

## PHARMACEUTICAL ENTERPRISES' MARKET ENTRY STRATEGIES

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**Abstract.** The pharmaceutical sector encompasses a wide range of business activities – research and product development, manufacturing, marketing, international business, wholesale, retail and services. Consequently, it is facing the contemporary challenges of globalisation, sustainable development, social, economic and political change. At the same time, pharmaceuticals have a significant impact on the provision of health care, which limits the freedom of business. In framework of this research the applicability of the International business theories to pharmaceutical sector, as well as the major factors influencing the enterprise' choice of the market entry mode are explored. The organisation of healthcare and its financing system are important external factors influencing the market entry strategy of the pharmaceutical company. Focusing on the healthcare market as a platform for medical entrepreneurship and significant regulatory interventions, it should be noted that, in a context of globalization, healthcare is characterised as both an international business and an area to strong government influence and demand generation. In the process of market entry strategy development, pharmaceutical enterprises more often choose the direct exporting, contractual modes and foreign direct investments as the market entry modes. In these circumstances, the Managed Entry Agreements become topical to ensure the availability of new medicines for patients and to encourage the pharmaceutical enterprises to come into market.

**Keywords:** *market entry strategy, pharmaceutical enterprise, Managed Entry Agreements.*

**JEL code:** F2

### Introduction

The European Commission, in the Communication on Effective, Accessible and Resilient Health Systems (European Commission, 2014), stated that European health systems have faced common and growing challenges in recent years: rising healthcare costs, aging populations, resulting in increased rates of chronic illness and mortality, there is also greater demand for health care, health professionals, equity in access to health care. Health is a prerequisite for economic prosperity, and human health affects economic outcomes in terms of productivity, labour supply, human capital and public spending. In its turn, medicines and medical treatment are one of the main medical technologies. As stated in the Communication from the European Commission (European Commission, 2008) on a Renewed Vision for the Pharmaceutical Sector, the pharmaceutical sector contributes significantly to the well-being of Europe and the world by making medicines available, contributing to economic growth and sustainable employment. Most importantly, with innovations in human medicines, patients have received treatments that would not have been possible a few decades ago.

At the same time, the pharmaceutical sector is also facing contemporary challenges. Divergent national pricing and reimbursement systems pose a complex situation in the European Union (EU), while Member States share a common challenge of striking a balance between three key objectives: optimizing the use of resources to ensure sustainable healthcare financing for an aging European society, availability of medicines for patients and incentives for pharmaceutical innovations. The High-Level Pharmaceutical Forum (2005-2008) had produced 10 sets of recommendations for further action by EU Member States, one of which aims to promote rational use of resources:

- allocation of national budgets according to patients' needs;
- developing national drug pricing and reimbursement policies that will ensure effective price control at the supply and demand stages, as well as promote price competition;
- exchange of information and experience between Member States' competent authorities on pricing and reimbursement of medicines;

- further activities towards mechanisms such as risk sharing, conditional pricing, tenders and generics use.

The recommendations remain relevant, given that the measures to be taken will be implemented slowly and without appropriate cooperation between countries. It should be borne in mind that, as laid down in the Treaty on the Functioning of the European Union, the Member States are responsible for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States include the management of health services and medical care and the allocation of resources assigned to them (Intergovernmental Conference, 2007).

The problems of healthcare and pharmaceutical market fragmentation are reflected in European Union policy planning documents and policies, are addressed at national level and scientifically researched, but the practical solutions for these problems are not complete and not always universally applicable for all countries. Availability of medicines mostly depends on the pharmaceutical value chain, which consists of manufacturing, distributing and dispensing the medicine. This research mainly focuses on the pharmaceutical manufacturing enterprises' market entry strategies, taking into account that the largest pharmaceutical enterprises are running as the Transnational Corporations, and factors which influence their decisions. The hypothesis of this research is defined as an assumption that pharmaceutical enterprises have the additional significant elements which are applied in process of development of the market strategy and choosing the market entry mode, in comparison with classical market entry strategies, and these preferences can be influenced by external factors, such as amount of the public pharmaceutical expenditures of particular country. Based on the topicality of these issues, the author defines the aim of this research – to identify the specific elements applied in process of development of the pharmaceutical enterprise's market strategy and choosing the market entry mode; and characterise the specific external factors that mainly influence these choices.

To achieve the aim of this research, the following research tasks are defined:

- 1) to study the international business theories and their applicability to the activities of pharmaceutical enterprises;
- 2) to study the factors influencing the choice of the market entry mode of enterprises and to identify the most applicable for pharmaceutical enterprises;
- 3) to conduct the empirical analysis of pharmaceutical enterprises' market entry strategies applied in Latvia.

The research methods (quantitative and qualitative) used to perform the research tasks are theoretical (literature analysis, document content analysis, electronic resource analysis) and empirical research methods. The selected research work covers multidisciplinary aspects, combining international business and health care. Consequently, the specialised literature on international business and health care was used to achieve the aim of this research. The scientific publications, materials prepared by the European Union institutions and international organisations, normative acts and development planning documents, general and special literature, as well as statistical data have been used as the resources. Descriptive analysis of both pharmaceutical enterprises and conventional business strategies assumes some problematic issues of the applied research approach (e.g. possible selection bias by working data).

Limitations of the study are set according to the aim and tasks of this research. The health care system is viewed in a generalised way, whereas the pharmaceutical sector focuses on the activities of pharmaceutical companies, as they are mainly marketing authorisation holders and more interested in transnational activities than wholesale pharmaceutical companies and pharmacy networks. At the regional level, the study focuses on the Member States of the European Union.

Pharmaceutical manufacturing is a high-tech industry, the creation, research and development of a medicine requires significant investments to ensure its efficacy and safety. The life cycle of a new medicine begins with a new chemical (biochemical) compound, usually discovered in fundamental research by originator companies or

independent research bodies (universities, specialised laboratories), often with public funding. The originator companies then test whether the product containing such a chemical compound will be safe and effective. During the development phase, potential medicinal products are first evaluated in laboratory tests (including on animals) in the so-called pre-clinical phase. The first step involves the creation of a structure for the main chemical compound of the medicine using several specific test techniques to test its safety, efficacy and effectiveness. This is followed by clinical trials (in humans) consisting of three phases. Clinical trial is a study performed to investigate the safety or efficacy of a medicine. Once studies show that the new medicine is effective and safe, the company takes intellectual property protection measures (earlier in some cases) and applies for a marketing authorisation from a regulatory agency – either the European Medicines Agency (in the case of centralised registration) or the national competent authority (the State Agency of Medicines in Latvia). In parallel, commercialisation efforts are underway and the implementation phase of the life cycle begins.

The final phase of clinical trials is the post-authorisation monitoring, which takes place after the product is authorised and marketed, and collects additional safety data for a large number of patients. The registration of a medicine is followed by an active marketing phase, which allows the medicine to enter the market as quickly as possible before new competitors appear, considering that this is the most profitable phase of the medicine's life cycle.

Before launching into market – in pre-clinical and clinical stages – the development of new medicinal products may be a source of competitive pressure on existing medicinal products as well as on other medicinal products during the development phase. After entry, new medicines compete for prescribing, either by relying on market share for other drugs or by stimulating overall market demand. At this stage, competitive pressure is mainly exerted by other similar medicines. As the end of the exclusivity period for the originator medicine (patent protection is lost), the pressure from generic versions of the same medicine begins to increase. When generic medicines enter into market, the sales of the originator company usually fall significantly and average market prices fall sharply (European Commission, 2019). A generic medicinal product is a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies (The European Parliament and the Council, 2001). The price of a generic medicinal product is lower because the expenditures do not include the cost of clinical trials and patenting.

### **Literature Review**

In the context of *International trade theories*, the research limitations focus on the *Product Life Cycle Theory* specific to the pharmaceutical sector as a representative of the modern trade theories. The theory is written by Raymond Vernon, who formulated product life cycle stages (introduction, growth, maturity, depreciation), product categories (new products, maturity products or standardized products) and marketing strategies at each stage of the life cycle (Vernon, 1966).

According to the *Product Life Cycle Theory*, new product development takes place in highly developed countries, as there are more appropriate circumstances for research and development (R&D), highly qualified professionals and innovation potential. For a limited time, the producer (including the state) maintains a monopoly on production and exports. In the future, as technology are standardised, the production can be relocated to middle-developed countries to benefit from skilled, but lower-wage labour, and to expand production. Originator companies do not seek to shift production of finished products to developing countries. Developing countries are mainly used for contract production of raw materials. In the case of medicines, the moment when the originator company loses market exclusivity and generic medicines enter the market plays an important role. In order to maintain market positions for as long as

possible, originator companies have developed a new strategy in recent years, creating units that produce generic medicines for their originator medicines at significantly lower prices and compete with other generic companies.

In terms of pricing and market differentiation, the activities of pharmaceutical companies can also be seen in the context of the *Porter's Generic Competitive Strategies Model* proposed by Michael Porter. In next chapter of this article, the author offers a variant of M.Porter's model for description of the activities of pharmaceutical companies. The *Porter's Diamond Model* remains relevant, but since the 1990s several extended models have been created. The model expansion took place mainly because the classic Diamond Model did not consider the transnational operation of companies, whereas the Double Diamond provided two dimensions of classic Diamond – global and local, with the potential for dynamic change. The nine-factor model introduced a distinction between internal factors (physical and human) and external factors (such as global economic and political changes). The Dual Double Diamond is a combination of the Double Diamond Model and the Nine Factor Model, which offers a comprehensive analysis of competitiveness for countries with heterogeneous characteristics (Cho, 2013).

In context of factors influencing the enterprise' decision on the market entry mode, the *Eclectic Theory* developed by John Harry Dunning, a British economist and one of the founders of *International business theory*, especially in the field of *Foreign Direct Investments* (FDI), is crucial. The classical *Eclectic Theory* provides the OLI model (Ownership, Location, Internalisation) to identify and assess the benefits before making an investment decision. The FDI theories are largely in line with Raymond Vernon's *Life Cycle Theory* discussed in Subsection 1, assuming that the investments are in compliance with the product's life cycle. The model of eclecticism has been revised several times by the author himself, as well as by other authors (Tallman, 2003).

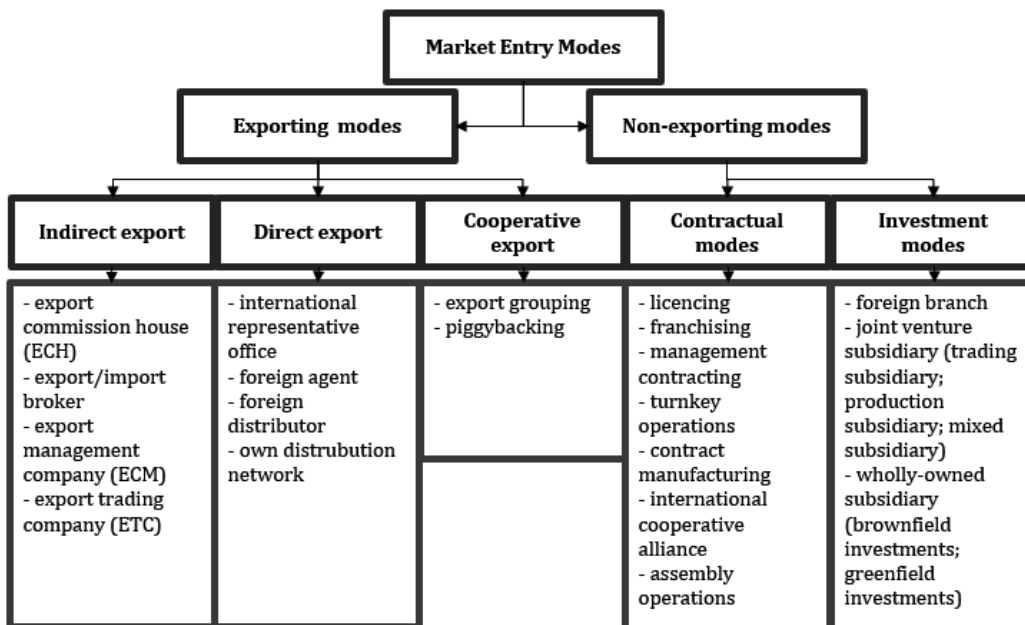
Under the concept of *Investment Development Trajectory* created by J.H. Dunning, each country undergoes five stages of investment development that characterise its ability to be an importer or exporter of direct investments (Dunning, 1998). Depending on the level of each country on the 'Investment Development Trajectory', the country's investment policy is shaped accordingly, which also significantly influences the decision of foreign entrepreneurs to enter the particular market. The potential of a country also depends on the relationship between OLI values (Dunning, 2001). Analysing the classic OLI model, the scientists had pointed out some of the weaknesses of this model, which mainly ignore internationalisation and confusing the way of entering the market. As a result, the OLIM model was offered as a solution that incorporates both the internationalisation dimension and adds a 'M' (Market entry mode) to the OLI (Batalla, 2015).

In preparation for entering a foreign market, a company must carefully develop a strategy and a detailed plan, using all available information on the macro and micro environment in a particular country, industry and market. There are several modes of market entry, which are basically divided into exporting and non-exporting modes (Fig. 1).

The export modes are the most popular, as these modes provide less financial risk compared to contractual modes and investment modes, but also offer less control and potential profit opportunities (Fig. 1). In indirect export modes, the manufacturer uses the independent exporting agents located in the country, so the producer has no direct contact with international customers or partners and the transaction is treated as domestic. The types of indirect export agents are (Hollensen, 2007; Cullen et al., 2010):

- the export commission house (ECH) that is a representative of foreign buyers and is located in the exporter's home country, offering services to the foreign buyers such as identifying potential sellers and negotiating prices;
- the export / import broker as specialist in performing the contractual function, and does not actually deal with the products for sale and purchases, but facilitates contact between a seller and a buyer;

- the export management company (EMC) that is an intermediary specialising in specific products or in particular countries or regions;
- the export trading company (ETC) that is an EMC-like intermediary, but usually takes the claim to the product before exporting.



(Cavusgil et al., 2008; Wach, 2014; Shen, 2017)

Fig. 1. Market entry modes (compiled by the author using sources)

In reason of the direct exporting modes, the exporters take on the duties of intermediaries and establish direct contacts with customers in the foreign markets. There are several ways to make a direct exporting, most often using (Hisrich, 2010; Stone McCall, 2004):

- own representative office, operating on a transfer of rights and obligations of the parent company, since its functions is reduced to marketing activities,
- a foreign agent acting on behalf of the exporter and its name,
- a foreign distributor acting on its own behalf and account,
- its own distribution network abroad, when exporting is combined with FDI, mainly in the form of a trading or commercial subsidiary.

The representative office can act as a seller of foreign trade contracts (negotiating the terms of delivery and conduct the market analysis, which is necessary for organising of the direct exporting). There are three ways in which sales agents in a given country can act:

- an own employee of a company delegated to work abroad for a given period,
- an own local employee of a company directly employed by the parent company abroad,
- a local business partner (representing only the interests of the parent company authorised).

Cooperative exporting is particularly recommended for small and medium-sized enterprises, due to their limited resources (mainly financial and human). There are two main types of cooperative exporting: the export grouping (export consortium) and piggybacking. Export consortia are most often defined as voluntary alliances companies tied to foreign joint promotion of products or services its members. Their cooperation may be formalised or based on free cooperation between enterprises, especially micro, small and medium-sized enterprises (SMEs). Their greatest advantage is the sharing of the cost of organising export among the consortium members, which allows SMEs to overcome one of the main obstacles to internationalisation, which is their limited financial resources.

Piggybacking (Hollensen, 2007; Terpstra and Chwo-Ming, 1990) is the market entry mode where two entities, known as a rider and a carrier, are the contract parties. The first one is usually a small entrepreneur, while the other one is a large company. The carrier is established in foreign markets, offering the rider to use its own distribution network. For the access of network, it charges a commission from the entrepreneur planning to start exporting. The products offered by the cooperating companies should be complementary. This type of export is beneficial to both parties, but also involves some risks. The carrier can thus complement its product range with lower network maintenance costs, as they are partially covered by the partner. However, a partner's potentially poor product quality can endanger the company's reputation and lead to problems with the timeliness of deliveries. The biggest advantage for the rider is access to the foreign distribution network, while the disadvantage is the loss of control over the distribution of its products. This type of market entry modes is recommended for micro and small businesses that are unable to make significant foreign investments.

Contractual modes for market entry are mainly based on cooperative relations implemented through contacts with foreign partners, mostly manufacturers. These modes include international licensing, international franchising, international subcontracting and other joint contracting.

International licensing is a contractual arrangement between a domestic licensor and a foreign licensee (the licensor usually has a valuable patent, technological know-how, trademark or business name that it provides to the foreign licensee) (Cullen, 2010).

International franchising is similar in nature to licensing, but it is applied to sales and distribution in the broader service industry. Since the cost of setting up such activities is much lower, this form is particularly popular among the SMEs, self-employed and micro-enterprises, particularly in the European Union (Stone, 2004).

Management contracting is a type of knowledge-based service of management (know-how). A foreign firm purchases operational management services from a domestic firm, that after the execution of the contract usually does not intend to be present in the market, although the accumulated experience may prove to result of permanent presence in foreign markets (Wach, 2014).

The turnkey operations contain an element of cooperation, and they are carried out as de facto export of services, but their main characteristic is contractility. This is a type of contracts between an importer (buyer) and an exporter (seller), whereby the seller undertakes to make the investment specified in the contract, in a given period of time in accordance with the requirements of the buyer, resulting in a turnkey investment. Often, these investments are monitored by the importer's agents (Onkvist and Shaw, 2004).

Contract manufacturing, also known as international subcontracting, is used by companies that outsource part of their production resources, mainly to reduce labour or raw material costs. According to J.H. Dunning's concept, such activities are related to the search for resources and motives for improving efficiency. SMEs are the most often involved in contract manufacturing. Subcontracting may deal with components or semi-finished elements and, in these circumstances, it takes the form of the exporting. As a finished product is outsourced to a finished product, the parent company performs control, marketing and sales as well as R&D functions. Whereas for complete products, it is done as means of production outsourcing, and the parent firm only takes control, marketing and trading, as well as research and development functions (Hollensen, 2007).

Assembly operations rely on a certain form of cooperation between companies, whereby the foreign company contracts to a local company, which performs extensive and precise operations in accordance with the contractual instructions (Onkvist and Shaw, 2004). These modes of entry can be divided into a number of specific options, such as:

- part fit-up and shimming operations during which a semi-finished product which is sent abroad to continue to undergo various stages of production or processing and then returns to its country of origin,
- drilling operations and fastener installations, in which well-known companies outsource their products in accordance with the specifications, based on supplied designs, projects, and sometimes using customer materials,
- repairs and overhaul operations, where goods are sent abroad for repair and then returning to the country of origin.

An essential feature of investment modes is the physical and permanent presence of multinational companies in foreign markets by investing in the establishment of foreign branches or foreign subsidiaries (partially or fully depended). The investment modes are based on FDI, which provide lower production costs and direct presence in a foreign market. Foreign investment can be invested in two ways – brownfield investment that is the mergers and acquisitions (M&A) of local companies; and greenfield investment that is by investing from the beginning. As for organisation term, the investment modes are usually divided into two basic types: a foreign branch, and a subsidiary company (Czinkota and Ronkainen, 2007).

The foreign branch is wholly owned by the parent company. It does not have a separate legal status as an integral part of the parent company, and thus subject to both the legislation of the country of origin and the host country. The division operates under the management of the parent company and its liabilities are fully consistent with those of the parent company. The scope of activities of the branch may not extend beyond this of the parent company. Branches are early modes of hierarchical forms of internationalisation that, due to their success, very often lead to the transformation into subsidiaries (Hollensen, 2007).

The concept of a subsidiary is not clearly defined in the literature. In practice, it more often refers to an enterprise in which the parent company holds a majority of shares or other resources that are controlled. In the case of a wholly-owned subsidiary owned by the parent company, it is referred to as a wholly-owned subsidiary, or partly as a joint venture subsidiary (minority interests, joint control, majority interests). The subsidiary has a separate legal status and it is a separate company operating under the law of its home country, but the legal subsidiary must be established in one of the forms of commercial activities recognised in the host country (Poynter and White, 1984).

Each market entry mode has certain advantages and disadvantages that companies need to consider when planning and operating in external markets. Scientists offer the different insights into the key factors a company should take into considerations, such as capital, management, control, risk management, expected investment, and potential returns. The performed empirical analysis show that the pharmaceutical enterprises more often choose the direct exporting, contractual modes and foreign direct investments as the market entry modes in the process of market entry strategy development. The internationalisation of business is largely viewed in the context of SLEPT (social, legal, economic, political, and technological), focusing on the situation in particular country.

### **Research results and discussion**

In context of International business theories the author offers a variant of M.Porter's model for the description of the specific activities of pharmaceutical companies, which is illustrated in Figure 2. The Segment 1 (Fig. 2) demonstrates a generic medicinal product's entry into the market that was considered in the context of the *Product Life Cycle Theory*. The Segment 2 is characterised by market differentiation. Pricing policies between pharmaceutical manufacturers and sometimes pharmaceutical wholesalers are characterised by price differentiation for groups of customers with different consumer rents (horizontal price differentiation) or with different elasticity of demand (vertical price differentiation), both within the national territory and offering the product in different countries and markets. However, vertical differentiation allows for a larger share of the pharmaceutical market than horizontal differentiation.

Differentiation of medicines' prices also leads to a phenomenon called as a parallel import and parallel distribution (depends on marketing authorisation form). It is known that the same product (which may differ in the excipients used and in the language of the label) is marketed by the manufacturer in different countries at different prices depending on the purchasing power of the population in particular country. In view of these trends, the wholesalers of medicines, where they are financially viable, buy medicines from wholesalers in low-income and, consequently, lower-priced countries and sell them in higher-income countries at prices below their manufacturer's prices in those countries, thus creating so-called parallel imports. Parallel imports create a disadvantage for manufacturers and some competition, while at the same time discouraging excessive pricing.

		COMPETITIVE ADVANTAGE	
		LOWER COST	DIFFERENTIATION
COMPETITIVE SCOPE	BROAD TARGET	<b>1. COST LEADERSHIP</b>  <i>Generic medicines</i>	<b>2. DIFFERENTIATION</b>  <i>Market differentiation (results - paralel import and distribution)</i>
	NARROW TARGET	<b>3A. COST FOCUS</b>  <i>Personalised medicines</i>	<b>3B. DIFFERENTIATION FOCUS</b>  <i>Biological medicines produced by SMEs (initially - in labs)</i>

Fig. 2. Performance of Pharmaceutical Companies in the Context of M.Porter's Global Competitiveness Strategies Model (adapted by the author, based on (Porter, 1985))

The Segment 3A (Fig. 2) may be related to personalised medicine and personalised pharmaceuticals. Personalised medicine is a model of the treatment process that relies on a molecular approach to choosing the appropriate therapeutic strategy for a given patient at a given time, taking into account the predisposition to the disease and providing timely and targeted prevention. Personalised medicine is a new approach that uses data generated by new technologies to better understand the specific state of a person's health and provide the right care at the right time for the right person. New technologies open up wider use of information on the genome and other aspects (such as molecular profiling, imaging, environmental and lifestyle data), helping doctors and scientists better understand, predict, prevent, diagnose and treat diseases (European Commission, 2018 (1)). The basic principles of personalised treatment require the pharmacogenetic tests performed prior to initiation of therapy to determine as accurately as possible the outcomes of the treatment, to avoid inefficiencies for the individual patient, and to minimise the potential adverse reactions.

However, the author notes that, in the context of M.Porter's Global Competitiveness Strategies Model, personalised treatment is not unambiguously specific to segment 3A because, although it tailors treatment to meet the needs of a narrow group of patients, this method requires additional costs. The benefits of personalised treatment come in the long term, as the savings by avoiding of ineffective treatment (medicines) for the individual patient and the reducing needs to treat the consequences of adverse reactions. Currently, pharmaceutical companies are actively involved in the development of personalised treatment, expanding their activities in the field of diagnostics and offering complex solutions.



The pharmaceutical segment 3B (Fig. 2) may be represented by manufacturers of biological medicines. Innovations in the pharmaceutical sector, particularly for biologicals, are shifting from large pharmaceutical companies to small players. While large companies continue to invest heavily in clinical trials and bring innovation to the market, today most of the major innovations comes from small and medium-sized enterprises (SMEs). However, innovative SMEs in Europe face financing problems, partly because European public markets are fragmented (European Investment Bank, 2018). Biological medicinal products contain active substances of biological origin, such as living cells or organisms (human or animal and micro-organisms). They are often manufactured using advanced technologies. Compared to chemically synthesised medicines, biologicals are usually much more difficult to produce, therefore biological therapy is one of the most expensive therapies, but its usage is steadily increasing. In 2017, 13.7% of sales of pharmaceuticals were spent on research and development of new drugs, while 24% was spent on biologicals (European Commission, 2018 (2)).

The personalised approach is associated with implementation of personalised medicine and rapid entry of new medicinal products (especially those of biological origin), high prices and high levels of uncertainty about treatment outcomes, as well as a lack of experience with these medicines. In a time of high uncertainty, some countries gradually introduce the Managed Entry Agreements (MEAs). A MEA is an arrangement between a manufacturer and payer that enables access to coverage (reimbursement) of a health technology subject to specified conditions. In the author's view, these agreements can be classified as an additional element which distinguish the pharmaceutical enterprises' market entry strategies and conventional business strategies (Fig. 3)

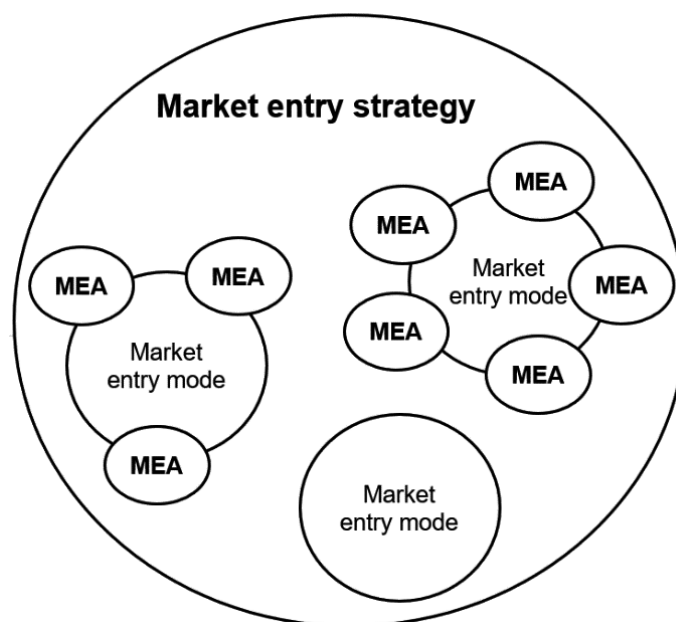


Fig. 3. The main elements of the pharmaceutical enterprises' market entry strategy

(MEA – Managed Entry Agreement) (*the author*)

The MEAs' nature and volume are highly depending on public pharmaceutical expenditures of particular country. The influencing circumstances can be either financial or health outcome-based, and different types of MEAs exist for each of these two main groups (Ferrario and Kanavos, 2013). These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies, to reduce uncertainty around the clinical effectiveness and cost-effectiveness, and to limit the budget impact of a technology in real life, to manage the adoption of technologies in order to maximise their effective use or limit their budget impact.

In accordance with the report 'Managed entry agreements for pharmaceuticals: the European experience', prepared in framework of the European Medicines Information Network (EMINET), the most common features of MEAs across

European countries are Price-volume agreements (39% of total MEAs), followed by requirement for data collection (29.5%) and limited access to eligible patients (13.1%) (Ferrario et al., 2017). MEAs are often used for high-cost patented drugs for which there is limited evidence of effectiveness in a noncontrolled environment and of their long-term effects.

Initially, countries prefer financial schemes because they are clearer and easier to administer, whereas performance-based contracts require precise and measurable criteria and are more complex to administer, but they provide the patient with an opportunity to be treated with medication, which gives them additional expectations over the alternative treatment available. Among Western European countries, MEAs is more widely used in the UK, Sweden, Germany, Austria and Italy.

Later MEAs are introduced in Central and Eastern European countries. Across the five countries with available data on the number of different MEA instruments implemented by type (Slovenia, Hungary, Latvia, Estonia and Romania), the most common MEAs implemented were confidential discounts ( $n = 495$ , 73%), followed by payback ( $n = 92$ , 14%), price-volume agreements ( $n = 37$ , 5%), free doses ( $n = 25$ , 4%), bundle and other agreements ( $n = 19$ , 3%), and payment by result ( $n = 10$ , 1%). Although the implementation of health outcome-based agreements is allowed in Estonia, Hungary, Latvia and Romania, most of the agreements implemented were financial ( $n = 668$ , 99% financial vs.  $n = 10$ , >1% health outcome-based agreements) (Ferrario et.al. 2017). The existing and potential MEAs in Latvia are shown in Figure 4.

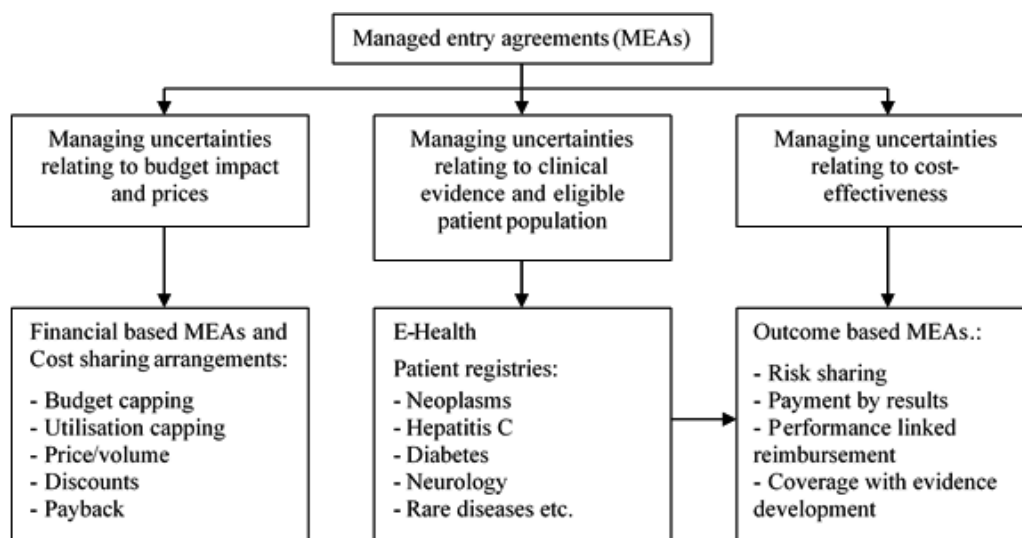


Fig. 4. Existing and potential Managed entry agreements in Latvia (the author)

The MEAs allow decreasing the uncertainties, which exist in case of new medicines, on clinical and economic evidence, fair price and budget impact, as well as eligible patient population (Fig. 4). Generally, the MEAs should encourage the entry of new medicines into the market. At same time there are some risks for countries with low purchasing power:

- new medicines initially are launched in countries with high purchasing power and their prices are set according to the purchasing power of the wealthiest EU countries,
- confidential agreements can decrease competition on prices of innovative medicines,
- agreements for confidential discounts are mostly agreed by the external price reference systems, which exist almost in all EU countries, and significantly decrease the transparency of pricing due to hiding the real prices.

The hypothesis of this research is justified, that the pharmaceutical enterprises have additional significant elements (MEAs) which are applied in process of development of the market strategy and choosing the market entry mode, in comparison with classical market entry strategies, and these preferences can be influenced by external factors, such

as amount of the public pharmaceutical expenditures of particular country. In circumstances of the strictly limited state budget a necessity to use the additional possibilities to optimise the resources allocation to the health care programmes and prevention activities remain topical.

### Conclusions, proposals, recommendations

1. Focusing on the healthcare market as a platform for medical entrepreneurship and significant regulatory interventions, it should be noted that, in a context of globalisation, healthcare is characterised as both an international business and an area to strong government influence and demand generation.
2. In the pharmaceutical field, the international business is more typical for manufacturing enterprises and pharmaceutical wholesalers that may also be holders of a marketing authorisation for a medicinal product. In light of the international business theories' applicability to the pharmaceutical companies, international trade theories (particularly R.Vernon's *Life Cycle Theory* and M.Porter's *Model of Global Competitiveness Strategies*), as well as the Foreign Direct Investment (FDI) Theory (particularly John H. Dunning's *Eclectic Theory* and *Investment Development Trajectory Concept*) are more relevant.
3. The organisation of healthcare and its financing system are important external factors influencing the market entry strategy of the pharmaceutical enterprise. Pharmaceutical enterprises more often choose the direct exporting, contractual modes and foreign direct investments as the market entry modes.
4. The Managed Entry Agreements (MEAs) become topical to ensure the availability of new medicine for patients and to encourage the pharmaceutical companies to come into market. Explicitly dominated financial contracts, while performance-based contracts are more likely to be awarded in the pay-for-performance category.
5. The MEAs provide both advantages and disadvantages in circumstances of uncertainty. Therefore, the additional measures and multi-criteria decision analysis should be applied in process of creation of the MEAs to improve their quality and transparency.

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