[2]
gbejjani@hct.ac.ae[3]
sarachaito@gmail.com[4]

Ms. Sara Cheaito is the **head of the Regulatory Department** at **Algorithm Pharmaceutical Firm** (covering the MENA Region). Leading a team of 14 regulatory specialists/seniors focused on 5 therapeutic areas: Oncology-Hematology, NeuroSciences, Rare Diseases, Primary Care Immunology and Inflammation, and Cardiology line. Proud and grateful to have been exposed to a three-dimensional experience over a decade: at the level of local regulations for registration of fully manufactured or packaged products (innovative or generics) in Lebanon, imported products regulations in Lebanon, and to the MENA region regulations. I strongly believe that we do not build businesses; we build and develop people within a good culture, and then those people build the business.

ABSTRACT
This study analyses the effect of continuous innovative strategies in the shortrun via life cycle management (LCM) strategies and the longrun via Open InnovationOI strategies, on companies' sustainability and growth.We verify that innovative strategies primarily influence pharmaceutical companies' long-term sustainability and growth. We use a qualitative method based on multiple case studies of8 pharmaceutical manufacturers in Lebanon and the UAE in 2023-2025.This research providesevidence that a direct relationship existsbetween innovation and long-term sustainability and growth, and reveals a new dimension, the diversification of LCM and open innovation strategies, as a key driver of sustainability and growth,which reduces risk to current and future performance.
This research emphasizes that the continuous use of innovative strategies enhances a firm's resource base by optimizing product life cycles and minimizing risks. This research investigates the successful development and deployment of LCM strategies by pharmaceutical companies of diverse sizes, particularly in the Middle East. It examines as well the role of open innovation OI in fostering long-term growth and sustainability in the area, aiming to provide practical insights for firms to overcome regulatory, commercial, and resource-based challenges for enduringcompetitiveness and risk mitigation.

Keywords: Life Cycle Management strategies, Open Innovation strategies, Strategic adaptability, Long-term sustainability, Growth,Diversification, Middle East
JEL: O330

1. Introduction

Pharmaceutical companies do not have long-term exclusive ownership over their innovations. In the industry, exclusivity is granted through the application and registration of patents in accordance with the laws of each country. Patent registration secures exclusivity for a period of 20 years, as outlined in TRIPS and Pharmaceutical Patents by the World Trade Organization (WTO). Once the patent for an

invention expires, competitors rush to imitate it in order to capture a share of the market, marking the beginning of intense competition. (Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020)This situation is perceived as unfair to pioneers in the sector for two primary reasons. Firstly, companies that did not contribute to the costs of the initial invention gain the right to compete for market share once the patent expires. Secondly, the 20-year patent duration and exclusivity period often prove insufficient to generate optimal return on investment (ROI), as a significant portion of that time is consumed in the development and regulatory approval processes. Given the limited duration of patents and the restricted possibilities for extending them, this paper argues that pharmaceutical companies have only one viable option, achieving outstanding performance while maintaining market leadership; *innovate continuously or die*. Although the life cycle management (LCM) importance for maximizing return on investment (ROI) is well documented (Barbieri & Santos, 2020), there remains a significant gap in the literature on how open innovation strategies can be adapted in the pharmaceutical industry for ensuring companies' sustainability through innovative capabilities. In the meantime, little research has examined how companies in the Middle East can leverage LCM to sustain their growth in the face of declining R&D productivity and increasing innovative directions. This gap creates a challenge for pharmaceutical companies - particularly those with limited resources – who must continuously innovate to survive in a competitive market. Without clear guidance on how to shape LCM strategies to specific operational environments, these companies face uncertainty in ensuring their long-term viability, growth, and competitive advantage. The decline in R&D productivity among innovative pharmaceutical companies, coupled with legal and regulatory constraints that limit intellectual property rights and reduce revenue, poses significant threats to survival, sustainability, and growth of these companies. Developing life cycle management (LCM) strategies as early as possible is crucial for maximizing return on investment (ROI) (Kvesic, 2008). In addition, several research papers show that innovation capacity regulates growth, both within companies and in the entire pharmaceutical industry (Jorgenson, Gollop & Fraumeni, 2016; Leigh & Blakely, 2016). Innovation is generated by various internal and external factors, including knowledge and interaction between economic subjects (West & Bogers, 2014). A favorable business environment and the openness of the economy are two important constituents (Belás et al., 2015) promoting innovation. External technological sources help create competitive advantage, mainly by reducing the time needed to create and market innovations (Feniser, Lungu & Bilbao, 2017). Small and medium-sized enterprises (SME) also have the advantages of OI, cost sharing, experience sharing, and risk sharing associated with the production of innovative products or services (West et al., 2014). SMEs do not have the resources to cover high technology or innovation costs. Some scholars suggest that SMEs with limited resources and knowledge (Feniser, Lungu & Bilbao, 2017), specifically for research and development (R&D), compete through price, and possibly small innovation changes. Thus, collaboration within knowledge-based networks is becoming more frequent (McCann & Ortega-Argilés, 2015; Hájek & Stejskal, 2018). SMEs form cooperative chains and regional innovation systems in many developed European countries, which helps them increase innovative absorption, use spill-over effects (not only knowledge spill-over), and realize technology transfer (Hajek, Henriques & Hajkova, 2014). All these abilities strengthen competitive advantage. One possible method is through open innovation (OI), with many SMEs collaborating with external partners to innovate successfully, complement their capabilities, and improve their profitability (Vanhaverbeke et al., 2012). These collaboration strategies take the form of inflows or outflows of knowledge and require redefining R&D models to focus on OI (Barei, et al 2014). Michelino et al. (2014) argue that OI practices (inbound and outbound) are more prevalent among small or young biotech pharmaceutical companies, and are the core business that generates the majority of revenue. This is evidence that SMEs and start-ups find a major source of their income in collaboration with larger companies via OI strategies. Regardless of the type of OI pursued, the main conclusion is that shifting towards OI can overcome stagnant R&D productivity and generate new sources of revenue (Schuhmacher et al., 2013). (Pisano, 2019)

This study has two main objectives. *Firstly, it aims to validate the influence of implementing Life Cycle Management (LCM) strategies and Open Innovation (OI) models on the long-term sustainability and*

growth of pharmaceutical companies. Secondly, it seeks to measure the extent to which pharmaceutical firms employ a diversification strategy to mitigate risk and enhance competitiveness.(Bogers et al., 2018) (Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020)

The primary research question of this study asks: *How do LCM and OI strategies influence the long-term sustainability and growth of pharmaceutical companies while mitigating their risk and enhancing competitiveness?* (De Marchi et al., 2019)

This research is structured around three strategic perspectives and their impact on sustainability and growth. The adoption of LCM strategies involves innovating within existing product portfolios. This innovation can take various forms, such as introducing fixed-dose combinations with enhanced efficacy, reformulating products to provide medical benefits or added value, enhancing product loyalty through customer-centric packaging or delivery methods, conducting intensive promotional activities, investing in generic or second-generation products with unique advantages over existing competitors, transitioning from prescription-only medicines (POM) to over-the-counter (OTC) status to capture a larger market share, investing in regulatory strategies for expedited approvals and market access, or pursuing legal strategies to secure market exclusivity. These strategies differentiate the company and provide a competitive advantage that boosts market share and profitability.(Pauwels & Senechal, 2020)

The adoption of an OI approach involves entering into licensing agreements with multinational research-based companies. OI offers several advantages, including exclusive and non-imitable competitive advantages for customers, such as exclusive market share and revenue, the ability to command premium prices and profitability, a reputable company image, reduced R&D and manufacturing costs, and expanded knowledge and experience levels. (Ahuja et al., 2019)

A diversification approach adoption is, also, a key factor for long-term sustainability and growth. It entails developing a robust pipeline that includes products developed internally (LCM), in-licensed products (OI), as well as high-profit generics or biosimilars. This multi-source income strategy mitigates the risk associated with relying on a single income stream, thus ensuring company sustainability and long-term growth. The degree of diversification in the managerial strategies implemented positively correlates with the company's competitive position, reduces risks to current revenues, and enhances long-term sustainability and growth. Most manufacturers in the study exhibit a high to medium degree of diversification. These perspectives suggest that pharmaceutical companies in Lebanon adopt mature mindsets regarding market risks and opportunities to secure competitiveness.(Scalera et al., 2018)

2. Literature Review

2.1 Life Cycle Management(LCM) Strategies

LCM strategies are consistently at the core of business for many multinational pharmaceutical companies, including industry giants such as Novartis, Pfizer, Biogen, and numerous others. These strategies also have relevance for generic-oriented companies. As noted by Kvesic (2008): "LCM plans are an essential tool to ensure pharmaceutical companies remain successful". Pharmaceutical companies that implement LCM strategies with the aim of minimizing substantial R&D costs and extending periods of commercial exclusivity can potentially experience a significant boost in profits (Graysmark, 2016). The pioneers in this sector often find themselves facing unfair rules, primarily for two reasons. Firstly, other companies,which do not contribute to the development costs of their inventions, gain the right to compete for market share once the patent expires. Secondly, the 20-year patent and exclusivity period is insufficient to yield an optimal ROI, largely because the extensive timelines involved in developing a drug product consume a significant portion of the patent exclusivity period (McNamara, 2004). Approximately 12-15 years are devoted to drug development, testing and regulatory approval, leaving just 5-8 years out of the total 20 for commercialization and generating exclusive returns following patent registration (Kvesic, 2008), (Pisano, 2019), (Munos, B. & Chin, W. (2021))

In addition, Kvesic (2008) argues that pharmaceutical companies face other significant challenges, such as a dry pipeline and a limited number of blockbuster drugs resulting from costly R&D efforts. These challenges drive companies to develop LCM strategies early in a product's life cycle to maximize their

ROI. Escalating failure rates of new molecular entities (NMEs) during clinical trials and rising costs associated with discovering these molecules add pressure to pharmaceutical companies to find new or renewed sources of income from existing product portfolios(Sandner & Ziegelbauer, 2008). To address these challenges, pharmaceutical companies employ patent and regulatory strategies to extend their marketing exclusivity periods by introducing new versions of existing products.These strategies include reformulation, the addition of new routes of administration, new indications, improved synthetic processes, and novel product combinations (Prajapati et al., 2013). (Pisano, 2019)

The strategy of developing second-generation products or reformulations is a resource-intensive endeavour, both in terms of time and money (Graysmark, 2016). This approach requires innovators to conduct costly clinical trials to establish the effectiveness of the new indications, and ensuring the competitiveness of the product requires the implementation of an appropriate pricing strategy (Kvesic, 2008). Another challenge is the need to explore indications that fall outside the company's usual therapeutic focus, which often involves significant investment in external preclinical testing and exploration before progressing to human trials (Sandner and Ziegelbauer, 2008). (Pauwels & Senechal, 2020)

The EU market emerges as one of the most appealing for patent term extensions and data exclusivity periods, especially for manufacturers focusing on orphan drugs intended for use by both paediatric and adult populations. In this context, the EU offers the world's lengthiest non-patent exclusivity period, extending up to 12 years (Prajapati et al., 2013). According toGraysmark (2016), building and sustaining brand loyalty requires early engagement with patients, healthcare providers, and payers (reimbursement bodies) to highlight the unique advantages of the product compared to alternatives.Enhancing the value of a drug, securing customer loyalty, and delaying the decline phase of a brand can be achieved through product differentiation at various levels, including packaging design, introducing new flavours, or offering additional value-added services (Graysmark, 2016). According to Kvesic (2008), generics can easily mimic these strategies, and the additional costs cannot be passed on to consumers.

In the case of a brand company licensing its product to a generic company, the brand company gains revenue (royalties) but also faces a reduction in brand-related revenue due to the increased competition.(Kvesic, 2008) Alternatively, when a brand company produces its own generic versions, it can lead to an expansion of its market share by attracting new customers or capturing the market share of alternative brand products, due to the generally lower pricing strategy employed by generics. Another advantage of this approach is the first-to-market incentives provided by the United States Food and Drug Administration(USFDA) regulations (Graysmark, 2016). The USFDA grants a 180-day exclusivity period to the first generic entrant (Tuttle, Parece & Hecrot, 2004).

According to Kvesic (2008), strategic methods allow pharmaceutical businesses to control post-patent expiration times and product life cycles (LCM). Reclassifying prescription drugs as OTC medications is one strategy that increases the income source for the brand and helps to stop generic market share loss after the patent expires. Not all prescription medications, however, may be turned into OTC products as eligibility requirements call for safety demonstrated by clinical research, mild side effects, simplicity of use, and suitable packaging.

Concerning the theory of resource-based view (RBV), Graysmark (2016) stresses the need for resource management to guarantee long-term sustainability in pharmaceutical enterprises. According to the RBV hypothesis, companies have to be always innovating and implementing LCM-style tactics if they are to remain competitive and long-term viable. Long-term sustainability and development mostly depend on a strong and successful R&D pipeline. But firm sustainability and growth run the danger given declining R&D productivity and innovation inclination. Thus, given an emphasis on maximizing ROI in the face of generic competition, the relevance of LCM tactics following patent expiration is underlined (McNamara, 2004). (Pisano, 2019)

To get over the present production problem in the pharmaceutical sector, Schuhmacher et al. (2013) underlined that pharmaceutical businesses must show innovation in modifying their knowledge strategies and reviewing their R&D models. New molecular entities (NMEs) are expensive and challenging to

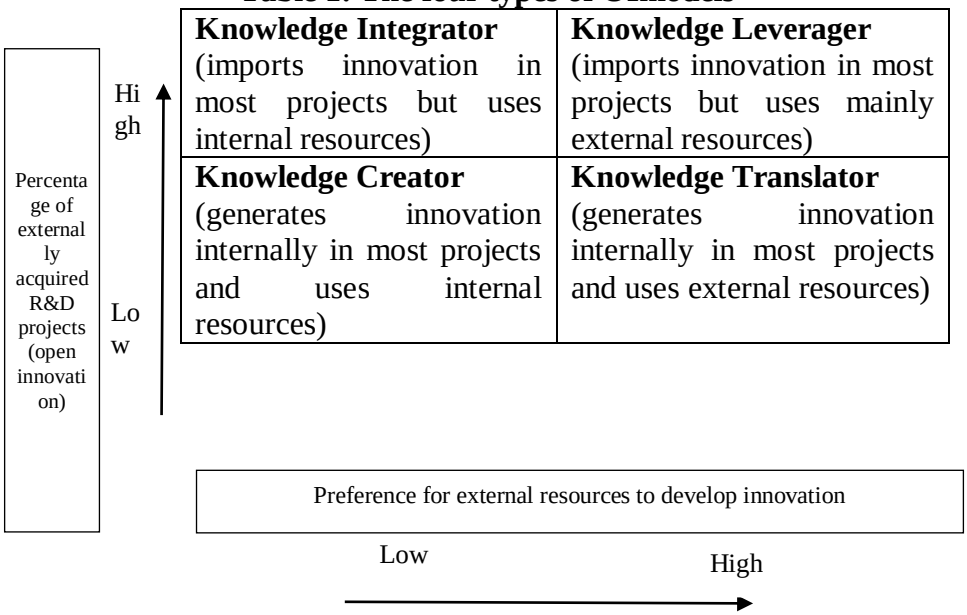
identify and produce; clinical development phase failure rates are very high. This decrease in inventive inclination is a main flaw of multinational research-based pharmaceutical businesses and a huge danger to generic enterprises, which depend mostly on the creative efforts of large pharmaceutical corporations (Schuhmacher et al., 2013). Barei et al. (2014) indicate that research-based pharmaceutical businesses require fresh streams of income apart from new molecular entities (NMEs) filing techniques if they are to thrive in a time of a dry inventive pipeline. Generic businesses additionally must identify fresh R&D models to guarantee their viability and expansion. (De Marchi et al., 2019)

2.2 Open Innovation (OI) Strategies

According to Bogers et al (2018), "high innovative propensity yields a series of temporary monopoly positions at the product level which, when aggregated to the firm level, translate to persistent profitability". This superior financial performance resulting from monopoly positions can be sustained only when innovation is continuous or there is anti-competitive behavior, such as isolating capability that can't be imitated by competitors.(Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020)Pharmaceutical companies should make sure they have a continuous flow of innovation to maintain superior financial performance and guarantee sustainability and growth in the longrun. They cannot stand still with stagnant innovative productivity but mustmake drastic changes to their R&D models, switching to OImodels which give them access to external sources of innovation. OI models allow the pharmaceutical companies to find new sources of income to improve financial outcomes and guarantee long-termsurvival.(De Marchi et al., 2019)

Collaborative strategies, or OI approaches, take the form of inflows or outflows of knowledge. SMEs are innovative when they use external knowledge to develop new products or services or license their new technologies to large companies (Vanhaverbeke et al., 2012).In the same context, Michelino et al. (2014) argue that OI practices (inbound and outbound practices) are more prevalent among small and young biotech pharmaceutical companies, and the core business that generates the majority of revenue. This is evidence that SMEs and start-ups find a major source of income by collaborating with large companies via OI strategies. The benefits of collaboration with external partners exceed the financial risks as there is a competitive power derived from the development of strong partner networks. Over time, SMEs can evolve into integral, if not central, components of broad networks of companies on which they can depend (Vanhaverbeke et al., 2012).The concept of a shift from closed innovation to OI as a business model to create value was first suggested by Chesbrough (2003). OI in the pharmaceutical industry is a driver of its sustainability and growth because of the complex technologies required the need for highly skilled personnel, and pressure from investors and other stakeholders to minimize the cost and time of drug development. Given the importance of access to external sources of innovation provided byOIR&D models, Schuhmacher et al., (2013) study the R&D models of 13 multinational pharmaceutical companies in order to classify them according to the percentage of externally acquired innovation and tendency for innovation management. They determine the following four types of OI (see Table 1)(Dezi et al., 2018) (Munos, B. & Chin, W. (2021))

Table 1: The four types of OImodels



Source: Schuhmacher et al. (2013)

Barei et al.,(2014) ask how generic companies can redefine their R&D models to adopt open innovative strategies taking into consideration value creation which secures sustainability and growth in the market. The study is based on a qualitative method using in-depth interviews with US and EU pharmaceutical company senior managers. It explores new R&D model designs (apart from the classic model) in generic companies, taking into consideration that models should result in lower cost and lower risk, along with long-term sustainability and growth.

According to Barei et al., (2014), generic companies can no longer rely on imitative lower pricing strategies relative to originators, since innovative large pharmaceutical companies face declining R&D productivity and have fewer blockbuster products. Accordingly, for generic companies to secure sustainability and growth in the longrun, they must redefine their R&D models, becoming less dependent on big pharmaceutical innovation to enrich their own pipeline. The use of new R&D models is essential, because traditional R&D requires huge investment and is not affordable to generic companies. These new models aim to generate value without incurring high costs. One important model is OI, such as in-licensing activities which allow firmsseeking leadership positions in the industry to access novel technologies in a cost-effective manner (McNamara, 2004).The only other option for generic companies is to concentrate on their own R&D as a value generator. (De Marchi et al., 2019)

According to the RBV, companies organize operations to maximize the value of their distinctive resources (Ray et al., 2013). Companies gather resources and use them to make money (Anand and Singh, 1997). These resources can be useful in more than one market or product, especially if the company looks for new prospects.

2.3 Diversification Strategy

In order to exploit their strategic resources in new product markets and acquire new distinctive resources to incorporate into existing customer markets, firms expand according to the logic of product diversification, from a RBV perspective (Mahoney and Pandian, 1992; Montgomery and Wernerfelt, 1988; Penrose, 1959; Teece, 1982). A company's ability to redeploy resources to the most profitable purposes, especially in achanging competitive landscape, can reduce risk. Resources can be used to seize market opportunities (Castanias and Helfat, 2001; Seth et al., 2002). By redeploying resources to emerging markets, diversification enables companies to make better use of resources (Anand and Singh,

1997; Mahoney and Pandian, 1992; Seth et al., 2002). The potential for development across industries is advantageous to a company. It presents the option to partially transfer the allocation of resources to a more advantageous product markets if there is a fall in demand or a rise in competition threatening revenue. A company can limit the negative effects of a single business operating in a decreasing or more competitive industry in the short term, which decreases risk. Reduced risk comes from the flexibility to reallocate resources to areas with quicker growth or higher profits.Businesses have the option to expand their assortment of materials, reorganize resources, and produce fresh combinations of distinctive resources for both current and new markets. For instance, resources such as brand image (Hoskisson and Hitt, 1990; Ray et al., 2013) and market power (Mahoney and Pandian, 1992; Nayyar, 1993; Peteraf, 1993; Teece, 1982) can be leveraged across multiple markets, providing greater opportunities and lowering the volatility of returns. Overall, product diversity generally lowers risk and presents opportunities to use resources strategically and achieve growth. Resources can be redeployed to more advantageous markets, or new resources can be acquired from other markets to use in current products. Each presentsa company with the potential to increase growth and sustainability. Crucially, more specialized businesses do not have such possibilities. When a company limits diversity, it essentially 'puts all its eggs in one basket' and depends on the success of a relatively small number of products. A company with a narrow focus is vulnerable to risk from market competition. Focused businesses, on the whole, incur more risk, supporting the fact that managers diversify to reduce vulnerability to their incomes. (Scalera et al., 2018)

3. Methodology

This research study employs qualitative methodology to explore the interplay between LCM and OI strategies and their influence on pharmaceutical long-term sustainability and competitiveness. The investigation is based on 8 case studies (8 pharmaceutical companies), providing a detailed and contextual analysis of each company's strategic practices. Data was collected through semi-structured interviews with 4 managers from each pharmaceutical company, totaling **32** interviews. These interviews targeted managers occupying the following positions: CEO, COO, operations manager, product development manager, and R&D manager.The semi-structured format, consisting of 14 open-ended questions, allowed for both flexibility and consistency in exploring key themes across the selected cases. Interview durations ranged from 40 to 70 minutes, enabling thorough discussions about LCM, OI strategies employed by managers and their influence on organizational sustainability and competitiveness. Thematic analysis, facilitated by Nvivo, was used to analyze the interviews, uncovering patterns and insights common to studied cases. (Braun & Clarke, 2019)

This analytical method was chosen for its ability to systematically identify recurring themes, particularly regarding how do LCM and OI strategies influence the long-term sustainability and growth of pharmaceutical Lebanese companies while mitigating their risks and enhancing competitiveness. Topic such as product loyalty, pricing strategies, investments POM to OTC, and OI (knowledge exteriorization) and competitiveness were explored. Multiple rounds of coding ensured the reliability of the findings, which were compared across the 8 case studies to highlight both common and unique approaches. (De Marchi et al., 2019)

According to De Marchi et al., (2019), the qualitative approach, using case studies and semi-structured interviews, was essential for capturing the complexity of LCM strategies and OI models. Qualitative methods were deemed more appropriate than quantitative approaches, given the context-specific and often informal nature of these processes. This framework provided a comprehensive understanding of how Lebanese pharmaceutical companies develop their LCM strategies to enhance sustainability and competitiveness. During the interviews, data saturation was reached when no new information emerged, and theoretical saturation was achieved in analyzing the qualitative data, particularly in relation to the advancements of the RBV and their influence on organizational competitiveness.

The thematic and structural analysis of the responses provided key insights into addressing the research questions and contributed to the broader understanding or LCM strategies, OI and diversification in the pharmaceutical sector.

Table 2: Themes structure and analysis

Categories	Themes	Sub-themes	Definition	References
Life cycle management strategies	Regulatory and legal	Compliance with regulations, adapting to legal frameworks	Interviewees emphasized the need for continuous adaptation to shifting regulatory frameworks, highlighting that compliance is a key factor in lifecycle management decisions.	Prajapati et al., 2013; Kvesic, 2008
	Product loyalty	Customer retention, repeat business strategies	Several managers noted that building brand loyalty is essential for maintaining a competitive edge. especially in mature product stages where differentiation becomes more challenging.	Graysmark, 2016; Schuhmacher et al., 2013
	Pricing strategies	Dynamism pricing and yield management	Pricing strategies were seen as dynamic, with pharma companies adjusting rates based on market demand. Managers stressed the importance of flexible pricing models for optimization.	Pauwels & Senechal, 2020
	Invest in Generics	Resource allocation, cost control measures	The concept of investments in generic drugs was likened to investments in repeatable, lower-cost strategies that ensure baseline revenue.	Usha Lenka & Gokhale, 2019
	POM to OTC	Expand service offerings, mass-market transition	Transitioning strategies were likened to moving from niche prescription (POM) to mass-market approaches (OTC). with several managers discussing the challenges of broadening product offerings.	Kvesic, 2008
Open innovation	Knowledge creator	Generating new ideas, an innovation culture	Innovation was viewed as a collaborative effort, with interviewees discussing the role of generating creative ideas to address strategic and operational challenges and create new product offerings.	Michelino et al., 2014
	Knowledge integrator	Cross-functional collaboration, integrating stakeholders' insights	Managers stressed the importance of integrating insights from customer feedback and market data in decision-making processes to refine service offerings.	Lee & Trimi, 2018; Bogers et al., 2019

	Knowledge translator	Adapting global practices locally, turning data into action	Translating market insights into actionable strategies was highlighted as a key skill, especially when adapting international best practices to the local pharmaceutical sector	Vanhaverbeke et al., 2012
	Knowledge leverager	Building on past experiences, maximizing existing resources	Leveraging past experiences and lessons learned was seen as vital for improving future decisions and adapting to evolving market conditions.	West & Bogers, 2017
Diversification	Level of risks	Risk mitigation, diversification strategies	Interviewees noted that diversification strategies often carry high risks but are necessary for long-term sustainability, with a focus on minimizing risk through careful market analysis.	Mahoney & Pandian, 1992
	Competitive-ness	Market positioning, differentiation	Many managers saw diversification as a way to maintain competitiveness, especially in a challenging market. However, they emphasized the need for strategic alignment with core strengths.	Hanelt et al., 2021; De Marchi et al., 2019

Source:Authors' compilation

NVIVO results' analysis can be categorized into three main areas, grouped under the primary category of sustainability and growth (innovative strategies). The central focus has three main themes: life cycle management (LCM), Open Innovation (OI), and diversification.(Bogers et al., 2018) (Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020)

In the initial stage of data analysis, we code specific elements of discourse to organize the data. Subsequently, we revisit the data to assess their relevance and examine how the re-presentation aligns with, or modifies, the initial findings. This iterative process involves continuous coding and analysis until a coherent and comprehensive organization of the discourse is achieved, ensuring comprehensibility. We conclude the process when the various coded meanings become saturated, indicating that the data has reached a point of saturation. The figures below illustrate data redundancy and saturation, highlighting each interview's contribution to the identified themes.

Figure 1: Research Map I

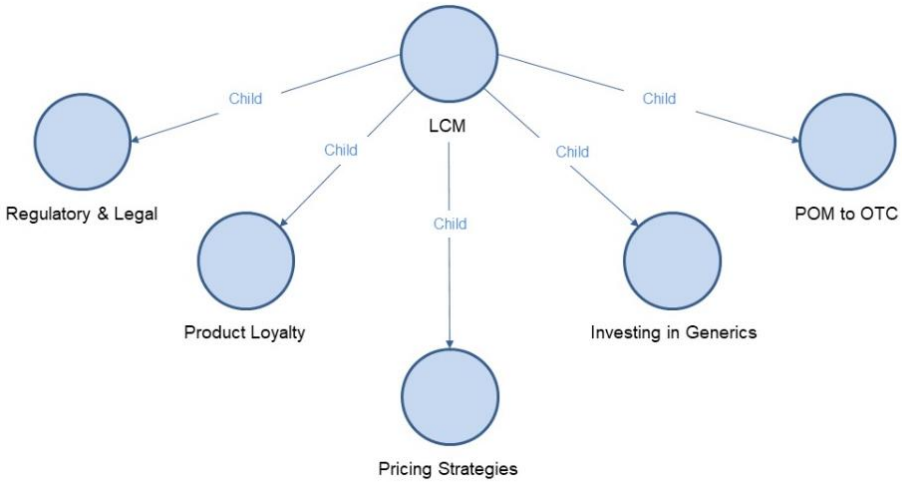


Figure 2: Research Map II

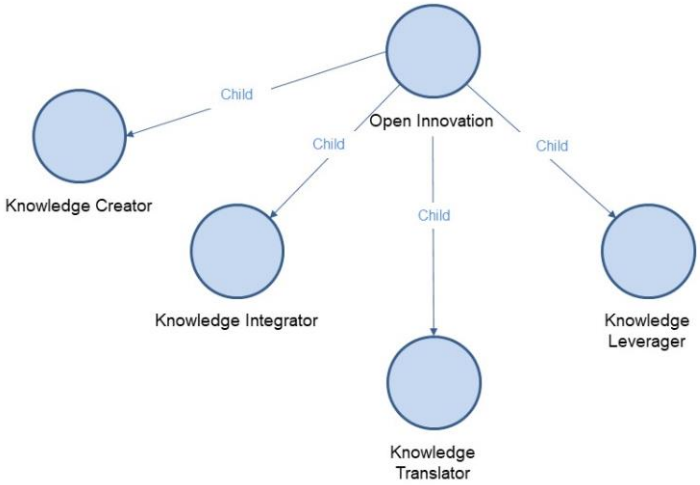
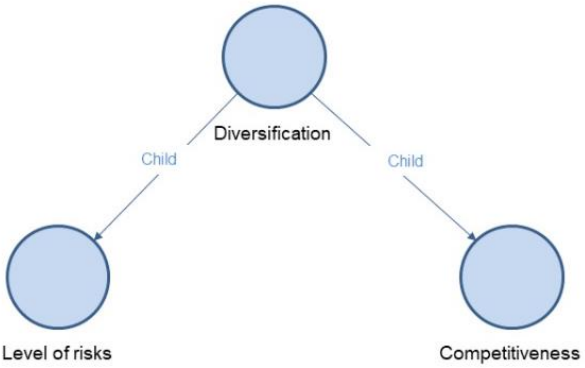


Figure 3: Research Map III



4. Findings and Discussion

All the interviewees highlighted the pivotal role of innovation as a strategic cornerstone for achieving long-term sustainability and growth. However, not all the interviewees were in agreement regarding the specific innovation strategies or approaches to be adopted. One striking revelation from our analysis of multiple cases is the absence of a singular method or strategy employed by each manufacturer. Instead, each company implements a diverse array of strategies, substantiated by a varied portfolio of innovative and imitative products. We see variations in the extent to which innovative strategies are applied by the manufacturers. Nonetheless, a unanimous perspective emerged when the interviewees were probed about the viability of relying solely on undifferentiated generic products (imitation) for long-term survival. Without exception, the interviewees agreed that the generic market has substantial risks, due to the intense competition and stringent pricing regulations. On the other hand, Lebanon stands out as a nation thatupholds registered patents and safeguards intellectual property rights. Consequently, a considerable number of patents are registered in Lebanon, and this poses a challenge for local manufacturers solely reliant on the production of undifferentiated generics, as it constrains their opportunities. (De Marchi et al., 2019)

4.1 Extent and reasons for applying LCM strategies

Among the eight manufacturers participating in the case study, seven performed LCM strategies and believed that these strategies positively influenced their sustainability and growth in the long run. One

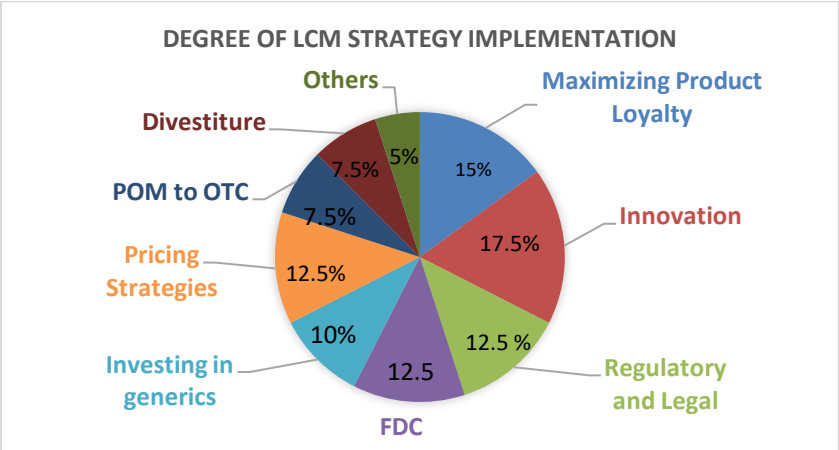
manufacturer did not perform LCM strategies and therefore did not rely on this strategy for long-term sustainability and growth.

The reasons most manufacturers in Lebanon implement LCM strategies are discussed below.

*Smart LCM generates profits and lowerscosts which help sustain launches of new products and services:*Smart LCM strategy means successfully managing established portfolios leading to financial stability. The consequent cashflow can be used to introduce new products and services to the portfolio that ensure long-term sustainability and growth. For established products, the financial outcomes of smart LCM strategies mainly result from a reduction in the promotional mix, such as adding innovation to an established active molecule to create a fixed-dose combination (FDC). In this case a company can focus its promotional strategy on one product among its two or three, reducing its promotional expenses (input),while the output and impact affect all products by reducing manufacturing costs and optimizing the use of resources and protective pricing mechanisms.The LCM of established portfolios is vital for pharmaceutical companies' long-term growth, ensuring financial stability and generating profits to support new product launches.(De Marchi et al., 2019)

*LCM generates a competitive advantage that justifies premium prices and attracts market share:*Engaging in LCM strategies means offering differentiated innovative products by continuously updating portfolios. This differentiation enables companies to acquire greater market share through unique offerings and competitive advantage. Therefore, LCM strategies and the resulting innovative differentiated products positively influence the sustainability and growth of pharmaceutical manufacturers in the long run by increasing market share and revenue. The absence of innovation via LCM strategies implies more competition from substitutes (‘me too’ products), lower prices (with many competitors), limited market share, lower profits, less chance for leadership to drive the business,increasing risk and more chance of exiting the market. Competition from imported generics can offer lower prices due to lower costs of manufacturing in countries of export.For these reasons, companies should not rely purely on generics and should embed LCM strategies to differentiate offerings. Although a company cannot discover or offer new molecules through LCM strategies, it brings added value to patients, and reveals untapped opportunities. The LCM strategies applied in the local pharmaceutical industry include: innovation through super generics, fixed-dose combinations (FDC), and generally enlarging the portfolio into new areas such as OTC products. Venturing into new technologies and new therapeutic areas (indication expansion) gives a company a boost that impacts market share (revenue) and market position (competitiveness and leadership). A company that can maintain a leadership position is able to neutralize risks that impact sustainability and growth while capturing untapped opportunities to boost performance, sustainability, and growth.These key findings from the case study are endorsed by seven of the manufacturers which participated. (Ahuja et al., 2019)

Figure 4: Degree of applying each LCM innovative strategy among the Lebanese pharmaceutical manufacturers



As seven of the eight manufacturers applied LCM strategies, believing it positively influenced their long-term sustainability and growth. The link between long-term sustainability and growth and LCM strategies is evident from the rationale shared by the participants,who suggested that LCM promotes profitability and provides financial stability to maintain launches of novel products and services. LCM generates a competitive advantage that justifies premium pricing and drives the company to a leadership position. The achievement of superior profitability, aggressive competitiveness, and market leadership via LCM strategies resultsin long-term sustainability and growth.Only one manufacturer did not apply LCM strategies (score of 0), however, the company relied on OI models and undifferentiated generics produced at low costs to generate profits and maintain sustainability and growth. Two of the manufacturers scored 8 (full score) for LCM strategy implementation, which means all the proposed LCM strategies were implemented. One manufacturer scored 6, which means 6 of the proposed LCM strategies were implemented, while three scored 5, and one scored 3.This implies that six of the eight (75%) manufacturers scored above average. While two of the eight manufacturers scored below the average. This means that, in total, seven manufacturers heavily implementing LCM strategies and one poorly implementing LCM strategies. Conclusively, the analysis does not end at identifying whether manufacturers endorse LCM; we want to know the reasons behind not implementing the strategy, although this was only the case for one manufacturer. We asked whether the manufacturer did not believe in the benefits of LCM or there were other environmental inhibitory factors. The manufacturer advised us that they had financial reasons,as they believed that Lebanon was too smallas a market for innovating through LCM strategies. In other words, they believed the financial input (costs and capital) did not justify the output (revenue). They preferred to focus on finding new generic products with high-profit yield, optimizing marketing and sales teams to be as efficient as possible, optimizing production with lower costs, and not relying on generics only but keeping a diversified portfolio by introducing in-licensed brands through OI to reduce risks in the long term.(Ahuja et al., 2019)

4.2 Extent and Reasons for applying Open Innovationstrategies

Among the eight manufacturers participating in the study, five performedOI, mainly executed through under license agreements to manufacture or package innovative products at their premises following a technology transfer from a multinational or research-based company. Accordingly, five of the manufacturers believed that OI models were essential for their sustainability and growth in the long run, while threedid not rely on OI for survival. It is worth noting that we encountered no case where the manufacturer did not apply any innovative strategy (LCM or OI)(Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020). In all cases, the manufacturer applied LCM innovative strategies or OImodels or both. This means that the three manufacturers that did not rely on OI models did implement LCM innovative strategies to ensure their survival. This is evidence that all the manufacturers interviewed (eight of a total population of eleven) believed in the incorporation of innovation into their portfolios as a vital component of sustainability. The main reason most manufacturers in Lebanon implement OI models to ensure sustainability and growth in the long run is that it is a win-win situation for the licensor and licensee(Bogers et al., 2018).The key benefits and learnings from each manufacturer endorsing OI models are discussed below.

*Knowledge Leverager:*Under-license manufacturing in Lebanon can be a strategic approach to enhancing the knowledge and expertise of local pharmaceutical companies. By acting as an affiliate or revenue generator for the licensor, the local manufacturing company gains expertise and know-how from the technology transfer process, which can be used internally for other products in the manufacturer's portfolio.(Arora, A., & Gambardella, A. (2023))

*Knowledge creator:*the value of an in-licensed brand lies in its differentiated unique quality, but at the same time, the cost is localized, making the prices of innovative products affordable for patients and healthcare payers. This unique value proposition results in a competitive advantage, greater exclusive

market share, and revenue, significantly impacting long-term sustainability and growth.(Ahuja et al., 2019)

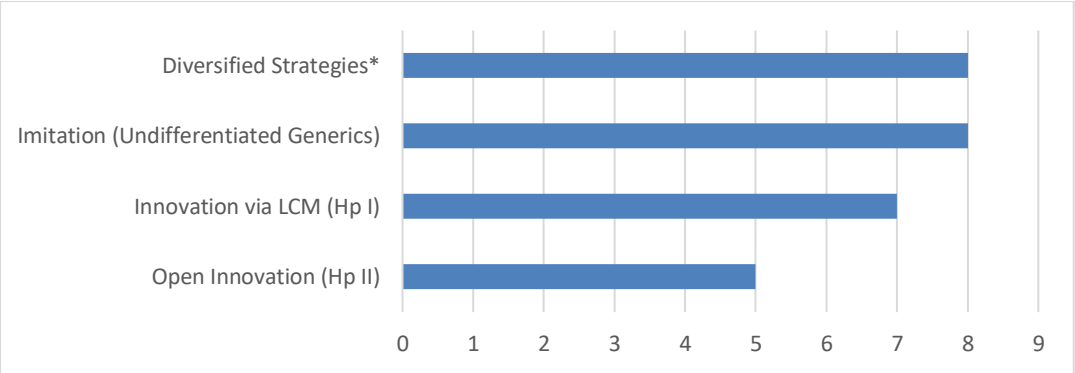
*Knowledge integrator:*OI also boosts the pharmaceutical companies' image and reputation, making them trustworthy and attracting partners and clients who know the company is manufacturing up to multinational standards. This positively influences the sustainability and growth of local manufacturing companies due to the unique differentiated value delivered at localized costs, the exclusive market share and revenue generated from monopoly acquisition of licensed brands, enhanced technical expertise, reputable image due to partnership with multinational companies, cost savings in R&D and manufacturing, risk reduction, and diversification.(Scalera et al., 2018)

Knowledge translator: OI also generates high financial returns due to the monopoly position in the market, as the products are brands protected by worldwide patents. This allows local manufacturers to enjoy a monopoly position in the market, providing an exclusive source of revenue. under-license manufacturing in Lebanon offers several benefits, including increased knowledge, competitive advantage, and access to innovation at lower R&D costs.Five participating manufacturers supported these important results from the case study. Only three manufacturers did not use OI models (score of 0); yet, these businesses utilized LCM methods and produced undifferentiated generics at a low cost to achieve profitability and continue growth. Five firms achieved a score of 1 (full score) for OI models, indicating their active implementation of OI via the production or packaging of licensed trademarks on their premises. This suggests that a significant majority (63%) adopted OI and saw it as beneficial for their long-term sustainability and development. Thirty-seven percent of the minority did not use the OI model, opting instead for other creative strategies to achieve sustainability and development. In conclusion, five manufacturers supported hypothesis II, whilst three manufacturers opposed it. When asked about the reasons for not implementing OI, two manufacturers cited the lack of financial resources necessary to finance and invest in such a strategy, indicating their support for the concept but their incapacity to actualize it. One firm said that in-house development via R&D operations was enough for sustainability and growth since it enables a local manufacturer to operate independently and retain all earnings without incurring royalty payments to the licensee. In conclusion, hypothesis II proposition II is supported. (Ahuja et al., 2019)

Extent and Reasons for applying a diversification strategy

New data from the case study relates to diversification, i.e. the implementation of more than one strategy at the same time. Diversification, as a strategy,was recommended by all the interviewees. Due to its importance as a risk reducer promoting long-term sustainability, we add it as a parameter, measuring the degree of diversification and competitiveness (percentage) in each company. The degree of diversification and competitiveness increases if the manufacturer applies more than one strategy. The degree of diversification is considered high fora score between 7 and 10, medium fora score between 4 and 6, and low fora score between 1 and 3. The degree of diversification is linked to competitive advantage. The more diversified strategies a company uses, the more competitive advantage they have and therefore the higher the degree of competitiveness. The degree of diversification and competitiveness are also linked to the ability to reduce risk. For example, if the diversification strategies of a company are 70%, it means their diversification capabilities reduce the risk to current revenues to 70%, hence the possibility of risk is expected to be low, and the long-term sustainability should be high. Figure 5shows the degree of diversification and competitiveness of pharmaceutical companies. (Scalera et al., 2018)

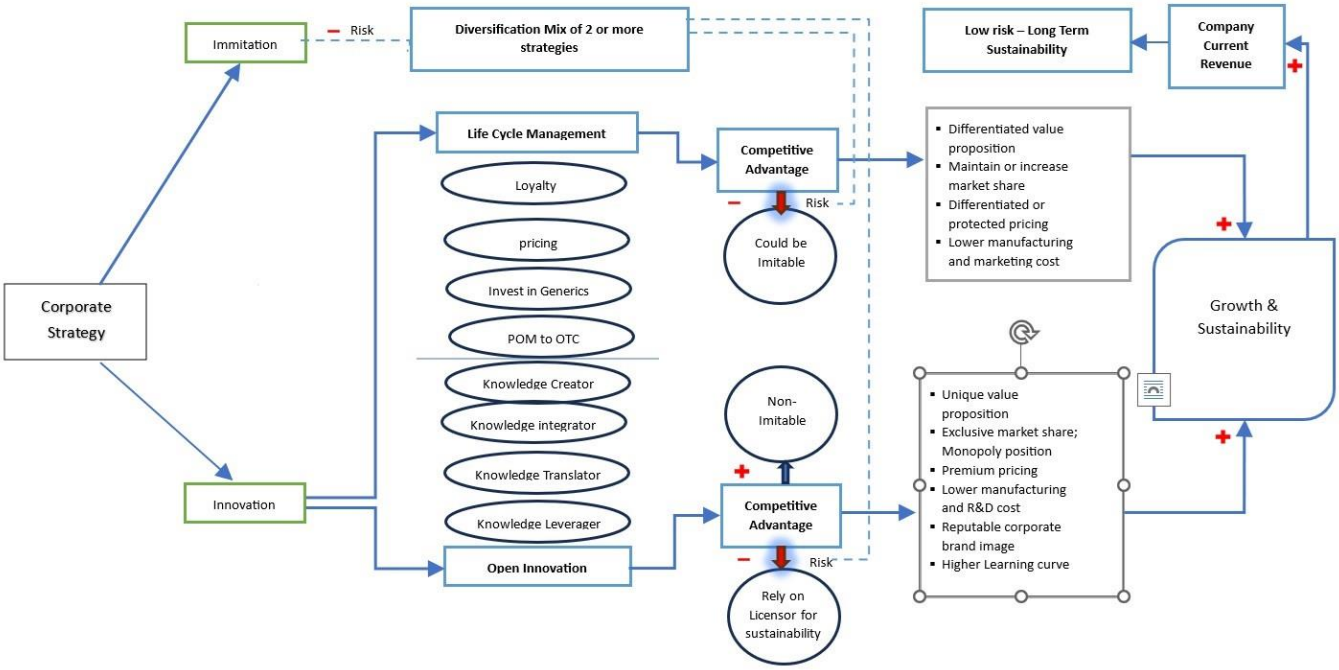
Figure 5: Statistics of the Applied Strategies by the Pharma Industry in the Middle East



The results generated bythe multi-case study show that four manufacturers had a high degree of diversification and competitiveness in their strategies: Algorithm (100%), Benta (100%), Chalhoub (80%), and Pharmaline (70%). This means that their diversification capabilities reduce the risk of current revenues up to 100% for Algorithm and Benta, 80% for Chalhoub, and 70% for Pharmaline. The risk to current revenues is low, avoided to a great extent by this matrix strategy. As the risk to current revenue is low, the degree of sustainability is high.Three manufacturers had a medium degree of diversification and competitiveness in their strategies: Mediphar (60%), Alfa Labs (60%), and Arwan (40%). This means that the diversification capabilities to reduce risk to current revenues are 60% for Mediphar and Alfa Labs, and 40% for Arwan. Hence, the possibility of risk to current revenue is low to medium for both Mediphar and Alfa Labs, resulting in a high to medium degree of sustainability. While the possibility of risk to current revenues is high for Arwan, resulting in a low degree of sustainability. (Scalera et al., 2018)

One manufacturer had a low degree of diversification and competitiveness in its strategies: Pharmadex (20%). This means that the diversification capability to the risk to current revenues is 20% for Pharmadex. Hence, the possibility of risk to current revenue is high, since the company adopts only a few strategies,posing major risk to profits if one strategyfails due to competition or the model itself. As the risk to current revenue is high, the degree of sustainability is low.Matching these results with the market leadership position and performance reported in the IMS data published in September 2017, we recognize a great deal of coherence in the outcomes. According to the IMS data, the top two manufacturers in Lebanon are, respectively, Algorithm and Benta. According to the results of this research, Algorithm and Benta are the leaders in the market, reflect a maximum degree of diversification in their strategies (100%), apply LCM and OI , and enjoy a high degree of sustainability in the long run. Hence, linking the IMS data to the outcomes of this research, we conclude that they are market leaders because they apply innovative strategies that guarantee superior performance and diversification strategies that minimize risk to their current revenue and secure their sustainability in the long run. (Scalera et al., 2018)

Figure 6: Risk-neutralizing effect of diversification and positive impact of innovation (LCM and/or OIstrategies) on long-term growth &sustainability



Source: Scalera et al., (2018)Knowledge connectedness and the inventive performance of technology sectors: A multi-technology analysis

The results of this study confirm that innovation is a strategic pillar of the long-term sustainability and growth of pharmaceutical manufacturers in Lebanon. This result aligns with existing knowledge from previous literature, which indicates that the survival of pharmaceutical companies, generic or research-based, is essentiallylinked to the implementation of innovative strategies embedding competitive advantages, particularly LCM and OI strategies. Most management in Lebanese pharmaceutical manufacturers is aware of the importance of innovative strategies and their impact on profitability, performance, sustainability, and growth in the long run.(Ahuja et al., 2019)

5. Conclusion and Recommendations

5.1 Main Findings

This paper provides substantial evidence, supported by theoretical replication, that the long-term sustainability and growth of pharmaceutical manufacturers are predominantly realized through innovative strategies, be that LCM or OI. Based on empirical evidence, all the participants unanimously agreed that innovation is a central driver of sustainability and growth. They suggested that companies should adopt a blend of strategies, encompassing LCM, OI (in-licensed brands), and high-profit generics, to ensure long-term sustainability. Most participants explained that, by implementing OI strategies through in-licensed brands, companies have access to innovation at lower R&D costs and enjoy exclusive market share and revenue as a result of the monopoly benefits of the granted license and patent rights. This coincides with the findings of Vanhaverbeke et al., (2012) and Barei et al., (2014), who suggest a shift to OI models to guarantee new sources of income and access to new discoveries at lower cost. The results also align with the findings of Roberts (1999), who concludes that the monopoly resulting from innovation intensity leads to superior profitability in the market. The superior financial performance found through OI models is emphasized by Schuhmacher et al., (2013) and Michelino et al.,(2014), who argue that SMEs and start-ups find a major source of income through collaborating with large companies via OI strategies. (Dezi et al., 2018)

Toconclude, seven of the eight participating manufacturers applying LCM strategies, as they believed it positively influenced their sustainability and growth in the long run. as five of the eight manufacturers applied OI, as they believed it positively influenced their sustainability and growth in the long run. An additional criterion appeared from the results of the study,as all eight participants suggested that long-term sustainability and growth cannot be achieved through the application of only one strategy. Relying on one strategy carries huge risks for current revenues emerging from the environment in which manufacturers operate, coming from competition or from the model itself. Therefore, from the analysis of the multiple case studies, we reach the conclusion that the degree of sustainability and growth in the long run is influenced by the extent of diversification in the strategies applied. This means that it is not sufficient to apply only a few LCM strategies (as in the case of Arwan) because it results in a low degree of diversification, high risk to current revenue, and a low degree of sustainability and growth. (Scalera et al., 2018)

LCM strategies can be quickly imitated by competitors, unless they are eligible for patent protection, which is rare. Local manufacturers that wish to focus on LCM innovative strategies should heavily apply most LCM strategies along with a generic portfolio to achieve a moderate degree of diversification and therefore low to medium risk and a high to medium degree of sustainability and growth in the long run (as in the case of Medipar). The same applies to OI models, where it is not sufficient to apply OI alone without any focus on, or investment in, internal R&D, i.e. without developing and updating the company's own portfolio (as in the case of Pharmadex). There should be equilibrium between the company's internally managed portfolio (LCM) and in-licensed portfolio (OI). A licensor might withdraw a license from a local manufacturer at anytime for any reason, which would jeopardize the sustainability and growth of companies that rely only on OI strategies. Moreover, not investing in LCM implies that a company could lose the opportunity to manage and maintain the capital of its established products which constitute cash-cows. These cash-cow generators are crucial to sustain launches of novel products and services in the long run. In conclusion, it would be optimal to apply LCM strategies combined with OI strategies and a portfolio of high profit generics in order to achieve the highest possible degree of diversification and competitive advantage. The greater the diversification and competitiveness in company strategies, the more they are capable of reducing risk to current revenue, and thus the more they are sustainable in the long run (as in the case of Algorithm, Benta, and Pharmaline).The findings introduce a novel dimension not previously addressed in the literature, namely the diversification of managerial strategies. All the manufacturers agreed that growth and survival are not sustainable in the long run by adopting an exclusive imitation approach (pure generic adoption), due to aggressive competition and strict pricing policies that limit profitability. However, they conveyed a common managerial recommendation to adopt a matrix of diversified strategies, including innovation, as a main driver of new or rejuvenated sources of income that reduce the risks of adopting imitation exclusively. Diversified strategies include a mix of innovative strategies (through LCM andOI) and imitation. (Scalera et al., 2018)

5.2 Theoretical contribution

The findings support the concept of the innovation ecosystem, where pharmaceutical companies collaborate with external partners to create value. Integration of LCM strategies with open innovation enablesthese firms to demonstrate that innovation ecosystems are essential for product development and sustainability.

This study shows that LCM (internal focus) and open innovation (external focus) improve adaptability, bringing a sustainability perspective to innovation ecosystem literature. It describes how organizations balance short-term efficiency with long-term creativity. The research shows as well that pharma firms attain flexibility by deliberately diversifying LCM strategies (exploitation) and open innovation strategies.

This study demonstrates that innovative strategies, especially Life Cycle Management (LCM), enhance product life cycles and minimize risks, hence reinforcing organizations' resource base. Open innovation

enables the company to build on external resources that exhibit consistent development and require the dynamic orchestration of internal (LCM) and external (collaborative) resources.(Bogers et al., 2018) (Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020)

5.3 Research limitations

The research focuses on pharmaceutical companies in Lebanon, which may not apply to other regions with different innovation ecosystems or market dynamics. The study's multiple case study approach provides rich insights but limits the ability to make statistical generalizations about the relationship between LCM, OI, and sustainability. The time-bound findings may be partially affected by external changes, such as disruptions in global supply chains, and rapid technological advancements.(De Marchi et al., 2019) (Albort-Morant, G., & Leal-Rodríguez, A. L. (2020)

The sample size limit is small, which might not fully capture all possible innovation dynamics. This may result in conclusions lacking representativeness for companies with different sizes, structures, or innovation capacities.(De Marchi et al., 2019)

The research may also focus only on strategic dimensions, overlooking operational factors that contribute to sustainability and growth. This narrow focus might limit the comprehensiveness of the strategic framework and miss important non-strategic drivers of business performance.

Innovation is inherently dynamic, and new trends like AI could alter the relationship between LCM, open innovation, and sustainability soon. Therefore, the proposed strategic framework may require regular updates to remain relevant as innovation practices evolve.(Bogers et al., 2018) (Gassmann, O., Schuhmacher, A., & von Zedtwitz, M. (2020)

5.4 Future research for the study

Future research could explore the differences in innovation strategies across several industries (e.g., tech, manufacturing) and countries with different market dynamics, and track the outcomes of Life cycle Management (LCM) and Open Innovation (OI) over several years. Future research could use a mixed-methods approach, an approach that combines qualitative insights with quantitative analysis (e.g., surveys or regression models).

Future research could examine the influence of emerging technologies like AI in the pharmaceutical industry, and analyze the role of leadership, culture, and organizational learning in the success of LCM and OI strategies. The study also explores the network effects and interdependencies within open innovation ecosystems, focusing on sustainability and the adoption of LCM and OI strategies by SMEs. (Dezi et al., 2018)

5.5 Recommendations

The findings of this research allow us to conclude a set of recommendations that constitute decisions or actions that need to be made by local pharmaceutical manufacturers in the Middle East to secure their sustainability and growth in the long run.

*Invest in innovation:*The introduction of biosimilars can offer comparable quality and clinical benefits at localized affordable prices relevant to expensive originator biological products, which matches with De Marchi et al., (2019)research.

Diversify R&D models: A mindset oriented towards diversification is key to sustainability and growth in the long run, as it plays a critical role in creating multiple sources of income that reduce risk to current revenue. (Scalera et al., 2018)

*Maintain highly innovative standards of the 'how':*It is not only what we bring to the market that makes a difference, as at one time, as competitors bring identical or similar offerings, it is the high standards of 'how we do it', with added value, with a twist, and with an innovative approach to service provision at the market access, medical, and regulatory levels that makesa big difference and secures customer loyalty and, thus, sustainable market share. In other words, be a value innovator.(Battistella et al., 2021)

All authors declare that they have no conflicts of interest.

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