the LISBON MBA
católica|nova
In collaboration with MIT Sloan

Title: Internationalisation models: how should research-based pharmaceutical companies select the most suitable operational model to enter small to mid-size European markets?

Field of study: Strategic Management

Purpose: Dissertation for obtaining the Degree of Master in Business Administration

Author: Ricardo Jorge Vitorino

Thesis Supervisor: Prof. António Marinho Torres

Date: 12th December 2022

Acknowledgement

The decision to advance to the thesis after a very intense and extended program was not an easy one. In the end, the choice was not to leave a loose end without being tied up and continue gaining options for the future.

I would like to thank my supervisor Professor António Marinho Torres for the wise guidance and feedback. His assertive direction has been of great help and made a difference for me during the whole process.

I also would like to express my gratitude to participating interviewees for taking the time and energy from their busy schedules to give me many interesting insights and the opportunity to conduct the research for this thesis.

A word also to my work colleagues that had to hear from me probably more details than they would have liked on this topic during these months. Thank you for the support and understanding the split focus.

Finally, a very special word to my family that once again was pulled to a new project that reduced the time available for us to spend together and my capacity to be present and support in all activities that a large family is always juggling.

Executive Summary

Research-based pharmaceutical (RBP) companies have a strong direct presence in key world markets, and, as opportunities in these markets shrink, are increasingly searching for new sources of revenues and growth. Small to mid-size European (SME) markets, which account for 16% of the total European Pharmaceutical market in value, could qualify, however, they tend to be on the borderline of direct presence sustainability. RBP companies are, thus, faced with numerous operational entry mode options, from exports to indirect (licensing, commercialisation partner) and direct investment.

The objective of this research is to describe the most common operational entry models for RBP companies and the key drivers that should guide their selection in SME countries to unlock patient access and business potential. The reflexive thematic analysis framework applied to interviews with 12 subject matter experts led to the identification of the research question crucial themes. RBP companies enter SME countries with tailwinds such as access and money and headwinds such as limited experience with alternative entry models. No single entry model is the best solution for every situation faced by RBP companies; the decision should be driven by two key variables: financial outlook and strategic relevance.

The deliverable of this work is a matrix that helps RBP companies navigate the different entry mode options (international pharmacy, distributor – wholesaler, distributor – additional services, licensing, and affiliate). This matrix is based on the two key variables identified in the study, namely, 5-year financial outlook and strategic importance of each market. Its four quadrant – small/non-strategic; small/strategic; big/strategic and big/ non-strategic – define the recommended entry modes for each market.

This study responds to the need for further exploratory research from an entry mode assessment perspective. It adds a practical description of the available entry options, the key drivers for selection and is expected to support managers in identifying the best-fitted entry mode for a SME country market.

Keywords: *Internationalisation, pharmaceutical company, entry model, mid-size European market, small European market*

Reference: Vitorino, R. J. (2022). *Internationalisation models: how should research-based pharmaceutical companies select the most suitable operational model to enter small to mid-size European markets?* Master in Business Administration Thesis. Católica-Lisbon School of Business and Economics. NOVA School of Business and Economics

Key Concepts

Entry model: An operational set-up for the entry of a company's products in an international market associated with the transfer of financial, human, technological, or other resources (Root, 1994) or as a governance structure that gives a company control under its international business (Anderson & Gatignon, 1986).

Internationalisation: A company's internationalisation entails the expansion of its products-markets strategies to other countries (Freire, 2020). The company rises its activity level outside the country where it started functioning by adjusting the operations (strategy, structure, resources) to international situations (Calof & Beamish, 1995). The presence is grounded on choices such as market, product, time, and performance (Ruzzier, Hisrich, & Antoncic, 2006).

Research-based pharmaceutical (RBP) company: A company that creates innovative medicines with capabilities ranging from discovery, development, production and commercialisation of pharmaceutical products (MBN - Market Business News, 2022).

Small to Mid-size European (SME) markets: In total there are 45 countries in Europe today (SchengenVisaInfo.com, 2022). SME markets while not being established in previous research, for the current study refer to European countries with a population of fewer than ten million inhabitants. Examples include Hungary, Bulgaria, Croatia, Slovenia, Lithuania, and Malta (List of European countries by population, 2022).

Table of Contents

1. Problem Statement and Relevance

The extension of business operations to a new international market is one of the most competitive, difficult, and defining moments of a company's life (Wheelen, Hunger, Hoffman, & Bamford, 2018). RBP companies have a strong direct presence in key world markets (EFPIA, 2022) with SME markets being on the borderline of direct presence sustainability and triggering the discussion of what is the most appropriate operational model.

The objective of the research is to address the question of what operational entry modes are available and how they should be selected by RBP companies to unlock patient access and the business potential of these markets which represent 16% of the European market. From the entry mode assessment perspective, there is a need for further exploratory research instead of the previous focus on explanatory and predictive research (Schellenberg, Harker, & Aliakbar, 2018)

2. Business Context

2.1. Pharmaceutical Industry and Market

The pharmaceutical industry addresses the discovery, development, production, and commercialisation of medicines with pharmaceutical companies being commercial businesses that are licensed to take care of these steps in the healthcare context (MBN - Market Business News, 2022). RBP industry drives medical progress bringing innovative medicines into the market that advance health and quality of life for patients while being associated with better margins than generic medicines and being the drivers of market growth (Karampli, Souliotis, Polyzos, Kyriopoulos, & Chatzaki, 2014) These companies currently have hundreds of new products with approvals anticipated for coming years reinforcing the need to find adequate pathways and models to deliver this innovation (Market.Us, 2022).

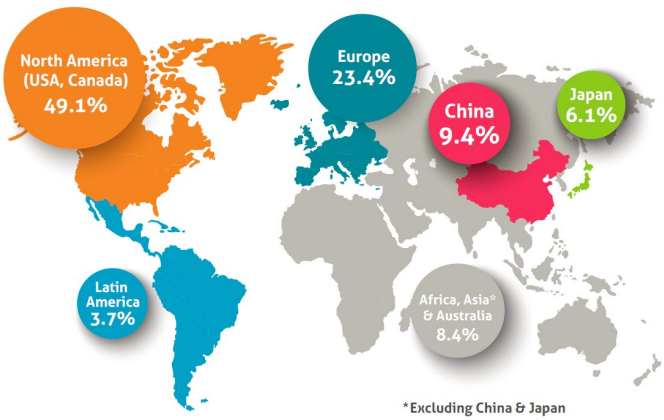


Figure 1 - World Pharmaceutical Market Sales by Region 2021 (IQVIA, May 2022)

The global pharmaceutical market has grown significantly since the beginning of this century. The total global revenues got to $1 420 billion in 2021, up from $1 270 billion in 2020. The 2021 total was 3,6 times bigger than it was at the beginning of the century ($390 billion) and the trend continues positive in the coming years (MBN - Market Business News, 2022). The top global regions in pharmaceuticals are

North America and Europe. In 2020, North America's pharmaceutical market represented more than 49% of the world's pharmaceutical sales and the expectation is to continue to be the leading global pharmaceutical market. Europe was the second-largest region and generated around $228 billion (IQVIA, May 2022) (Market.Us, 2022).

EFPIA 2020	€ million		€ million
Austria	4 827	Latvia	275
Belgium	6 303	Lithuania	866
Bulgaria	1 414	Malta	196
Croatia	1 036	Netherlands	6 185
Cyprus	177	Norway	2 597
Czech Rep.	3 389	Poland	7 239
Denmark	3 243	Portugal	3 524
Estonia	359	Romania	4 500
Finland	2 762	Russia	18 398
France	29 552	Serbia	871
Germany	42 962	Slovakia	1 461
Greece	5 381	Slovenia	743
Hungary	2 558	Spain	17 604
Iceland	183	Sweden	4 570
Ireland	2 354	Switzerland	5 920
Italy	23 446	United Kingdom	24 569
		TOTAL	**229 464**

Table 1 - European Pharmaceutical Market Value (at ex-factory prices) by Country 2020 (EFPIA, 2022)

There is a flattening of the growth in developed countries' pharmaceutical sales and companies are increasingly watching additional markets for new sources of revenues, growth, and patient access. This leads to a need to focus on strategies tailored to local markets (Market.Us, 2022). The globalisation business opportunity and the ethical need for patient access are urging pharmaceutical companies to expand beyond existing markets and continuously provide access to their products in new geographies.

2.2. Small to Mid-size European Markets

In the European Union (EU), great progress has been made in human health with average life expectancy at birth increasing by 3.3 years since the beginning of the century. Innovative medicines have helped to tackle some of the most important causes of disease. Still, many patients do not benefit from these innovations because they aren't available in their countries. Companies can choose not to market their medicines in some countries, with this situation occurring in particular in SME countries and both in the EU and its neighbouring countries (European Commission, 2020).

This occurs for reasons such as the size of the country's population, health system organisation, the national pricing and reimbursement framework, and national general and administrative procedures that result in markets that become smaller and less attractive. Recent experiences in Europe with medicines for rare and child diseases showed that it is possibly to increase the availability of these medicines with specific regulations, but the access level still is not homogeneous (European Commission, 2020).

The current business model of RBP companies has evolved from being sustained by blockbusters to more products with more narrowed indications referred to as "niche-busters". This is an additional

reason for the reduced likelihood for some patients to have access to innovative medicines and this need to drive adaptations in the future (European Commission, 2020). SME markets are at the borderline of the sustainability of a direct presence by an RBP company and trigger a broader discussion of what is the most appropriate operational model to be implemented in such markets.

There is a need to work with partners to tackle political, social, geographic, and economic barriers. Growing internationally is positively associated with company profitability and there is a need to also find a sustainable model for all stakeholders to allow broader geographic patient access (Wrona & Trapczynski, 2012). Small to mid-size Europe countries account for 38,5 billion euros of yearly revenue and represent 16% of the total European Pharmaceutical market in value (EFPIA, 2022). The present estimate of the current market addressed with a commercialisation partner is 10% with the future market potential to more than double its size to 25% (Boston Consulting Group, 2020).

3. Literature Review

3.1. Review of Conceptual Frameworks

There are diverse theoretical conventions and foundations embedded in the internationalisation of companies and literature research allowed the identification of the key ones that aim to enlighten a company's entry mode choice. The following frameworks have been identified: the Transaction Cost (Williamson, 1975), the Eclectic Paradigm (Dunning, 1988), the Uppsala Internationalisation Model (Johanson & Vahlne, 1977), the Resource Based View (Root, 1994), and the Institutional Theory (Di Maggio & Powell, 1983) (Schellenberg, Harker, & Aliakbar, 2018).

3.1.1. Transaction Cost Theory

The transaction cost theory is the most applied internationalisation theory (Canabal & White, 2008) (Zhao, Luo, & Suh, 2004). It assumes that players function and select rationally but companies can also act in an opportunistic way (Seggie, 2012). The four key dimensions of transactions in this theory include the specificity of assets, uncertainty of environment and behaviour, and frequency of transactions (Williamson, 1975). In a situation of high uncertainty, it is hard to plan for all future eventualities for which revisions and contract adjustments with a partner are going to be needed (Anderson & Gatignon, 1986). In some cases, uncertainty leads to a scenario where the international opportunity dimension cannot be established in a precise way. In these cases, the theory suggests that companies should keep the investment low while keeping the possibility for investment scale-up (Brouthers, Brouthers, & Werner, 2008). In uncertain scenarios such as these, entry modes including a commercialisation partner are seen as an interesting option (Morschett, Schramm-Klein, & Swoboda, 2010). The entry mode selection is a financial decision and the company is expected to choose the entry mode that offers the higher return on investment (Anderson & Gatignon, 1986).

3.1.2. Eclectic (OLI) Paradigm Theory

The eclectic paradigm theory is the second most adopted (Canabal & White, 2008). The main theoretical foundations are that a company's entry mode selection is grounded on the ownership (O), location (L),

and internalisation (I) dimensions (Dunning, 1988) (Dunning, 1993) (Dunning, 2001). The theory proposes that international entry mode decisions are rational and are grounded on the analysis of the transaction costs in a similar way as in the transaction cost theory (Whitelock, 2002). The ownership advantages refer to the build-up of intangible assets, technological skills, and new product innovations (Dunning, 1993). The ownership advantages have to be capable of creating a competitive advantage that is sustainable in the international setting (Brouthers, Brouthers, & Werner, 1996). The location advantages denote institutional and productive dimensions that exist in an international market. The internalisation advantages denote lower coordination and transaction costs from the internalisation of added-value activities (Ruzzier, Hisrich, & Antoncic, 2006). The Eclectic Paradigm theory is considered a multi-theoretical approach as it ponders Transaction Cost, Resource Based, and International Trade Theories.

3.1.3. Uppsala Internationalisation Theory

The Uppsala internationalisation model illustrates company internationalisation as a step-wise learning process (Johanson & Wiedersheim-Paul, 1975) (Johanson & Vahlne, 1977). In this model, a company starts international operations with lower commitment (i.e., exporting) and proportionally strengthens dedication. If successful, this sequence of steps evolves the company to operational models that have a bigger commitment and financial exposure – from an export partner to a subsidiary (Johanson & Vahlne, 1977). This model has been challenged by scholars but is still considered as it contributes to the theoretical knowledge of international entry mode patterns and increased commitment in foreign markets (Canabal & White, 2008). The literature also indicates that strategy formation can't be as systematic as this staged model indicates. Instead, executives anticipate and react to internal and external events with different approaches that influence opportunities being chased that can be either planned or opportunistic (Crick & Spence, 2005) (Crick & Crick, 2014). It is now also noted that some companies have the capabilities and competencies to operate internationally from an early stage instead of using a stepwise approach (Bell J. , 1995) (Oviatt & McDougall, 1995).

3.1.4. Resource-Based View Theory

For the resource-based view theory, the company is an inimitable package of tangible and intangible resources, with these being assets, processes, knowledge, and capabilities (Roth, 1995) (Sharma & Erramilli, 2004). This theory emphasises unique, costly, and difficult-to-copy characteristics and resources of the company that are levers of sustainable competitive advantage and the organisational performance that is needed for the internationalisation process (Ruzzier, Hisrich, & Antoncic, 2006). Resource-based models address the proprietorship of the current assets and also the organisational capabilities to develop new assets. This highlights how important intangible, knowledge-based resources are in creating a competitive advantage (Canabal & White, 2008). The decision maker's influence on internationalisation process decisions has been fully incorporated into the resource-based view theory (Alvarez & Busenitz, 2001) (Herrmann & Datta, 2005). In an international context, novel experiences occur and are a way for key employees to learn. This 'organisational memory' reserve can shape decision-making (Moorman & Miner, 1998).

3.1.5. Institutional Theory

The institutional theory examines how companies function in external markets using a company framework, defined by specific rules, norms, and values (Meyer & Nguyen, 2005). An idea that is crucial for the institutional internationalisation theory is isomorphism, which represents the situation when a company has to make itself similar to companies that are successful in the same environmental conditions (Di Maggio & Powell, 1983). Companies are expected to have a better performance in international markets if they chase both the legitimacy of the institution and efficiency in transaction cost efficiency when defining the entry model in a foreign market (Davis, Desai, & Francis, 2000). The institutional variables combined with transactional variables, add in a significant way to the understanding of the entry mode selection and have supplemental power to predict the mode result (Canabal & White, 2008).

3.2. Review of Existing Knowledge

3.2.1. Research-Based Pharmaceutical Companies Internationalisation

The internationalisation of companies has been a theme of numerous research with some work focused on RBP companies' internationalisation (Fina & Rugman, 1996) (Buckley & Chapman, 1997) (Javalgi & Wright, 2003) (Chittoor & Sougata, 2007) (Wrona & Trapczynski, 2012) (Kuntluru, Muppani, & Khan, 2012) (Chitour, 2013) (Barbosa, Ayala, & Sandoval, 2016) (Pereira & Gomes, 2017) (Lyckenblad & Nygren, 2019) (Teramae, Makino, Lim, Sengoku, & Kodama, 2020) (Zhai & Ghosal, 2022). The most often mentioned theories of internationalisation are the ones based on resources (Roth, 1995), incremental internationalisation (Johanson & Vahlne, 1977), and eclectic paradigm (Dunning, 1993). The challenges to the internationalisation process include product development costs that are high, entry barriers that are also high due to the heavy regulatory and legal frameworks and return on investments that is low (Laurell, 2015).

The company almost always has already begun an export phase when starting an internationalisation process and typically initiates international development in countries that have similarities with its country of origin and progressively develops to different countries (Pogrebnyakov & Maitland, 2011). The internationalisation process cannot be seen only as a progressive process, and it should also expect setbacks. The company may even choose at some point to revert the internationalisation process. It can stop working on a product in an international market, hand over foreign direct investment, and as an alternative change again to exports and reduce or even terminate its international activities (Chetty & Campbell-Hunt, 2001) (Roque, Alves, & Raposo, 2019).

3.2.2. Entry Mode Options Available for Research-Based Pharmaceutical Companies

There are numerous operational entry mode options for a company, from exports to indirect (licensing, commercialisation partner) and to direct investment (Anderson & Gatignon, 1986) (Hill, Hwang, & Kim, 1990). Each operational entry mode options have its consequences for the control of operations,

commitment of resources, and spreading of risk levels (Hill, Hwang, & Kim, 1990) (Roque, Alves, & Raposo, 2019).

Export Options

The export possibility uses production from countries where the company is already present to sell in international markets and it is common for the RBP company to be supported by an intermediary in the new country. It can be verified that most of the time companies have already begun an export phase when starting an internationalisation process (Pogrebnyakov & Maitland, 2011). Many RBP companies start with reactive sales in SME countries triggered by international pharmacy chains and/or local wholesalers which is a good way to allow patient access while minimising risk and operational complexity. The evolution of the demand eventually leads to a point where the company must assess and decide the most appropriate and sustainable entry option for these new markets.

Indirect Options

In the indirect options, the RBP company agrees on a contract with a local commercialisation partner. In this contract, the company transfers to a local commercialisation partner the right to use certain assets (patents, trademarks, brands, technology) and defines the activities that are the local partner's responsibility. This mode of entry occurs when a company has the technological expertise but doesn’t want to use its resources to enter a market (Anderson & Gatignon, 1986).

The licensing entry model represents a sophisticated arrangement in which the company transfers the right to use and sell a product or service to another company. There are licenses for marketing and production. The licensee pays compensation to the licensing company in return for technical and marketing expertise and operates with a hands-off approach to the licensing company (Hodzic, 2020).

Another option is for the company to appoint a commercialisation partner (distributor or agent) to represent them in that market. Agents and distributors work to represent the RBP companies' interests in the market and the choice of agents and distributors must be handled in the same manner as hiring key staff personnel (Hodzic, 2020). It can also begin partnerships such as joint ventures or strategic alliances in an indirect increasing commitment approach (Almeida, 2018).

A distributor is an independent trader that buys products from RBP companies and sells them to its customers, the end customers are customers of the distributor, not of the RBP company and the goods will normally pass directly from the principal to the distributor and on to the end user. An agent on the other hand acts on behalf of the RBP company, the end customers are customers of the principal, and while the agent is promoting the sale of the RBP company goods, the goods will normally pass directly from the RBPcompany to the end customer (Commercial agents, 2022). There can be different types of agreements, from simple wholesaler services to additional added value services like medical affairs, marketing, and sales that are agreed to be remunerated by a margin.

An agent and a distributor are intermediaries between the RBP company and the end customers. These labels are sometimes used interchangeably but there are key differences that affect the decision to

appoint a distributor or an agent. The distinguishing factor is the position of the intermediary concerning the RBP company and the end customers (Nourry & Harrison, 2022).

	Agency	Distributorship
Price and other sale terms control	Yes	No
Ability to choose customer	Yes	No
Customer "Ownership"	Yes	No
Control over marketing	Yes	No, can have obligations to implement consistent programs
Ability to off-load financial stock risk	No	Yes
Lower commission payable	Yes	No
Compensation for termination	Yes	Not in the UK
Competition law complications	No	Yes
Simpler tax position	No	Yes

Table 2 - Summary comparison between agency and distributorship relationships from an RBP company perspective (Nourry & Harrison, 2022)

Direct Investment Options

The direct investment possibility occurs when the company decides to take the investment associated with this mode of entry either alone or through partnerships with other companies, sharing the costs, risks, and revenues (Osland, Taylor, & Zou, 2001). The company has total responsibility over the operations and can choose between an option in which it establishes operations from zero (*greenfield)* or another option in which it acquires a subsidiary with established activities in the international market (Almeida, 2018).

In an affiliate model, pharmaceutical companies have a local presence, with dedicated full-time employees, and take ownership of the strategy and operations sustaining the short-term commercial objectives and the mid to long-term vision for the company and the country's development. Affiliates have full ownership of the commercialisation of their medicines and represent the most evolved model reached when there is a sustainable business, reliable and stable environment, and long-term perspectives for the country and it represents the most rigid one with the higher strong fixed costs. This strategy is the riskiest for the company and requires high levels of investment (Hodzic, 2020).

3.2.3. Determinants of Entry Mode Selection

The entry mode choice is a strategic decision in an internationalisation procedure (Hollensen, 2011). It has a direct impact on the RBP company performance and a long-term impact on the strategy and future. The entry modes can be clustered according to the need for investment with exports and licensing representing no-investment options and affiliates in their various formats representing investment options (Root, Entry strategies for international markets, 1994). The determinants that drive the entry mode decision include investment level, exposure to risk and the control level the company intends to have in the process (Hollensen, 2011) (Ulrich, Boyd, & Hollensen, 2012) (Erramilli & Rao, 1993).

The lower amount of money and resources the RBP company is prepared to devote to this process, the higher the likelihood of selecting an entry mode with a commercialisation partner. The country's risk and business environment volatility must also be taken into account in the selection of the entry mode, which can consider risks and cost-sharing to achieve a higher flexibility in the response to eventual changes in the country (Almeida, 2018).

It is not clear if the entry mode is a determinant itself in the process of a company's internationalisation. A review observed that relatively low importance has been given to this factor (Chen, Sousa, & Xinming, 2016) and it appears to be more of a predictor of risks, control, and return once integrated with other determinants, such as barriers for the internationalisation process (Hollensen, 2011) (Wrona & Trapczynski, 2012) (Ulrich, Boyd, & Hollensen, 2012). The entry mode decision is a consequence of dimensions like the potential of the market, the product differentiation level and the characteristics of the managers concerning international experience and risk perception (Wrona & Trapczynski, 2012). (Vieira, Frade, Ascenso, Martinho, & Martinho, 2021).

4. Methods

4.1. Research Approach

The current research follows an inductive approach as there is limited literature on the research topic and there is no theory to test. The research started with the observation of how RBP companies enter SME markets, collected empirical data relevant to the topic and then develop a general conclusion. The choice of the inductive approach for this research can also benefit from my knowledge of the topic and working in the space that allows me to bring hands-on experience to the research. I am aware that an inductive approach has the risk of being flawed as the conclusions go outside the information in the empirical data (Bell, Harley, & Bryman, 2022).

This thesis also follows a qualitative approach as the objective is to gain a deeper understanding of how RBP companies should select the most suitable operational model to enter SME markets and the most appropriate way to answer this question appeared to be by running several in-depth interviews with subject matter experts with these reasons being aligned with available theories to choose a qualitative approach. A qualitative research strategy underlines words instead of data quantification and is used when the researchers want to address a topic in more detail to find perspectives not possible to explore with quantitative data. This approach allows the interviewees to answer more freely to the interview questions more without the precision from quantitative data and this way allowing to identify new and fresh perspectives. Some disadvantages of the approach also need to be highlighted such as the high demand and time consumption of the interviews and the risk that the research becomes too subjective with deductions not based on the theories and empirical data (Bell, Harley, & Bryman, 2022).

4.2. Research Process

The research course for the thesis has been organised in steps that weren’t followed in strict chronological order to allow flexibility to navigate between them as new insights and data were collected

and analysed. The research was initiated with a literature review to gather a robust view of the internationalisation process and more specifically the internationalisation process of RBP companies. The literature material was collected from Google Scholar, Emerald, Wiley Online Library databases, Harvard Business Review and MIT Sloan Management Review management journals and McKinsey and BCG consulting companies' websites. The following words have been used in the research - internationalisation, entry model, pharmaceuticals, Europe, pharmaceutical company, mid-size European market and small European market – with them also having been used in combinations.

The second step was to collect empirical data from subject matter experts by having 12 one-to-one interviews (Appendix 2 – Interview List). The research followed the semi-structured interview method where the researcher starts with a list of questions addressing the research topic and the interviewee openly answers them. A semi-structured interview maintains the interviewee close to the topic while allowing freedom in the answers to collect additional insights (Bell, Harley, & Bryman, 2022). An interview guide was developed to guide the interviews (Appendix 3 - Interview Guide). A few days before the actual interview, an email was sent to the interviewees with additional context on the research and the main topics to be covered. The interviews were all done on Zoom software as the interviewees were geographically dispersed across Europe and these were also transcribed to allow a structured analysis after they were performed. The empirical data collected on the most common entry models for the RBP industry in SME countries and the key considerations when selecting and evolving an entry model in these countries were analysed by using the reflexive thematic analysis framework (Braun & Clarke, 2006) (Braun & Clarke V., 2013) (Braun & Clarke, 2020) on Miro software that permitted to identify from user interviews the research insights and build the five themes crucial for the research question. During this analysis, the theoretical framework was enhanced with further studies that supported the empirical findings such as the collection from additional subject matter experts of the current operational models of the top 20 RBP companies in a selection of SME countries (Appendix 4 – Current operational models in a sample of countries).

In the last step, the theory and empirical findings were discussed and analysed allowing the design of a matrix proposal aiming at helping to navigate the different entry mode standard possibilities (international pharmacy, distributor – wholesaler, distributor – additional services, licensing, and affiliate) for from RBP companies in SME countries. The work contribution, limitations and suggestions for further research were also addressed at this point.

4.3. Data Treatment

The thematic analysis was selected as the method for the analysis of the interview transcripts and the framework used was the six-phase one proposed by Braun & Clarke because it is very clear and practical (Braun and Clarke 2006) (Braun & Clarke, 2012) (Braun & Clarke V., 2013) (Braun, Clarke, Terry, & Hayfield, 2018) (Braun & Clarke, 2020). The thematic analysis objective is to identify, describe, analyse, and report patterns and themes within qualitative data. Then analyse, interpret, and build on these patterns and themes to report back to the research topic. It is not tied to a particular theoretical perspective which makes it a very flexible method (Braun & Clarke, 2006).

The analysis process starts with becoming familiar with the data, generating initial codes and then searching for themes, their development and refinement. In parallel to this analysis process, there was the development of the narrative to communicate the themes in a logical and meaningful way for the research question (Braun & Clarke, 2012) (Maguire & Delahunt, 2017). After the application of the framework, one of the reported outputs was a visual map for themes (Figure 2) and a visual map for themes and subthemes (Figure 3) that were selected to be the focus of this thesis.

5. Results and Analysis

The work explored the most common entry models for the RBP industry in SME countries and the key considerations when selecting and evolving an entry model in these countries. The reflexive thematic analysis framework applied to the 12 interviews led to the identification of five themes that stood out as crucial for the research question.

In short, RBP companies enter SME countries with tailwinds such as access and money and headwinds like limited knowledge of country complexities and experience with alternative entry models. No entry model is identified as a silver bullet and is the best operational solution for all entry situations faced by RBP companies with financial outlook and company strategy as the two key variables driving the entry model decision. There is also an ongoing movement from RBP companies in SME countries to change the business model and move into an indirect presence.

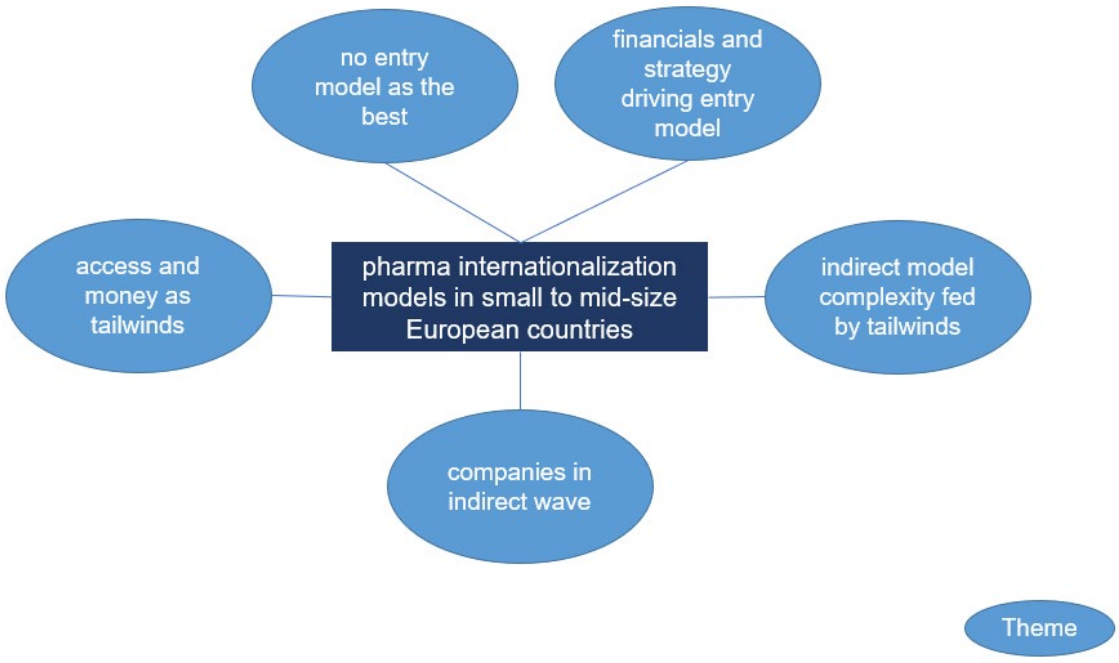


Figure 2 - Thematic analysis map for the entry mode decision of RBP companies in SME countries

Theme #1 – RBP companies enter SME countries with access and money as tailwinds

There are two obvious reasons why RBP companies enter SME countries such as the expectation of patients to access the medicines once it receives marketing authorisation in the EU and to grow revenues further once the launches in the top 15 global markets are on the right track.

Patient Access

In the EU, once a company receive marketing authorisation approval for a new medicine it gets approval for all countries part of the European Economic Area (EU countries and Iceland, Liechtenstein, and Norway). This approval comes with an expectation from all stakeholders in each of the countries that the medicines will become available as these address an unmet medical need. From an ethical perspective, companies also mention the ethical obligation to make innovative medicines available to patients no matter the dimension of the country. In some cases, there is even a regulatory obligation to launch as in the example of pediatric formulations that have to be launched 2 years after approval in the markets where the adult presentation is available.

> *"Innovative and promising medicines do not always reach the patient and patients in the EU still have different levels of access. Companies are not obliged to market a medicine in all countries; they may decide not to market their medicines in one or more countries. This can impact patient access in smaller and less wealthy markets." EU Pharmaceutical Strategy* (European Commission, 2020)

In practice, we know that there are still patient access inequalities in the EU and also in European countries that aren't part of the EU where there is the additional hurdle of needing an additional country marketing authorisation leading to further delayed patient access. The European Commission is currently preparing a revision of the EU Pharmaceutical Legislation and one of the proposals to address patient access inequalities across EU member states is to add a requirement for MAHs to place a centrally authorised medicine on the market in most of the Member States (including small markets) within a certain period from authorisation (European Commission, 2020). This situation makes the point to us that RBP companies need to find the right entry models for each country.

Revenue growth

The central approval from the European Medicines Agency simplifies the process for EU Member States which makes these countries a natural market expansion route allowing companies to grow revenues after bigger markets. It is also a matter of company reputation and awareness, as stakeholders and especially clinical leaders follow the science and are present in international congresses where innovative and best-in-class medicines clinical data is presented regularly.

> *"Get US right, then think about the EU in an efficient way to have patient access without bringing complexity to the company. The objective is to have access to the extra millions without the complexity of the additional organisation." RBP company executive*

Again, this is not the situation for SME countries not part of the European Medicines Agency network with the additional national hurdles leading to reduced revenues and profitability in small markets but with notable exceptions such as Serbia that in terms of the size of the population can compete with most EU countries what can hint a prioritisation of the countries with such characteristics.

Companies when deciding to market their medicines in these countries want patient access and revenue growth to be made in models that leave the additional complexity outside of the company as much as possible, optimise the business opportunity and mitigate risk as the pharmaceutical industry is highly regulated.

Theme #2 – Indirect entry models are seen as complex by pharmaceutical companies with limited understanding of the markets and organisation built for affiliates as headwinds

The second theme talks about the challenges and barriers for RBP companies to enter SME countries and deciding on an entry operational model in an SME market. In the past years, there has been an increase in the importance and prioritisation of pharmaceutical companies in the 10 to 15 key markets that make up eighty per cent of the global revenue. The rest of the markets are important from an unmet need perspective, but less so financially. Therefore, the interest in alternative commercialisation models increased. There are three reasons justifying this situation, the first is that SME markets have a reduced dimension but not reduced intricacy, the second is that RBP companies have an organisation built to manage affiliates and also need to have the right talent and decision makers to address these alternative entry models and the third is that is easier to take decisions in a blank sheet (entry model decision) than to change a model (change model decision).

SME markets are intricate

The SME markets intricacy is reflected in each country's political and economic stability that is not homogeneous across these countries even in the EU which brings unpredictability to the business. The other aspect is the level of risk that the business has in each country with the risk identified from laws and tax and business regulations that balance compliance and business conduct risks. The last dimension is the understanding of the country's potential in a situation where the company has limited local knowledge, need to rely mainly on external consultants and potential commercialisation partners and sometimes the availability of data (e.g., epidemiology, market sales) is either limited or not validated. These dimensions are even more important in the European countries not part of the EU that don’t benefit from the economies of scale linked to the single market and are generally more unstable, risky and the potential is more uncertain.

“A big challenge is the understanding of the country's potential and situation in full. I think that's the highest barrier, and you usually don't know, if you are not there. That this is the biggest challenge and then the second one is internal focus on the core markets with higher revenues which leads to companies not having the internal competencies beyond the affiliate models.” RBP executive

Different organisations, talents and decision-makers needed to address alternative entry models

The need for RBP companies to adjust their organisation, and have the right talent and decision-makers to address these alternative entry modes was also identified as a key challenge. The main competencies and experience of RBP companies executives lie within the affiliate model and the processes and structures from global to local reflect this model. There is a need to internalise talent that has experience and competencies to assess and manage these alternative entry modes with specificities to be also reflected in the processes, structures, and decision-makers to create an efficient model. This is the only way the organisations can effectively manage internal tensions and be effective in addressing the alternative models for entry in a time of significant organisational changes with a reduction in regional headquarters and reduced layers to manage such complex set-ups.

"Most companies are trying to centralise and have one or two partners maximum per continent. They are trying to cut costs and simplify their lives, and it's much easier to monitor and control one partner than six. This one partner, because he is regional, will probably listen to you more because he's got a big piece of business from you. Also, if you're going to have a distributor in each country you have to have sub-regional headquarters just to manage the distributors and reflect in the structure the audit burden." Pharma commercialisation partner executive

Initial entry model decisions are easier than change

It is easier to work on a blank sheet during an entry mode decision where the RBP company is expanding and building local relationships than to change or evolve a model where it is fixing a significant problem (e.g. performance, compliance, trust), breaking and re-building relationships and, transitioning between commercialisation partners with all the operational complexity and surprises that arise. Redesigning a footprint need strong leaders as it frequently leads to difficult decisions and can easily be captured by corporate inertia and politics. The complexity of a future change process stresses the need to have early plans on how to course correct between commercialisation models and plan for exit alternatives.

Theme #3 – There isn't an RBP companies entry model in SME countries that would offer a turn-key solution for all situations

There are five possible models established and described in the literature review – international pharmacy, distributor – wholesaler, distributor – additional services, licensing, and affiliate – and the current research collected the real-world attitudes of executives towards each model and aimed at understanding when each one is more suitable to enter SME countries.

International pharmacy model

The international pharmacy is a model that is simple to implement with no upfront investment and can include various countries according to the need of the company, with the commercialisation partner managing the complexity of the procurement processes while providing urgent access to innovative treatments and fulfilling the demand in an aligned way across geographies.

"The international pharmacy model requires no investment; it is easy to implement and solve the access issue in several markets with one non-exclusive partner. On the hand, don't create demand cannot scale up and has a higher margin." RBP company executive

It is also a model that is passive as there are no further business development activities to grow the market or promote the product/portfolio, cannot scale up with that exclusive commercialisation partner and has a commission in the region of 30% which is seen as high.

Key advantages of the international pharmacy model	Key disadvantages of the international pharmacy model
one partner - simple to implement	scale-up commercialisation model not possible
urgent access to innovative treatments	passive model focused on supply
several countries included and aligned	high commission

Table 3 - Advantages and disadvantages of the international pharmacy model for RBP companies' entry into SME countries

It is a sub-optimal model and suitable only for an early stage of the operations when there are no plans to apply for marketing authorisations or for before marketing authorisations and in-country-reimbursement are approved.

Distributor – wholesaler model

The distributor–wholesaler model provides a fast route to patients by leveraging the wholesaler country customer network and local presence, knowledge of the local market stakeholders and local procurement requirements. It has a relatively low margin (maximum of 10%) that in most countries is defined by law, it is non-exclusive and allows a rapid scale-up or exit when business conditions change.

"The distributor–wholesaler model provides knowledge of the local market, manages local requirements and has connections to country customers. The partner is reactive and not focused on the product. Some companies go for this low-cost model because they only pay the partner eight or ten per cent." Pharma commercialisation partner executive

It is also a reactive model with no further activities to grow the market or promote the product/portfolio that requires demand to be created by another commercialisation partner (or the pharma company directly) supporting additional services. It is a country-by-country approach that leads to a multitude of local preferred partners multiplying discussions and complexity around a very limited demand.

Key advantages of the distributor-wholesaler model	Key disadvantages of the distributor-wholesaler model
local presence and customer network	several country partners
low margin	model focused on the supply
scale-up model possible	no economies of scale

Table 4 - Advantages and disadvantages of the distributor–wholesaler model for RBP companies' entry into SME countries

The distributor–wholesaler model has similarities with the international pharmacy model and is also a sub-optimal model. It is suitable only for an early stage of operations when there are no plans to apply for marketing authorisation or before marketing authorisation and reimbursement are approved.

Distributor – additional services model

The distributor–additional services model also allows the RBP company to take advantage of the local presence, stakeholder networks and resources of the country's commercialisation partner with him taking a significant amount of the investment burden, and financial and logistics risk. It allows the implementation of the RBP company's global product strategies in the country with aligned operational execution and customer-facing communication. It also provides focus on the innovative product with the commercialisation partner building the brands with a mindset close to the innovative pharma. If an appropriate commercialisation partner is found, then it allows a level of services close to an affiliate leading to a reduced workload, risk mitigation and revenue maximisation for the RBP company.

"The distributor–additional services model provides a rapid scale-up approach taking advantage of the distributor resources and customers, the distributor takes most of the burden of the investment and is a good option when the scale doesn't justify going direct. Finding a good commercialisation partner and agreeing on its margin are key success factors." RBP company executive

It is a model that requires proactive management of the distributor needing dedicated resources from the RBP company side to manage these partnerships by continuous alignment for success, training and influencing not mandating. This represents a hands-on approach linked to the distributor performance, prioritisation, compliance, transparency, and contracting of complex distribution agreements,

The RBP company is removed from the interactions with local stakeholders and customers, doesn't have control over local processes (including key ones like price negotiations and sales) and there is significant competition law risk.

Key advantages of the distributor-additional services model	Key disadvantages of the distributor-additional services model
local knowledge, network and understanding of stakeholders	company removed from interactions with local stakeholders and customers
additional services at a good level of service managing risk	hands-on approach linked to the distributor performance and prioritisation
autonomy to manage local business and limited liabilities	no control over key activities such as price negotiations or business conduct
dedicated unit manages a handful of partners	complex distribution agreements required

Table 5 - Advantages and disadvantages of the distributor – additional services model for RBP companies' entry into SME countries

It is a model that minimises local shocks and is good to test the water in a defined time horizon to check what could be next permitting a rapid scale-up but also if needed a lighter exit strategy than an affiliate. Embodies a higher margin for the partner than a wholesaler and lower than the licensing option and the

RBP company needs to be willing to pay for these additional services. The current trend is to centralise and have 1-2 good commercialisation partners per continent and use the margin to incentivise key products (e.g., higher margins for launch products) and be prioritised in the partner's scope of work.

"You know when the distributor-additional services model it's good and when it is good, it's really good. When it is bad, is really bad. I don't believe there is a lot of middle ground here for the distributor-additional services model. The RBP company needs to manage its partners and have a few partners globally. So that their life is not miserable." Pharma commercialisation partner executive

The distributor–additional services model emerged as a model highly considered by RBP companies to enter an SME market due to its ability to provide a good level of service for the company and a flexible option appropriate for these markets.

There is also a variation of the distributor-additional services model in the case that the RBP company wants to have more control over the commercialisation model and partner and instead of a distributor it uses an agent as the partner. In this case, the RBP company has greater control over the commercialisation partner and its activities. Whilst using the agent knowledge it can control and direct activities such as pricing negotiations, sales and customer interactions. It also allows a lower short-term cost as agents usually negotiate lower margins in comparison to a distributor - additional services. On the other hand, the RBP company need to have in mind that as it is managing an agent then it is liable for its actions, there are tax issues and agents have more protection from termination which can mean higher compensation at the moment of termination.

Licensing model

In this model, the licensor company give the product to the licensee in several countries in a hands-off approach with the licensee becoming responsible for all activities surrounding the product maintenance and commercialisation against the payment of royalties. The RBP company prefers to direct its resources to key assets and projects with the product being licensed to another company that has the capabilities and can prioritise resources from its portfolio to benefit from economies of scale and launch the new product or extend the product lifecycle and sustain revenue generation. Need lower resources from RBP company to manage as the compliance risk is lower for the licensor.

"The licensing model is an option for a product that is not strategic to one company but can be to another that can quickly scale-up, incorporate in own portfolio and extend product lifecycle against a royalty payment to the licensor." RBP company executive

This model leads the RBP company to give away more than in any of the other entry models including but not limited to product marketing authorisation, trademarks, and commercialisation rights. It has the potential to create tension with global strategies implementation as it can even lead to having different brand names competing. The royalties usually mean that the licensee has better remuneration than in

other models and it is important to set these at the right level to manage licensed products and own portfolio prioritisation. It is also very difficult to take back without significant compensation.

Key advantages of the licensing model	Key disadvantages of the licensing model
direct own resources to key assets	give away significant part of asset
revenue generation	prioritisation uncertain in practice
hands-off approach – low risk	significant compensation to revert

Table 6 - Advantages and disadvantages of the licensing model for RBP companies' entry into SME countries

The licensing model is an entry model option for an RBP company when the product is not strategic either because it doesn't fit the current portfolio priorities or has become a mature product.

Affiliate model

The affiliate model is an entry model for an RBP company when there is a strategic interest from the company in the market that is reflected in the resources available and commitment, leading to the maximisation of revenues and higher success rates. It has a long-term view with the development of teams that can expand in terms of size and scope depending on the size of the opportunity and the need for additional services (e.g., research, clinical trials) when internalising these activities is cheaper.

A direct presence in the market means full responsibility for the business, full control of how the products are marketed with ownership of decisions, resources and activities. It is close to stakeholders, with an aligned global to local strategy implementation, full control of corporate reputation and assures quick responses to market events.

> *"An affiliate provides better company image, provides the company a seat at the table with key stakeholders and own voice, more focused in company interests and culture fit, provides access to better talent but has higher costs of exit and in most cases still retains a dimension of collaboration with a distributor in limited services." RBP company executive*

It needs scale to afford the general and administrative expenses and building such a model takes usually between eighteen to twenty-four months to be implemented. Different RBP companies have different revenue thresholds to trigger the discussion of setting up a new affiliate and these range from $5m to $50m annual revenue. No point in an affiliate model without reaching the yearly revenue threshold and having a portfolio of at least three products.

It also takes a long time and investment as there is a lack of local knowledge before, requires the highest research and resources in terms of time to implement, internal teamwork and finally cost of setting up an affiliate (e.g., licences, logistics, property, human resources, accounting, information technology) and creates fixed costs for the company.

In the case of SME countries, it also creates a distraction for central teams that defocus from main markets to others with much more limited scale and as complex to maintain business and limit compliance risk. Finally, market changes and country-related risks (e.g., FOREX risks, profits

repatriation) have bigger impacts as there is a commitment to operational expenses and human resources which makes the model more complex and costly to exit with the potential layoffs and overhead costs.

Key advantages of the affiliate model	Key disadvantages of the affiliate model
strategic interest from the company	long time and investment to implement
full responsibility and control of the business	distraction for central teams defocusing from main markets
more resources – quicker response to market events	impact from market changes and risks is bigger
long term - maximisation of revenues and higher success rates	exit is costly with potential layoffs and overhead costs

Table 7 - Advantages and disadvantages of the affiliate model for RBP companies' entry into SME countries

The affiliate model emerged as a model highly considered by RBP companies to enter an SME market due to its ability to maximise revenues and country reputation but there is also a clear perception that scale is needed to sustain such a model, and this isn't always possible to achieve.

A reflection of the above is a variation of the affiliate model that was mentioned as a light affiliate with an RBP company office in the country focused on marketing and sales activities with the other services being provided by a distributor. This model allows it to attract better talent and to grow its marketing and sales team focused on the company's global strategies and commercial goals leading to a better culture fit and performance (e.g. market shares) closer to company standard. The image of the company is still reinforced by the direct presence and is a stepwise approach that is less risky financially in terms of expenses and revenue metrics. It aims at maximising affiliate opportunities and minimising risks, but it also has high costs of exit and there is still a need for collaboration and alignment with a distributor.

The attitudes collected towards the different entry models during the interviews showed that the entry model decision and appropriability of an entry model depend on the perception of the assets, capabilities, and resources available to decide to enter and the market situation making it hard to find one that would be undoubtedly the most suitable making it hard to generalise.

Theme #4 – 5-year profitability outlook and corporate strategy/level of control needed appeared as the key variables for RBP companies' entry mode decision

I then probed what would be the key variables informing RBP companies' executives on deciding on an entry mode into an SME market and explored the variables' ranking and their weight.

"I think it starts on the financial dimension. It's probably a total profit, margin and growth discussion. Then you have a time dimension linked with the strategic rationale. What's the strategic rationale? Then you have a risk dimension, which is compliance. It's a very important one, then you have an impact dimension. Which are patients." Top consulting company executive

A key variable frequently mentioned was the financial variable which was always ranked highly in terms of importance. It was framed in different ways and sometimes even split into two variables to address separately the revenue and the expense aspects.

portfolio characteristics & outlook	financial review – net profit
financial outlook	financial: total profit; margin; growth
epidemiology - financial outlook	revenue outlook 3 years
potential revenues/profitability	portfolio profitability & available OPEX
revenue size (portfolio and launch estimates)	5-year forecast – revenues
internal budget	growth margin and revenues / 3-5 years

Table 8 - How the financial variable was mentioned and ranked in the interviews

This variable is broader than just the analysis of profits and considers the assessment of both the external and internal macro and micro dynamics and assumptions sustaining the case, the assessment of the company's product or portfolio to be available in the market and its evolution and then these are translated into the revenue, operational expenses, growth and profit outlook.

"Well, first it's scale, and that means they need a financial forecast that they need to fight for. And they're all looking at a five-year forecast. Then the other one is just coming back. I mean the key variable is how obsessed they are with compliance and risk mitigation" Pharma commercialisation partner executive

The other key variable that was mentioned by most of the interviewees is related to the company's corporate strategy. Again, this variable considers broad dimensions and includes the vision and strategic rationale for the entry, whether it is a short-term or a long-term perspective, the company operating model preferences, the level of control that the company needs, the structure needed to support each model on the ground and at an above country level to secure governance, and finally the risk (macroeconomic view, government stability, legal system, intellectual property protection, compliance risks and corruption index) and the ability to manage risk and mitigate it.

corporate strategy – model preference	structure needed
ability to support/manage risk	strategic rationale: portfolio, building the future
risk: compliance	company resources & structure needed
business risk; compliance risk & corruption	overall strategy (cash flow vs short term)
Compliance/risk mitigation	vision/aspiration and market potential including "Hub connections"
legal, tax and business regulations: cost/speed of setting up; "red tape"; licensing	amount of control

Table 9 - How the corporate variable was mentioned and ranked in the interviews

A final perspective on this theme relates to the threshold to have a direct presence. Different RBP companies have different revenue thresholds to decide on a direct presence in a specific market. Some companies define a threshold as low as $5M in yearly revenues while other companies define a threshold as high as $50M in yearly revenues. The threshold definition is also an indication of the company's willingness to go direct and balances the profitability of the operation and the complexity of the company footprint management. No thresholds were mentioned for other commercialisation models.

This theme can also be strengthened by the collection from additional subject matter experts of the current operational models of the top 20 RBP companies in a selection of SME countries that shows its diversity (Appendix 4 – Current operational models in a sample of countries).

Theme #5 – RBP companies are currently in an outsourcing wave in SME countries

There is an increased focus from RBP companies in key markets that provide most of the revenue with SME markets being serviced by wholesalers, distributors, or agents. This approach goes beyond entry decisions with RBP companies also applying this reasoning to operational model evolution decisions.

> *"The moving to indirect trend is going to continue because RBP companies benchmark each other, and before you know it, it starts. If a benchmark company is generating more profit for a headcount, the investors of the others will start to push this productivity and these will be forced to follow." Pharma commercialisation partner executive*

Several companies (e.g. GSK, ViiV, Sanofi and Bristol-Myers Squibb) appear to be in an exit wave moving from an affiliate to a distributor model with the choice to be mainly between a distributor – wholesaler, a distributor – additional services or an agent. The choice is the first option when there is a short-term need from the RBP company to improve the bottom line and pay a lower margin and the other two when there is a long-term perspective. This direction of travel hasn't been impacted by COVID-19, just the speed of execution.

A potential change in the commercialisation model needs strong arguments with the key reasons to change being mentioned being performance, compliance, change of company strategy, the management or both, mergers & acquisitions, and significant portfolio changes. There are a series of recent examples of changes in the operational model by RBP companies in an SME market such as Bulgaria, Hungary, the Baltic countries, and the Adriatic countries.

> *"The commercialisation partner should have the body tension to maximise the opportunity. I mean they are doing trade of choices all the time as well. How much effort to put into a product versus others? if you are the partner where you can together grow the pie, I mean. Then, while it's also in the interest. It takes two to dance." Top consulting company executive*

In these cases, the performance of the commercialisation model in place was always seen as sub-standard and this was the trigger for the change discussion. Additionally, the effective driver of the change decision can be either a financial metric such as a revenue miss, a way of working metric such as how difficult the management of the relationship or a strategic metric with the two partners diverging in terms of future priorities.

Finally, there is a clear concern and ultimately focus on efficiency in how to access the SME markets. In the old days, pharmaceutical companies had a direct commercial presence in all the markets where they had sales but more recently there were significant organisational changes with a reduction in

regional headquarters and now reduced layers to manage such a complex set-up. Companies want patient access and revenue growth to be made in models that leave the additional complexity outside of the company as much as possible, optimise the business opportunity and mitigate risk as the pharmaceutical industry is highly regulated.

There is a need to limit internal complexity as RBP companies have fewer resources coming from the United States to invest in other markets, organisational changes led to reduced layers of management (no regional headquarters) that can't deal with complexity and distributor management is not a core competency. The trend is to centralise and use fully-fledged pan-geographic distributors with deep expertise to optimise potential and limit to 2 partners per continent to balance efficiency and competitiveness. This strategic direction also makes companies less likely to have the critical mass needed to finance the extra general and administrative expenses in an affiliate model.

> *"The main reason why they are doing this is they can't deal with the complexity, and they're trying to simplify their businesses globally and they've almost all gotten rid of continental headquarters can't deal with the complexity because of the layers of management that have been taken out." Pharma commercialisation partner executive*

Finally, the quality of the set-up and economies of scale are key for success. More companies are asking the question of whether a commercial presence is essential. In the past, it was essentially about the numbers and finance metrics but now companies want peace of mind with the right set-up. They look more to the quality of the set-up beyond the commercial services (e.g. regulatory, pharmacovigilance, compliance, business conduct) and assess how the partner adjusted to its culture and ways of working, including digital capabilities.

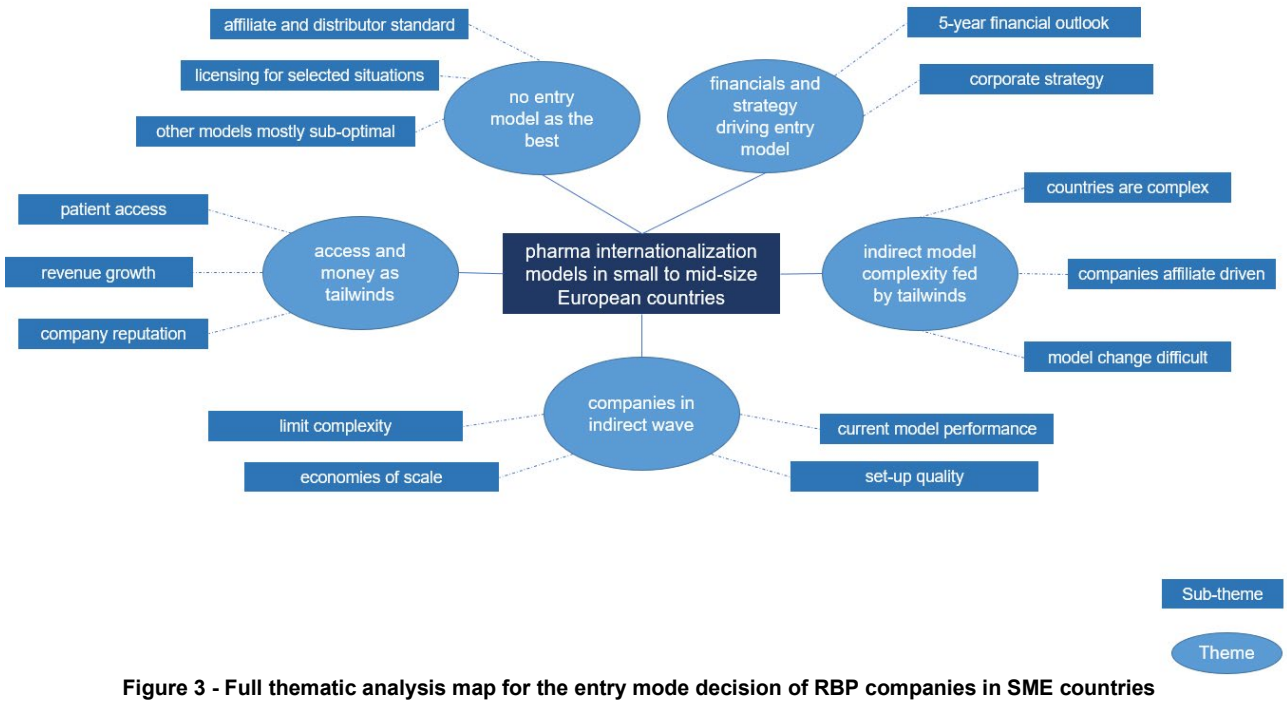


Figure 3 - Full thematic analysis map for the entry mode decision of RBP companies in SME countries

6. Discussion

The decisive deliverable proposed for this work is a matrix that helps to navigate the different entry mode standard possibilities (international pharmacy, distributor – wholesaler, distributor – additional services, licensing, and affiliate). The matrix is based on the two most important variables for the market entry mode decision from RBP companies in SME countries.

Entry model matrix proposal

The proposed matrix is expected to support managers in identifying the best-fitted scenario for a particular SME country market based on the two variables and then recommend an entry mode if the company is not yet present in the market or a transition if the company is present in a sub-optimal way. For the proposed matrix, the 5-year financial outlook and corporate strategy were selected as the two key variables that emerged from the interviews in an aligned way.

The 5-year financial outlook emerged clearly as the principal variable for this decision, with the need to have a healthy operation adjusted to the approach and resources needed to optimise the opportunity in each geography. This variable is placed as the variable that triggers the entry discussion. The other important variable is the RBP company corporate strategy. Again, this variable considers broad dimensions than the vision and strategic rationale for the entry. The possibility of having a third variable was assessed but the feedback was fragmented with references to the presence in other European markets focusing on interdependencies, to the external environment focusing on the external dynamics, to time to market focusing on patient access, and to a variable focused on the cost of entry. These were dismissed for the matrix design as too heterogeneous.

The variables can be incorporated into the matrix by interpreting the 5-year financial outlook into a small to big opportunity and the corporate strategy into non-strategic to strategic countries. This creates four quadrants in the matrix: small/non-strategic; small/strategic; big/strategic and big/ non-strategic.

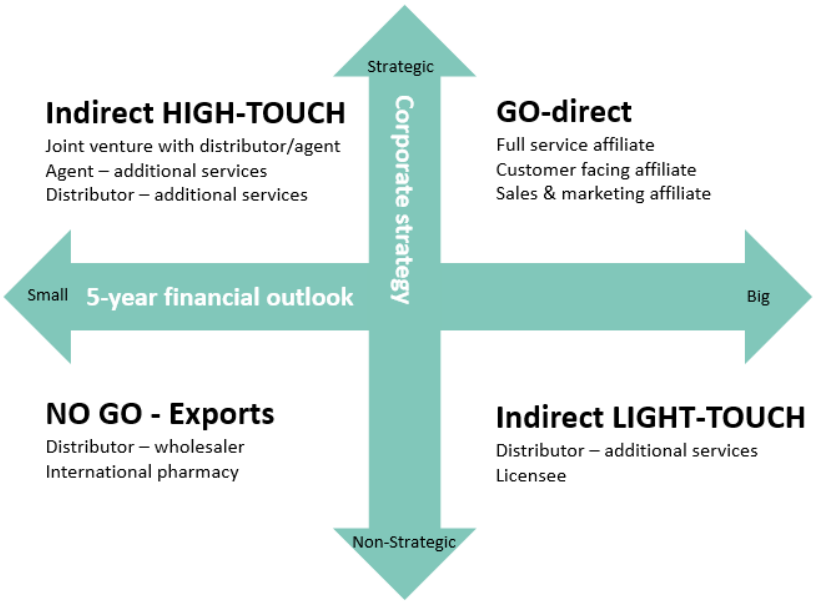


Figure 4 - Entry mode decision matrix for RBP companies in SME countries

Small/non-strategic | NO GO - Exports

The small/non-strategic quadrant is defined as a small business opportunity in a non-strategic country for an RBP company. In this quadrant, the access of a patient in the SME country to a given medicine is the main objective. The medicine isn't reimbursed in the country and/or is placed in a niche therapeutic area justifying the low volume expectation. The approach from the RBP company is standardised with a set price to the commercialisation partner, minimum quantities, upfront payment, no returns, and a delivery timeline aiming at a simple procurement process. The preferred models in this quadrant can be to have as a commercialisation partner either a distributor that provides a wholesaler service in the country or an international pharmacy that receives inquiries from hospitals or retail pharmacies and contacts the company. This would be the no go-exports quadrant.

Small/strategic | Indirect – HIGH TOUCH

The small/strategic quadrant is defined as a small business opportunity in a strategic country for an RBP company. In this quadrant, the company have a strategic interest in the SME country even if the dimension of the opportunity is limited at this stage. The medicine is in the early days of market access in the country, has achieved reimbursement for the first of a series of therapeutic indications or is the first of a portfolio to be available. There is a need for additional services (e.g. regulatory, pharmacovigilance, market access, sales, marketing,) to execute the opportunity and these additional services need to be aligned with the pharmaceutical company. A good example is the sales and marketing strategy and campaigns that are deployed in close alignment with the pharmaceutical company to take advantage of the synergies and the globalised world we operate today.

The preferred model in this quadrant is to have as a commercialisation partner a distributor that provides all the necessary services in the country. The option can be a full-service distributor or agent depending on how much control the RBP company wants to have in the operations. If the commitment becomes higher then the RBP company can establish a joint venture with the commercialisation partner by buying a stake. In this model, the RBP company benefits from the local expertise, connections, customers and stakeholder network of the commercialisation partner and benefits from the flexibility of the model and limited exit complexity and costs. The exit complexity and costs increase when there is a partnership with more oversight and control. This would be the indirect high-touch quadrant.

Big/non-strategic | Indirect – LIGHT TOUCH

The big/non-strategic quadrant is defined as a big business opportunity in a non-strategic country for an RBP company. In this quadrant, the opportunity in the SME country doesn't have a strategic fit to the company's corporate strategy but its dimension is big. It can be a situation where the medicine/portfolio coming from the company pipeline is not aligned to the therapeutic areas where the company wants to operate in the future (early-stage non-strategic assets) or a situation where the product or portfolio is now established, reaching the end of its life cycle (late stage non-strategic assets) and the company has deprioritised the resource and attention level to focus on other assets There is still a need for

additional services (e.g. regulatory, pharmacovigilance, sales, marketing,) to sustain the opportunity and these additional services need can be performed with a more hands-off approach from the pharmaceutical company in order not to deviate the attention from their strategic priorities. The preferred model in this quadrant is to have as a commercialisation partner a distributor that provides all the necessary services in the country or to a licensee depending on how hands-off the RBP company wants to be. This would be the indirect light-touch quadrant.

Big/strategic | GO – direct

The big/strategic quadrant is defined as a big business opportunity in a strategic country for an RBP company. In this quadrant, the company have a strategic interest and the opportunity is big in the SME country. The medicine/portfolio has achieved reimbursement and the revenues have grown to a level that justifies a direct presence in the country. There is a need for additional services (e.g. regulatory, pharmacovigilance, market access, sales, marketing,) but it is now cheaper for the pharmaceutical company to internalise the additional services and directly grow the opportunity further. The preferred model in this quadrant is to have a direct presence in the country with the approach usually to start by internalising marketing and sales services and with time internalising the other services with some companies to even internalise the wholesaling service.

The trigger to start the internalisation of the services and the go direct approach is usually related to the revenue level and depends on the company, with references in the interviews from $5M to $50M annual revenues what is a good proxy to how prone a company is to go direct or how conservative. This quadrant allows the pharmaceutical company to have the highest control on the execution of the global strategy and campaigns in the country, on local activities, resources allocation, local knowledge and decision-making agility to maximise the opportunity but also includes the highest commitment to resources and operational expenses and needs a significant amount of attention and governance from the above country teams of the pharmaceutical company. This model has been identified in the interviews as a preferred entry mode from an RBP company executives perspective with references for small to mid-size countries to lighter affiliate approaches like the by-sell and satellite affiliates. This would be the go-direct quadrant. The matrix proposal provides a framework that is straightforward and can be followed by executives when in front of the decision of which entry model is the most appropriate for an RBP company in an SME country.

Limitations and future research directions

The research involved in-depth interviews with highly experienced RBP companies, pharmaceutical distributors and top consulting company executives with the selection being made by the author based on his professional network, and experience with the research questions that might come with selection bias. Future studies can involve more participants, participants less involved with the indirect models and participants not within RBP companies' area of influence to bring more diverse viewpoints into the analysis.

The study participants spoke almost exclusively about their knowledge of RBP companies' choice of operational entry model and experience on how they work in practice leading to a set of primary qualitative data. For future work, it can be thought-provoking to have a second series of interviews to go in bigger depth into some of the topics discussed that were left open-ended or to get a hand with secondary data that support the primary data collected.

In thematic analysis, different types of themes are generated from qualitative datasets and the method is flexible which can lead to inconsistency and a lack of coherence when developing the themes from the research data (Holloway & Todres, 2003). This work being qualitative, reached a hypothesis and decision matrix proposal that in the next steps needs to be tested in further research with quantitative data and case studies to see if the proposed matrix stands for the quantitative and real-world test.

The matrix should also be tested in the context of the discussion of the evolution of the operational model of an RBP company in an SME country to confirm whether it can still be applied to inform this new managerial decision point and what would be the additional variables in this decision. Alternative entry models should be assessed periodically and systematically with comprehensive due diligence always including transition and exit alternatives and incorporating this validation in the matrix will make it more relevant to the problem being addressed.

Another area of future research can be how to provide an additional framework beyond the operational model and focused on the commercialisation partner itself to help the RBP company to identify and select the most appropriate commercialisation partner in an SME country for a given operational model.

Finally, the research done in this work started from the assumption that future launches and market entries in SME markets by RBP companies will remain largely based on traditional sales and marketing approaches while there are major shifts in the healthcare environment with the start of the next-generation customer engagement models (Lago, López, Meier, Saacks, & Schriver, 2021) and of data-driven entry models built on the Internet of Things ecosystem (Priporas & Vellore-Nagarajan, 2022).

References

Almeida, C. F. (2018). *Internationalisation Models and Entry Strategy Adaptation. The case study of H3.* Lisbon: Department of Engineering and Management, Instituto Superior Técnico.

Alvarez, S. A., & Busenitz, L. W. (2001). The entrepreneurship of resource-based theory. *Journal of Management*(27), 755-775.

Anderson, E., & Gatignon, H. (1986). Modes of Foreign Entry: A Transaction Cost Analysis and Propositions. *Journal of International Business Studies, 17*, 1-26.

Arregle, J. L., Hébert , L., & Beamish, P. W. (2006). Mode of international entry: The advantages of multilevel methods. *Management International Review*(46), 597-618.

Autio, E., Sapienza, H. J., & Almeida, J. G. (2000). Effects of age at entry, knowledge intensity, and imitability on international growth. *Academy of Management Journal*(43), 909-924.

Barbosa, D., Ayala, A., & Sandoval, A. (2016). The Colombian pharmaceutical industry: Factors affecting export. *Eur. J. Manag. Bus. Econ.* (25), 39-46.

Bell, E., Harley, B., & Bryman, A. (2022). *Business Research Methods* (Sixth Edition ed.). Oxford: Oxford University Press. Retrieved December 1, 2022

Bell, J. (1995). The internationalisation of small computer software firms. *European Journal of Marketing*(29), 60-75.

Boston Consulting Group. (2020). *Commercialization through 3rd party market - Increasing outsourcing creates the potential for growth.* Boston Consulting Group.

Braun, V., & Clarke V. (2013). *Successful qualitative research: A practical guide for beginners.* SAGE Publications. Retrieved from https://uk.sagepub.com/en-gb/eur/successful-qualitative-research/book233059

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3 (2)*, 77-101. doi:https://doi.org/10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2012). *Handbook of Research Methods in Psychology, Research Designs* (Vol. 2). Washington: American Psychological Association.

Braun, V., & Clarke, V. (2020). Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. *Counselling and Psychotherapy Research, 21 (1)*, 37-47. doi:https://doi.org/10.1002/capr.12360

Braun, V., Clarke, V., Terry, G., & Hayfield, N. (2018). *Handbook of Research Methods in Health and Social Sciences.* Singapore: Springer.

Brouthers, K. D. (2002). Institutional, cultural and transaction cost influences entry mode choice and performance. *Journal of International Business Studies, 33*, 203-221.

Brouthers, K. D. (2013). A retrospective on Institutional, cultural and transaction cost influences on entry mode choice and performance. *Journal of International Business Studies*(44), 14-22.

Brouthers, K. D., Brouthers, L. E., & Werner, S. (1996). Dunning's eclectic theory and the smaller firm: The impact of ownership and locational advantages on the choice of entry modes in the computer software industry. *International Business Review*, 377-394. Retrieved November 25, 2022

Brouthers, K. D., Brouthers, L., & Werner, S. (2008). Real options, international entry mode choice and performance. *Journal of Management Studies, 45*, 936-960.

Buckley, P., & Chapman, M. (1997). A longitudinal study of the internationalisation process in a small sample of pharmaceutical and scientific instrument companies. *J. Mark. Manag*(13), 43-55.

Calof, J., & Beamish, P. (1995). Adapting to Foreign Markets: Explaining Internationalization. *International Business Review, 4*(2), 115-131.

Canabal, A., & White, G. O. (2008). Entry mode research: Past and future. *International Business Review*(17), 267-284.

Chen, J., Sousa, C., & Xinming, H. (2016). The determinants of export performance: A review of the literature 2006–2014. *Int. Mar. Rev.*(33), 626-670.

Chetty, S., & Campbell-Hunt, C. (2001). Paths to Internationalisation Among Small to Medium-sized Firms: A Global Versus Regional Approach. *European Journal of Marketing, 37*(5/6), 796-820.

Chitour, H. (2013). Big pharma in China: The driving forces behind their success: A qualitative analysis. *Chin. Stud.* (2), 169-177.

Chittoor, R., & Sougata, R. (2007). Internationalisation paths of Indian pharmaceutical firms: A strategic group analysis. *J. Int. Man.* (13), 338-355.

Commercial agents. (2022). *Practical Law UK Practice Note Overview 8-107-3647*. United Kingdom: Thomson Reuters.

Crick, D., & Crick, J. (2014). The internationalisation strategies of rapidly internationalising high-tech UK SMEs. *European Business Review, 26*, 421-448.

Crick, D., & Spence, M. (2005). The internationalisation of 'high-performing' UK high-tech SMEs: A study of planned and unplanned strategies. *International Business Review, 14*, 167-185.

Davis, P. S., Desai, A. B., & Francis, J. D. (2000). Mode of international entry: An isomorphism perspective. *Journal of International Business Studies*(31), 239-258.

Di Maggio, P. J., & Powell, W. W. (1983). The iron cage revisited: Institutional isomorphism and collective rationality in organisational fields. *American Sociological Review*(48), 147-160.

Dunning, J. H. (1988). The eclectic paradigm of international production: A restatement and some possible extensions. *Journal of International Business Studies, 19*(1), 1-31.

Dunning, J. H. (1993). *The globalisation of business.* London: Routledge. Retrieved November 22, 2022

Dunning, J. H. (2001). The eclectic (OLI) paradigm of international production: Past, present and future. *Int. J. Econ. Bus*(8), 173-190.

EFPIA. (2022). *The Pharmaceutical Industry in Figures.* Retrieved November 19, 2022, from www.efpia.eu

Erramilli, M. K., & Rao, C. P. (1993). Service firms' international entry-mode choice: A modified transaction-cost analysis approach. *Journal of Marketing*(57), 19-38.

European Commission. (2020). *Pharmaceutical Strategy for Europe.* Retrieved November 18, 2022, from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0761

Fina, E., & Rugman, A. (1996). A test of internalisation theory and internationalisation theory: The Upjohn Company. *Manag. Int. Rev*(36), 199-213.

Freire, A. (2020). *Estratégia - Criação de Valor Sustentável em Negócios Tradicionais e Digitais.* Lisbon: Bertrand Editora. Retrieved November 23, 2022

Herrmann, P., & Datta, D. K. (2005). Relationships between top management team characteristics and international diversification: An empirical investigation. *British Journal of Management*(16), 69-78.

Hill, C. W., Hwang, P., & Kim, W. C. (1990). An Eclectic Theory of the choice of international entry mode. *Strategic Management Journal, 11*(2), 117-128.

Hodzic, B. (2020). *International market entry strategies: The case of Bosnia and Herzegovina.* Vienna: Universität Wien.

Hollensen, S. (2011). *Global Marketing: A Decision-Oriented Approach* (5th ed.). Harlow, UK: Pearson Education.

Holloway, I., & Todres, L. (2003). The status of the method: Flexibility, consistency and coherence. *Qualitative Research, 3*, 345-357. doi:10.1177/1468794103033004

IQVIA. (May 2022). *MIDAS.* Retrieved November 18, 2022

Javalgi, R., & Wright, R. (2003). An International Market Entry Model for Pharmaceutical Companies: A Conceptual Framework for Strategic Decisions. *International Journal of Medical Marketing, 3*, 274-286. doi:10.1057/palgrave.jmm.5040131

Johanson, J., & Vahlne, J. (1990). The mechanism of internationalisation. *International Marketing Review*.

Johanson, J., & Vahlne, J.-E. (1977). The internationalisation process of the firm—A model of knowledge development and increasing foreign market commitments. *Journal of International Business Studies, 8*, 23-32.

Johanson, J., & Wiedersheim-Paul, F. (1975). The internationalisation of the firm? Four Swedish cases. *Journal of Management Studies, 12*, 305-323.

Karampli, E., Souliotis, K., Polyzos, N., Kyriopoulos, J., & Chatzaki, E. (2014). Pharmaceutical innovation: Impact on expenditure and outcomes and subsequent challenges for pharmaceutical policy, with a special reference to Greece. *Hippokratia*(18), 100-106.

Kuntluru, S., Muppani, V., & Khan, A. (2012). Foreign direct investment and export performance of pharmaceutical firms in India: An empirical approach. *Int. J. Econ. Fin*(4), 216-226.

Lago, E., López, M., Meier, C., Saacks, D., & Schriver, S. (2021). *How the Power of People and Technology Can Build a New Biopharma Business Model.* Boston Consulting Group. Retrieved December 5, 2022, from https://www.bcg.com/publications/2021/how-biopharma-companies-can-transform-their-commercial-operating-model

Laurell, H. (2015). The role of industry context for new venture internationalisation. *Jönköping International Business School.* Jönköping.

List of European countries by population. (2022, November 10). Retrieved November 15, 2022, from Wikipedia: https://en.wikipedia.org/wiki/List_of_European_countries_by_population

Lyckenblad, G., & Nygren, L. (2019). *The role of networks in a Swedish medium-sized pharmaceutical firm's internationalization process.* Gothenburg: Bachelor Thesis. The University of Gothenburg, School of Business, Economics and Law.

Maguire, M., & Delahunt, B. (2017). Doing a Thematic Analysis: A Practical, Step-by-Step Guide for Learning and Teaching Scholars.*. *AISHE - All Ireland Journal of Teaching and Learning in Higher Education, 9*(3), 3351-3364. Retrieved from http://ojs.aishe.org/index.php/aishe-j/article/view/335

Market.Us. (2022). *Pharma Industry Statistics and Facts.* New York City. Retrieved November 18, 2022, from https://market.us/statistics/pharmaceutical-industry.

MBN - Market Business News. (2022, November 19). Retrieved from Market Business News: https://marketbusinessnews.com/financial-glossary/pharmaceutical-industry-definition/

McDougall, P., Shane, S., & Oviatt, B. M. (1994). Explaining the formation of international new ventures: The limits of theories from international business research. *Journal of Business Venturing*(9), 469-487.

Meyer, K. E., & Nguyen, H. V. (2005). Foreign investment strategies and sub-national institutions in emerging markets: Evidence from Vietnam. *Journal of Management Studies*(42), 63-93.

Moorman, C., & Miner, A. S. (1998). Organizational improvisation and organisational memory. *Academy of Management Review*(23), 698-723.

Morschett, D., Schramm-Klein, H., & Swoboda, B. (2010). Decades of research on market entry modes: What do we really know about external antecedents of entry mode choice? *Journal of International Management*(16), 60-77.

Mowla, M., Hoque, N., Mamun, A., & Uddin, M. (2014). Entry mode selection, location choice and the sequence of internationalisation: A case study on Ranbaxy Laboratories Ltd. *Asian Soc. Sc.* (10), 145-154.

Nourry, A., & Harrison, D. (2022). Distribution agreements: an overview. *Practical Law UK Practice Note Overview*. United Kingdom: Thomson Reuters.

Nowell, L., Norris, J., & Moules, N. (2017). Thematic Analysis: Striving to Meet the Trustworthiness Criteria. *International Journal of Qualitative Methods, 16 (1)*. Retrieved from https://doi.org/10.1177/1609406917733847

Osland, G. E., Taylor, C. R., & Zou, S. (2001). Selecting international modes of entry and expansion. *Marketing Intelligence & Planning*(19), 153-161.

Oviatt, B. M., & McDougall, P. P. (1995). Global start-ups: Entrepreneurs on a worldwide stage. *The Academy of Management Executive, 9*, 30-43.

Pereira, A., & Gomes, J. (2017). A study of the internationalisation strategies of the Brazilian pharmaceutical industries. *Account. Org. Mag.* (11), 68-79.

Pogrebnyakov, N., & Maitland, C. F. (2011). Institutional distance and the internationalisation process: The case of mobile operators. *Journal of International Management*(17), 68-82.

Priporas, C., & Vellore-Nagarajan, D. (2022). New-normal Market Entry Mode for Pharmaceuticals: an Internet of Things (IoT) market entry framework stemming from COVID-19. *International Marketing Review*. doi:10.1108/IMR-12-2021-0363

Reuber, A. R., & Fischer, E. (1997). The influence of the management team's international experience on the internationalisation behaviours of SMEs. *Journal of International Business Studies*(28), 807-825.

Ribau, C., Moreira, A., & Raposo, M. (2015). Internationalisation of the firm theories: A schematic synthesis. *Int. J. Bus. Glob*(15), 528-554.

Roberts, P. W., & Greenwood, R. (1997). Integrating transaction cost and institutional theories: Toward a constrained-efficiency framework for understanding organisational design adoption. *Academy of Management Review, 22*, 346-373.

Root, F. R. (1994). *Entry strategies for international markets.* New York: Lexington Books. Retrieved November 25, 2022

Roque, A. F., Alves, M.-C., & Raposo, M. (2019). Internationalisation Strategies Revisited: Main Models and Approaches. *IBIMA Business Review, 2019*. doi:10.5171/2019.681383

Roth, K. (1995). Managing international interdependence: CEO characteristics in the resource-based framework. *Academy of Management Journal*, 200-231.

Ruzzier, M., Hisrich, R. D., & Antoncic, B. (2006). SME internationalisation research: past, present, and future. *Journal of Small Business and Enterprise Development, 13*(4), 476-497.

Ruzzier, M., Hisrich, R. D., & Antoncic, B. (2006). SME internationalization research: past, present, and future. *Journal of Small Business and Enterprise Development, 13*(4), 476-497.

Schellenberg, M., Harker, M. J., & Aliakbar, J. (2018). International market entry mode – a systematic literature review. *Journal of Strategic Marketing, 26*(7), 601-627.

SchengenVisaInfo.com. (2022, November 26). Retrieved from Schengen Visa - Countries in Europe: https://www.schengenvisainfo.com/countries-in-europe/

Seggie, S. H. (2012). Transaction cost economics in international marketing: A review and suggestions for the future. *Journal of International Marketing*(20), 49-71.

Sharma, V. M., & Erramilli, M. K. (2004). Resource-based explanation of entry mode choice. *Journal of Marketing Theory and Practice, 12*(1), 1-18.

Teramae, F., Makino, T., Lim, Y., Sengoku, S., & Kodama, K. (2020). International Strategy for Sustainable Growth in Multinational Pharmaceutical Companies. *Sustainability*(12), 867.

Ulrich, A., Boyd, B., & Hollensen, S. (2012). Financial Performance of Entry Mode Decisions: Effects of Control in an Internationalisation Context. *Int. J. Bus. Man*(24), 12-28.

Vieira, J., Frade, R., Ascenso, R., Martinho, F., & Martinho, D. (2021). Determinants of Internationalisation as Levers for Sustainability: A Study of the Portuguese Pharmaceutical Sector. *Sustainability, 13*(9792). Retrieved from https://doi.org/10.3390/su13179792

Wheelen, T., Hunger, J., Hoffman, A. N., & Bamford, C. E. (2018). *Concepts in Strategic Management and Business Policy. Globalisation, Innovation, and Sustainability.* Pearson. Retrieved November 25, 2022

Whitelock, J. (2002). Theories of internationalisation and their impact on market entry. *International Marketing Review, 19*, 342-347. Retrieved November 25, 2002

Williamson, O. E. (1975). Strategy critical perspectives on business and management. In D. Faulkner, *Markets and hierarchies* (pp. 26-30). New York: Routledge. Retrieved November 23, 2022

Wrona, T., & Trapczynski, P. (2012). Re-explaining international entry modes – Interaction and moderating effects on entry modes of pharmaceutical companies into transition economies. *European Management Journal*, 295-315. Retrieved from https://doi.org/10.1016/j.emj.2012.02.004

Zhai, Z., & Ghosal, V. (2022). Internationalisation of innovation and firm performance in the pharmaceutical industry. *International Review of Economics and Finance*(80), 882-905. Retrieved from https://doi.org/10.1016/j.iref.2022.02.058

Zhao, H., Luo, Y., & Suh, T. (2004). Transaction cost determinants and ownership-based entry mode choice: A meta-analytical review. *Journal of International Business Studies*(35), 524-544.

Appendix 1 – Figures and Tables

Figures

Tables

Appendix 2 – Interview List

Interviewee #no.	International experience (years range)	Base country	Current role	Interview method and duration	Date
Interviewee #1	>15	Slovenia	RBP company commercialisation partner executive	Zoom - 45 minutes	12 Sept 2022
Interviewee #2	>20	Slovenia	RBP company commercialisation partner executive	Zoom - 45 minutes	12 Sept 2022
Interviewee #3	>20	Malta	RBP company commercialisation partner executive	Zoom - 45 minutes	13 Sept 2022
Interviewee #4	>15	Netherlands	RBP company executive	Zoom - 45 minutes	16 Sept 2022
Interviewee #5	>20	United Kingdom	RBP company commercialisation partner executive	Zoom - 45 minutes	16 Sept 2022
Interviewee #6	>20	United Kingdom	RBP company executive	Zoom - 45 minutes	16 Sept 2022
Interviewee #7	>10	United Kingdom	RBP company executive	Zoom - 45 minutes	22 Sept 2022
Interviewee #8	>20	Malta	RBP company commercialisation partner executive	Zoom - 45 minutes	22 Sept 2022
Interviewee #9	>20	Hungary	RBP company commercialisation partner executive	Zoom - 45 minutes	29 Sept 2022
Interviewee #10	>20	USA	RBP company executive	Zoom - 45 minutes	30 Sept 2022
Interviewee #11	>20	Dubai	RBP company executive	Zoom - 45 minutes	6 Oct 2022
Interviewee #12	>15	Germany	Top consulting company executive	Zoom - 45 minutes	6 Oct 2022

Appendix 3 – Interview guide

INTERNATIONALISATION MODELS: HOW SHOULD PHARMACEUTICAL COMPANIES SELECT THE MOST SUITABLE OPERATIONAL MODEL FOR ENTRY AND BEYOND IN SME MARKETS?

Qualitative Research Discussion Guide

For Research Purposes Only
Date of Preparation: September 2022

Introduction [5 minutes]

I am a student of The Lisbon MBA a joint venture of Católica/Nova SBE in collaboration with MIT Sloan and currently working on my thesis with the topic "Internationalisation models: how should pharmaceutical companies select the most suitable operational model for entry and beyond in SME markets?".

I would like to be able to interview you for the qualitative research part of this work. This interview will last approximately 45 min and I want to get your opinion on the subject. I will ask some questions to which there is no right or wrong answer, I just want to hear your opinion openly and sincerely.

To analyse the results, I would like to obtain your permission to record this interview. The answers will be anonymous and will not be contacted again about this work.

I would like to reassure you that:

- Your responses will be used by me for research purposes only
- Your responses will be collated with other respondents and presented in aggregated or anonymised form
- Your name will be kept confidential
- During the interview, please do not share information that you are not allowed to share
- You have the right to withdraw from the research at any time

Are you happy to participate in the interview on this basis?

a. Yes **[CONTINUE]**
b. No **[TERMINATE]**

1. Entry modes available for RBP companies in SME markets

[All Interviewees]

Motivation

1.1. What are the most common motives for an RBP company to enter an SME market?

- _____
- _____
- _____
- _____
- _____
- _____

Probe: patient access, reputation, corporate image, future outlook, stakeholder management, revenues

Entry modes available

1.2. Which are the most common entry modes available for pharmaceutical companies in SME markets?

- _____
- _____
- _____
- _____
- _____
- _____

Probe: international pharmacy, licensing to local partner, distributor – wholesaler, distributor – additional services, affiliate

1.3. Could you rank the listed entry modes for pharmaceutical companies by your view of their success?

International Pharmacy	Licensing	Distributor – wholesaler	Distributor – additional services	Affiliate	Other 1

1.4. Could you list the unique opportunities and risks of each entry mode?

International Pharmacy	Opportunities: Risks:

Licensing	Opportunities: Risks:

Distributor – wholesaler	Opportunities: Risks:

Distributor – additional services	Opportunities: Risks:

Affiliate	Opportunities: Risks:

Other 1	Opportunities: Risks:

1.5. What is your preference for the entry model of a pharmaceutical company in SME markets based on your experience?

- _____

Why this entry model is your preference to work:

- _____
- _____
- _____
- _____
- _____

Probe: adequate scale, success, empowering, stakeholder management

2. How the entry modes should be selected

[All Interviewees]

Key variables

2.1 What are the key variables that inform an entry mode decision for an RBP company to plan to enter an SME market?

- _____
- _____
- _____
- _____
- _____
- _____

Probe: patient access, reputation, corporate image, future outlook, additional services, stakeholder activism, revenue outlook, market entry feasibility, healthcare maturity, external environment, business stability

2.2 Could you rank the key variables that inform an entry mode for pharmaceutical companies by your view of their weight?

Key variable 1	Key variable 2	Key variable 3	Key variable 4	Key variable 5	Key variable 6
1	2	3	4	…	…

2.3 Could you define a percentage weighting the key variables that inform an entry mode for pharmaceutical companies by your view of its importance for the decision?

Key variable 1	Key variable 2	Key variable 3	Key variable 4	Key variable 5	Key variable 6
X%	X%	X%	X%	X%	X%

If not possible for all, focus on the percentages for the two main key variables informing the decision from the interviewee's perspective.

2.4 What are the biggest barriers to selecting an entry mode?

- _____
- _____

2.5 How, if at all, has COVID impacted how entry decisions are made?

- _____
- _____

3. How the entry modes should evolve
[All Interviewees]

Key variables

3.1 What are the key variables that inform an entry mode evolution for an RBP company to plan to enter an SME market?

- _____
- _____
- _____
- _____
- _____

Probe: patient access, reputation, corporate image, additional services, stakeholder activism, revenue outlook, market entry feasibility, healthcare maturity, external environment, business stability, previous entry model success, partner performance, partner reputation

3.2 Could you rank the key variables that inform an entry mode evolution for pharmaceutical companies by your view of its weight?

Key variable 1	Key variable 2	Key variable 3	Key variable 4	Key variable 5	Key variable 6
1	2	3	4	…	…

3.3 Could you define a percentage weighting the key variables that inform an entry mode for pharmaceutical companies by your view of its importance for the decision?

Key variable 1	Key variable 2	Key variable 3	Key variable 4	Key variable 5	Key variable 6
X%	X%	X%	X%	X%	X%

If not possible for all, focus on the percentages for the two main key variables informing the decision from the interviewee's perspective.

3.4 What are the biggest barriers to selecting an entry mode evolution?

- _____
- _____

3.5 How, if at all, has COVID impacted how entry decisions are made?

- _____
- _____

4. Trends, bibliography, and data support
[All Interviewees]

4.1 Have any recent trends been impacting how should pharmaceutical companies select the most suitable operational model in SME markets in the last few years?

- _____
- _____

Probe: companies changing current models, country stability, pharmaceutical companies' reputation, COVID-19, additional services

4.2 Are there any notable national policies or European Commission initiatives impacting how should pharmaceutical companies select the most suitable operational model in SME markets in the last few years?

- _____
- _____

Probe: country stability, COVID-19, additional services, European HTA, tendering and purchasing

4.3 Who (if any) are the main external stakeholders influencing how should pharmaceutical companies select the most suitable operational model in SME markets?

- _____
- _____

Probe: Government officials, clinicians, PAGs and KOLs, EU non-governmental associations

4.4 Are you familiar with any bibliography that you would recommend close to the topic of how should pharmaceutical companies select the most suitable operational model in SME markets in the last few years?

- _____
- _____

Probe: Books, journals, Consultancies papers, blogs, and other

4.5 Are you able to share any anonymised data that I could use to understand how pharmaceutical companies select the most suitable operational model in SME markets?

- _____
- _____

Probe: External company presentations, Business cases, anonymised P&Ls for different options

THANK YOU

Appendix 4 – Current operational models in a sample of SME countries

Research-based pharmaceutical company*	Operational model per country				
	Bulgaria	Bosnia and H	Croatia	Estonia	Hungary
Pfizer	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
abbvie	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Novartis	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Johnson & Johnson	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Roche	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Bristol-Myers Squibb	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Affiliate
Merck & Co	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Sanofi	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Affiliate
AstraZeneca	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
GSK	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Wholesaler
Takeda	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Gilead	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service
Eli Lilly	Affiliate	Distributor - Wholesaler	Affiliate	Affiliate	Affiliate
Amgen	Affiliate	Distributor - Full Service	Affiliate	Distributor - Wholesaler	Affiliate
Novo Nordisk	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Bayer	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Moderna	Distributor - Full Service	Distributor - Wholesaler	Distributor - Full Service	Distributor - Wholesaler	International Pharmacy
Boehringer Ingelheim	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Viatris	Affiliate	Distributor - Wholesaler	Affiliate	Affiliate	Affiliate
Regeneron	Distributor - Full Service	Distributor - Wholesaler	Distributor - Full Service	Licensing	International Pharmacy

* Top 20 research-based pharmaceutical companies by 2021 global prescription drug sales

Research-based pharmaceutical company*	Operational model per country				
	Latvia	Lithuania	Malta	Serbia	Slovenia
Pfizer	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
abbvie	Affiliate	Affiliate	Distributor - Full Service	Distributor - Full Service	Affiliate
Novartis	Affiliate	Affiliate	Affiliate	Affiliate	Affiliate
Johnson & Johnson	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Roche	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Bristol-Myers Squibb	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service
Merck & Co	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Sanofi	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service
AstraZeneca	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
GSK	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service
Takeda	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Gilead	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service	Distributor - Full Service
Eli Lilly	Affiliate	Affiliate	Distributor - Full Service	Distributor - Wholesaler	Affiliate
Amgen	Distributor - Wholesaler	Affiliate	Distributor - Full Service	Distributor - Full Service	Affiliate
Novo Nordisk	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Bayer	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Moderna	Distributor - Wholesaler	Distributor - Wholesaler	Distributor - Wholesaler	Distributor - Wholesaler	Distributor - Full Service
Boehringer Ingelheim	Affiliate	Affiliate	Distributor - Full Service	Affiliate	Affiliate
Viatris	Affiliate	Affiliate	Distributor - Wholesaler	Distributor - Wholesaler	Affiliate
Regeneron	Licensing	Licensing	Distributor - Wholesaler	Distributor - Wholesaler	Distributor - Full Service

* Top 20 research-based pharmaceutical companies by 2021 global prescription drug sales

Available operational models				
International Pharmacy	Distributor - Wholesaler	Distributor - Full Service	Licensing	Affiliate

Appendix 5 – Declaration of originality

DECLARATION OF ORIGINALITY AND INTEGRITY OF THE WRITTEN THESIS DOCUMENT

I Ricardo Jorge Clemente Vitorino hereby declare, to the best of my knowledge and ability, that the written thesis document I am submitting to The Lisbon MBA program, constitutes original work and properly acknowledges the intellectual contributions of others. I hereby certify that:

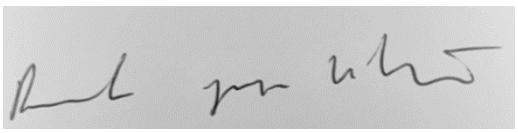
(1) The written text in the body of this work is my own, except explicit quotes from others and the proposed corrections by my Thesis Advisor.

(2) The information derived from the published and unpublished work of others, introduced in any part of this thesis, is identified with a citation in the text, and its source is fully identified in the references section.

(3) The persons who, by way of communicating with me in person or through any other means, have substantially contributed to the intellectual development of this work are explicitly acknowledged in the text.

(4) This is an original work, which has not been presented before. In case this work was performed as part of other research projects, this will be stated in the thesis.

I understand that the work I submit will be checked for originality upon submission.



_____

(signature of the candidate)

Lisbon, 12th December 2022

(place and date)

Internationalisation models: how should research-based pharmaceutical companies select the most suitable operational model to enter small to mid-size European markets?

(title of the thesis work being submitted)