

University of Economics Prague

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THE ECONOMIC CONSEQUENCES OF THE PRICE
REGULATION OF PHARMACEUTICALS IN THE
CZECH REPUBLIC AND SWITZERLAND
BETWEEN 2011-2016

Bachelor thesis

Author: Marie Fajstavrová

Supervisor of thesis: Ing. Josef Klement

Year: 2018

Declaration:

I declare on my honor that this bachelor's thesis was done by my own and I used only the materials that are stated in the literature sources.

In Prague, the 10th May 2018

.....

Marie Fajstavrová

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BACHELOR THESIS TOPIC

Author of thesis: **Marie Fajstavrová**
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Topic: **Economic Consequences of the Price Regulation of Pharmaceuticals in Czech Republic and Switzerland Between 2011–2016**

Guides to writing a thesis:

1. The aim and main objectives
The main objective of the bachelor thesis is to analyse and compare the approaches of the Czech Republic and Switzerland towards price regulation of pharmaceuticals during 2011–2016. The secondary objective is to create an outline of the economic consequences of price regulation of pharmaceuticals for each of the countries and to propose possible improvements for Czech regulation of the drug market.
2. The main importance and timeliness
The health system with drug market is important focus area of economic policy. Patients with politicians want affordable health care on the one hand, but it is also important to maintain functional pharmaceutical research and development processes leading to creation of new and improved medicaments on the other hand. How do different types of price regulation of drugs influence both goals? This thesis will refer to the success or the failure of the forms of price regulation of pharmaceuticals between 2011–2016 in the Czech Republic and Switzerland. The importance and timeliness of price regulation of pharmaceuticals are based on actual problems associated with setting prices on drugs. This influences not only the economy of the country itself but also the patients, consumers and companies which are involved in the drug industry.
3. Characteristics of theoretical part
The main content of the theoretical part will be the definition of important concepts regarding price regulation of pharmaceuticals. As an essential, the economically specialized theories entitled to the topic will be presented, supported by research of specialized literature. Subsequently, methodology of the thesis will be presented in its own chapter.
4. Characteristics of practical part
The practical part will be examining the legislation and federal law on medicine products. In particular, those that significantly affect price regulation as well as pharmaceutical reimbursement, pricing and innovation policies intended to influence drug use and sales. Expected contribution is to highlight the key differences between the Czech Republic and Switzerland, in terms of price regulation of pharmaceuticals. Additionally, detect the negative consequences of price regulation, the estimation of the black market and the economic development not only of the drug market but also of pharmaceutical companies in Switzerland and the Czech Republic. Summarizing with the sales and the functioning of the import. The underlining of the social-economic indicators will explain the impact of the price regulation on consumers and patients and how the amount of money spent monthly will distinguish the Czech Republic and Switzerland.

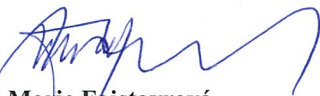
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Marie Fajstavrová
Solver



Ing. Josef Klement
Thesis supervisor



doc. Ing. Miroslav Ševčík, CSc.
Head of department



doc. Ing. Miroslav Ševčík, CSc.
Dean NF VŠE

Abstract

This bachelor's thesis deals with the problematic of pharmaceutical price regulation and its impact to public and pharmaceutical companies in the Czech Republic and Switzerland. The thesis examines the background of Czech and Swiss health system and outlines the issues with pharmaceutical pricing and price regulation. Furthermore, determines inequalities between individual reimbursement and price mechanisms. The interest of thesis is to refer to differences in both systems and assess the problem with unavailability of highly innovative medicines in the Czech Republic. Economic theories, which are contained within the theoretic part focus on problematic of market regulation and state's interventions. They present the summary of market mechanism functioning and price setting. It concludes by noting, that the reimbursement system of pharmaceuticals in the Czech Republic needs another examination and new mechanism, which would be implied more precise.

JEL classification: **I11, I18, I14, I13**

Keywords: regulation, health system, pharmaceuticals, reimbursement system

Abstrakt

Tato bakalářská práce se zabývá problematikou cenové regulace léčiv a jejím dopadem na veřejnost a farmaceutické firmy v České Republice a ve Švýcarsku. Práce zkoumá pozadí českého a švýcarského zdravotnictví a nastiňuje problémy při oceňování léčiv a cenové regulaci. Dále blíže determinuje nerovnosti mezi jednotlivými úhradovými a cenovými mechanismy. Předmětem zájmu bakalářské práce je poukázat na rozdíly v jednotlivých systémech a ohodnotit problém s nedostatkem inovativních léků v České republice. Ekonomické teorie, které jsou uvedeny v rámci teoretické části se zabývají problematikou tržní regulace a státních intervencí. Prezентují shrnutí fungování tržního mechanismu a nastavování cen.

Závěrem práce konstatuje, že systém úhrady léků v České Republice potřebuje další šetření a nový mechanismus úhrady, který by byl implicitně lepší a preciznější.

JEL classification: **I11, I18, I14, I13**

Klíčová slova: regulace, zdravotnický system, farmaceutika, system úhrad

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Introduction

The functioning of health system in the Czech Republic has been discussed several times. Mostly we can encounter with negative responses from Czech citizens to such topic. The objections are often raised towards wrong price setting of pharmaceuticals or gaps in health system. Especially nowadays, when several pharmaceutical companies have launched highly innovative drugs, the opinions of public are diverse. Whether the availability of such medicines is sufficient or if the patients pay accurate price for medicines, according to the real effects.

Therefore, the reason for the selection of this topic is to analyse, and where appropriate, critically assess the valid background of such concerns. The best way how to find the answers is to compare the situation in the Czech Republic to another country and observe, whether there is a room for improvements in the health system of Czech Republic.

Switzerland is well known especially for its pharmaceutical industry and various health care possibilities. Such patterns are useful to accurately examine the pharmaceutical industry and health system in the Czech Republic.

To understand better the market functioning itself the theoretic part presents some significant claims of famous economic schools as Austrian and Chicago school of economics. Competitive environment between individual firms is discussed primarily as well as the problematic of state's intervention.

The aim of the thesis is to determine the economic consequences of pharmaceutical price regulation in Switzerland and Czech Republic. The impact to Czech and Swiss citizens, as well as to pharmaceutical companies should be found out with help of synthetic analysis, statistical data and research.

I. Theoretical part

1. Theoretic excursion to the topic of economic regulation

1.1. Regulation appearance in daily life

Regulation itself belongs to our lives, and affects us, regardless if we notice it or not. This chapter will introduce main terms, that are connected to the regulation itself and in particular describe the different ways the regulation is implemented.

The thesis defines the main reason why the government is interfering in certain markets at a first place. The twentieth century represents itself with a possibility of independence, which can be observed also in terms of market functioning. But according to Shleifer (2005) unhindered and imperfect Markets often fail and it is the role of the government to mitigate the consequences and correct it.

There are other certain views how to determine regulation. One of them can be simply the regulation primarily instituted as a beneficial and protectionists for the very public. The second view might be rational and ethical.

Additionally, the government representatives try to fulfil the public interest, in which's behalf they impose taxes on certain industries and control the impact to its citizens by certain standards (Posner 1974).

Such actions are involved in so called “*public interest theory*”. According to this theory, government controls the maximum price and constrains the possible overcharge imposed by natural monopolies (Shleifer 2005). Pharmaceutical industry and health care are one of the most intervened ones, as the public uses its services daily. The affection by unfavourable market and price fluctuation can cause increased drug prices as well as prices of medical devices. Therefore, the government is sometimes forced to act *ex ante* to avoid unfortunate problems (Shleifer 2005).

1.2. Market regulation

The term market is defined as a place where the demand and supply operates and sellers interact to each other by trading superior goods (Prychitko 1995). Market itself includes a mechanism, that determines the price of the traded items.

Market regulation is tied to economic regulation itself, and works as a tool to protect the market integrity, market participants and risks occurring within the marketspace. Additionally, it consists of Structural regulation and Conduct regulation.

Structural regulation is used to regulate market structure. As an example we can mention the restrictions on entry and the exit of certain markets (Johan den Hertog 1999).

“Conduct regulation” is dealing with behaviour in the market. Price controls, minimum quality standards and rules against advertising belong under such problematic.

Both of these kinds of regulation can be encountered in excessive or limited competitive markets as well as in natural monopolies (Johan den Hertog, 1999).

1.3. The regulation process and its instruments as a necessary act

The degree of regulation depends mostly on the approach of the society to liberalism and paternalism. The state should primarily care about unequivocally determination of what behaviour or estate are the subjects of appropriate regulation (Howard Beales, et al., 2017). Regulation is divided into different forms, which is sometimes problematic in terms of comparativeness to economies of another country. Mostly is a term “regulation” perceived as a negative activity and attitude of public towards regulations is dismissive, due to the feeling of economic constraints. Nevertheless, well-chosen government instruments like regulation can actually protect the consumers from defective products and services and make sure they have all the information they need to buy goods without any harm. The right regulatory decision should be based on sufficient and quality information. The sources and data helping to imply the right regulation should be unbiased and accurate to give the consumers good outlook of the certain situation.

The main goals of regulation can be summed up as following: clean and healthier environment, acceptable and harmless conditions for employees, safe food and drugs (Howard Beales, et al., 2017).

The government intervention is the most common when the mechanism from certain spheres failed and there is a need to get things back in order. According to Bělohlávek and Hótová (2008) under such circumstances we can point out the market mechanism, which leads to effective acquiring of resources only under the conditions of perfect competition, which appears very rarely. Subsequently, in a real economy it is almost impossible to encounter these. For a good functioning market, it is necessary that both producers and consumers know all the information, which is in the era of asymmetric information not really common. Market failure usually occurs under the influence of imperfect competition, imperfect markets and no elasticity of demand and supply. As a consequence, all these factors cause a threat of market mechanism, which is then not able to effectively distribute limited economic resources. (Bělohlávek and Hótová 2008, p. 68-69).

The contractual relations and other factors needed for a good market functioning can't exist without any legislative framework. Therefore, the appearance of the government is crucial to keep both sides of the agreement within the law. The state regulation helps to mitigate the consequence of the black market and other externalities. Therefore, the cohesion of redistributive processes is crucial to make sure, that the allocation of justice is concessive to its powers (Bělohlávek and Hótová 2008, p. 70).

The reasons of state intervention can be summed up as follows:

I. Microeconomic reasons, which either force directly the government to intervene the economy, or leave the government a space to react to the extension of certain microeconomic actions.

II. Macroeconomic reasons, by which the government tries to eliminate the distortional consequences of ordinary macroeconomic development influenced by such factors as high level of unemployment, inflation, low economic growth and the balance of payment's deficits.

III. Noneconomic reasons, which are mainly connected to justice of economic system.

The government uses certain economic tools to make an accurate and appropriate regulation. These tools are mainly fiscal instruments, like taxes.

The tax instruments determine all the economic subjects by direct or indirect taxes. While implying the taxes there is a need to analyse the ones, who will be the most effected, more specifically, who will pay the most. Additionally, indirect taxes imposed to basic groceries or energetics are in particular regressive taxes, which could have a negative impact on low-income consumer groups. However, on the other hand side state provides certain subsidies, transfers or certain forms of negative taxes, which on contrary contributes to production of another commodities or services (Bělohlávek and Hótová 2008, p. 71-72).

An another instrument the government uses to regulate, is the tools who influence a daily life of all the participants of economic life. Under this group can be defined a scope of certain rules of acting individual market subjects, in particular in the form of law restrictions. One of the most important law restrictions is an establishing of ownership rights, which distributes available resources to three basic groups: the resources, which are free to used, the private resources and the resources under the government control (pharmaceuticals, alcohol, Research and Development (hereafter abbreviated as R&D)). Aside of determination of ownership rights the state influences the economical subjects through state intervention (Bělohlávek and Hótová 2008, p. 71).

The incentives of regulation are mostly required through political institutions. It is influenced by consumer's or producer's surplus and the amount of customers and producers. The regulation is offered by politicians or officers and its extent is given by the amount of economic objects which can increase their utility or possibly influence future results of election campaign through the regulation (Bělohlávek and Hótová 2008 p. 72).

Regulation processes are happening within state institutions. The highest representatives are mostly appointed by the government or another political influencing organ. Those

regulation authorities have a stable bureaucratic apparatus and its financial needs are covered mainly by the public budget (Bělohávek and Hóťová 2008, p. 79).

The most used type of regulation is a **price regulation**. The price regulation is from the administrative point of view one of the easiest instruments. It is based on a legislative framework, which interferes to the process of price creation.

The price regulation itself mostly conducts either direct price setting or streamlining through amending. Under these two methods we can determine the price range, where it is possible to use not only maximal but also minimal margins. Another instrument used in a practice, is a price streamlining in accordance to conditions emerging by price creation (Bělohávek and Hóťová 2008, p. 79).

1.4. The main economic theories dealing with a term of economic regulation

Compared to certain strategies of regulation described above we can also wide it up by certain economic schools and theories tied to the regulation topic. Since decades the economists are arguing about the appropriate approach towards market stabilisation, price setting and economic regulation. The opinions distinguish to each other especially by fiscal and monetary approaches in terms of government intervention. The following subchapters will help us to understand better the claims of famous economists towards regulation and give us the preparation for the whole “economic regulation” problematic.

1.4.1. The approaches of Milton Friedman and Chicago school of economics

The main approach of Chicago school of economics is based on the liberalism and limitation of government interventions within market. This theory is supported by belief of Adam Smith, who first used the term *Laissez faire*, which is crucial for Chicago school or then later neoclassical school. The individualistic market and free-enterprise economy are according many economists more productive than any other economic systems. The main claims stem to the assumption that the economy with flexible prices leads to full employment. Yet, the Chicagoans appear to be more committed to the market system functioning and to seek new ways of introducing market possibilities. They focus less on market imperfection and all the unfavourable aspects, try to adjust the visible benefits of certain market structure (Miller 1962).

The Chicagoans, who follow the footsteps of Milton Friedman stand to the big picture of consumers' protection, which is provided by high competition within markets. While the government is trying to set the mechanism, which constraints the possible price fluctuations and constantly competing companies, the followers of the Chicago school of economics believe that the competition is exactly what the markets and the consumers need. Increasing and decreasing prices within markets enable the costumers to choose between wide range of suppliers and intermediary goods. The companies try to provide the maximum possible services with a view of increasing profits from following costumers' needs, which are observed from the changing demand functions of certain goods. Only by selling the superior good at reasonable prices will attract the consumer and thus thrive the environment of the market (Chernomas and Hudson 2017).

Milton Friedman and his followers face here some criticism related to the consumer's protection by government regulation in terms of unfair pricing and complexity of purchasing, where the normal costumer is not able to recognize potential issues. Chicagoans oppose, that the consumer's protection is better done through private sector (Chernomas and Hudson 2017).

From this point of view, the consumer satisfaction is in the best interest of businessman. To sell and provide well-functioning merchandise and superior goods assures better profits. There is no need for regulation from the government, because there is a possibility of a reduction in reputation when something goes wrong. Furthermore, the competition within markets makes it unlikely that the businessman would want to provide worse quality for the costumers because it might cause the competitive advantage and in the worst case even a bankrupt of such facility (Chernomas and Hudson 2017).

The merchandisers are well aware of the importance of offering well functioned services. However, from the ordinary life we know, that the inferior product's appearance is sometimes unavoidable. The protection of costumers in this case is normally provided by testing organization. This results in "*Consumer Reports*", which can be used by consumers express their dissatisfaction (Posner 1974).

Since this thesis is in particular based on pharmaceutical industry situation, it is important to mention Friedman's dismissive attitude towards government intervention in terms of

medical care. Government imposes requirements to doctors about certain levels of training as a part of professional standards. For this case we can implement the same explanation as for the inferior products. According to Friedman, is it unnecessary to control such sphere by government. Now we are speaking about more than just about the barriers to entry the market. Sometimes almost unreachable requirements for doctor's proficiency are the cause of decreased quality and quantity of medical practices. They are not always able to cope with such restrictions. The government intervention has given away the opportunity for the customer to be treated by doctors, who are not less professional, but only without a specific training certificate (Chernomas and Hudson 2017).

The methodology of customer's satisfaction works the same way regardless of the product or service. The barriers are set by the labour market itself. Once the doctors do not prove their best knowledge and the will of doing their best for the patients, they might lose them and it might lead to the termination of the doctoral practice (Chernomas and Hudson 2017).

The main harm of this is about bureaucracy, which burdens the automatic functioning of the market increasingly. With these new restrictions there is less space for new participants. Therefore, there are less devices, services and good offered to the customers (Chernomas and Hudson 2017).

The possible reason of the government's lack of success by improving the market outcome, can be the fact, that most of the instruments involved in private businesses are developed overseas and the government of certain state is not competent to change the base the whole industry or the business is built on (Chernomas and Hudson 2017).

Sometimes the regulation itself is not only initiated by government but also by certain movements, that influence the political situation in general. In favour of their own interest, some of the political parties are trying to turn the reforms to some new cause and ensure that the law is used in their benefit. In the end of the day this is the exact opposite of the original claim with the main objective of regulation, to protect primarily the interest of the citizens.

Nevertheless, even the Chicagoans must admit the pressure on the government by passages of some law. Not every regulation imposed by government was primarily initiated by the politicians.

1.4.2. The approaches of Friedrich Hayek and Austrian school of economics

As one of the greatest representatives of the Austrian school of economics is professor Friedrich August Hayek with his claims specified by spontaneous order and independent actions. This leads us to the fact, that his claims are shared with Milton Friedman. Both of the economists stand to the idea of invisible hand. According him the function of free market and its institutions has been developing since decades by trial and error (Geoff Riley 2018).

To be more understandable for the public, he made a sharp contrast between his approach and Walrasian theory, described below. Hayek's dismissive attitude toward the walrasian theory is arising out of the walrasian ideas about the price-taking market equilibrium. According to Friedrich August Hayek, this would be Parreto -efficient¹ since the outcomes of such market can be delivered through a redistribution of subsidies or endowments (Bowles et al. 2017).

He declares, that the competition itself is a tool of continuously discovering unperfected gaps within certain markets. From the imperfectness of the markets we can conduct the methods, which lead to either success or failure in the market. We can then gain a new knowledge, which would remain unknown or would not be used. In this view we can also consider the basic explanation of the function of prices (described more detail in the next chapter) as an informative message for all the participants in the market. The price theory is a centrepiece of Hayek's theory. The consumers are automatically informed about the market reflection by price fluctuations (Bowles et al. 2017).

¹ Pareto efficiency- the state of allocation of resources, which is impossible to reallocate for the purpose of better individua or preference criterion

This brings us back to the Hayek's rejection of Walrasian economy. In one of his papers "The Use of Knowledge in Society" he gives the modern view and sophisticated understanding of the equilibrium theory (Hayek 1945). The pioneer approach about new ways of achieving the equilibrium is based on use of knowledge, earned by individuals throughout certain situations. Friedrich Hayek was not entirely interested in the equilibrium problematic itself. He saw the power of the market as an individualistic approach, gained by diffusion of new information shared through the whole market. Such action is mostly accomplished in disequilibrium, which is exactly the idea he has stated to (Bowles et al. 2017).

The main principal of his theory is the conception of competition. He deals with the question of perfect competition and the main role of the state. His disagreements are mostly about the "modern theory of competition" according to which the individuals are fully informed about the situation and the main data used for such theory are fully adjusted. The data we need are obtained from the nature of the process (Bowles et al. 2017).

Now here comes the idea of Hayek, who in his claims follows Samuel Johnson. While one element is discovered by ongoing information, the other one is still unknown. This means that it is impossible to provide the individuals the information without any uncertainty, because while you adjust some details, another undiscovered information influences the competitive environment at the same time. He uses the example on certain devices where he claims to the absurdity of the core idea of the modern theory of competition. Hayek believes that the advertising and improvements within the certain facilities is crucial for the good market functioning and the consumer's satisfaction. In his eyes the "perfect" competition leads only to the absence of all competitive activities (Bowles et al. 2017).

1.5. Price and its theory

The price and its function determine several actions within markets, the price behaviour and the importance of prices in general. The generalization concerning lowering utility, the maximization of profits and different proportions of physical productivity with a ratio

of certain external and internal factors are also included within the price theory. Additionally, it focusses on several aspects influencing the market environment.

We should distinguish between two approaches. An **empirical generalization** and the **logical deduction**. These two approaches are depending on the conclusions of individual preferences. Major attention is devoted to the groups with different interests and preferences (Bain 1942).

One of the theory intended to use the empirical generalization and the logical deduction is the so called “**Robinsonian theory**”. This theory is dealing with the question how the firm adjust its costs for its product and find the sufficient equilibrium between the price and the sales volume. First of all, the theory explains the situation in a short-run price equilibrium and how the price shifts. Subsequently the theory continues with the explanation of long-run price equilibrium and determines the differentiation between certain conditions, influencing the slope of the demand curves. The explanation of pricing provides several characteristics based on the given demand curves as well as cost curves. The theory says, that once we know the costs and the demand for certain goods, the firm can then set the appropriate price (Bain 1942).

However, the Robinsonian theory is a bit limited by its lack of empirical contents since it is mostly based on the price determinants. These are sometimes subjective, as they represent individual desires.

Therefore, it is worth mentioning the **Chamberlinian theory**, that possess, on contrary, greater empirical content. Chamberlin makes the empirical observation directly and explains how markets differ and so does the price behaviour (Bain 1942)..

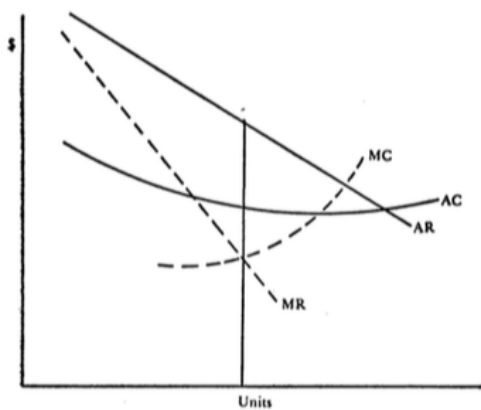
Chamberlin even came up with a suggestion how to distinguish the markets and classify each category according to the behaviour, which has impact on the price as well. The market distinction is described as markets with many sellers involving either undifferentiated product - (pure competition) or differentiated product that closely approximates to monopolistic competition. He categorizes the markets with few sellers where the crucial role is played by pure and differentiated oligopoly. As a last category are the markets with only one seller, so called monopoly (Bain 1942).

In response to market regulation and government intervention, the price is the main subject of the problematic. Following lines will examine the general theory of price and how to even create certain prices operating within the market. This is necessary for the comprehensive understanding of the topic.

The general theory of price starts with the features of monopolistic competition. How to create an appropriate price is showed in the figure 1. It is based on the negatively inclined average revenue function, each participant or seller on the market has his own average revenue curve, AR (Hawkins 1954).

The marginal revenue, MR is derived from it and then the price is determined by intersection of marginal revenue and marginal cost, MC. We get the marginal cost as a derivation of average cost, AC or average variable cost AVC (Hawkins 1954).

Figure 1 Creation of appropriate price

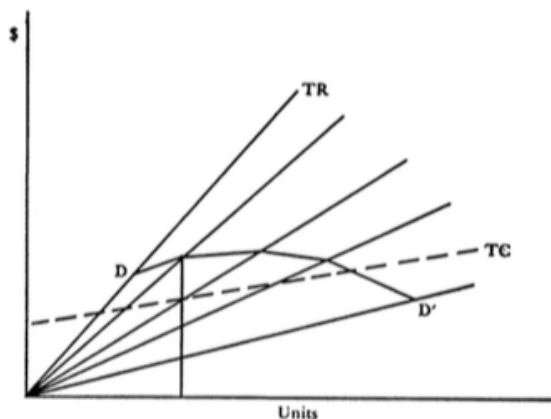


Source: Hawkins, 1954

Another solution, which may be more acceptable for businessman and people not well cooperating with economic terms, is a break-even chart. However, to be able to set the accurate prices for certain goods and services we have to modify the classic version. The customary break-even chart works only with one price and acknowledge only one quantity, that would be sold at that price. The modified version is built on the

cooperation with total costs, TC, and total revenue, TR curves. If we have a look on the figure 2, we can see the various TR curves, where the total sales volume is built on certain prices. We can indicate different demands (D, D'), the starting point and the ending point. If we connect these two demands, we get the total revenue. To get the correct price, we have to maximize a distance between DD' and then TC. This can be advantageous over the first model described above. Unlike the MC, MR model here we can indicate not only correct price, but also the total volume of sales as well as total net profit. Additionally, the second model is more common for entrepreneurs and businessman, who are used to break-even charts (Hawkins 1954).

Figure 2 Break –even chart



Source: Hawkins, 1954

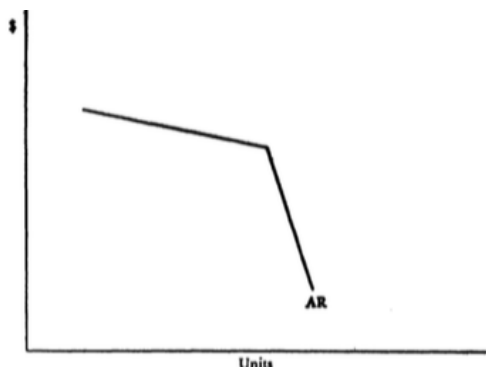
been found to have a little effect on total sales, as long as it does not get over a certain critical point. At this point, the consumers are starting to realize that the price has significantly changed and they are reluctant to purchase the goods or services on higher price levels than earlier (Hawkins 1954).

What is worth mentioning is a so called **“pricing at the market policy”**. Firms that adopt this policy, are usually aware of the fact that setting higher price than their competitors would diminish the sales sharply but lower price would not increase them either. The core of this theory is mostly based on imitation of competitors. As depicted in the Figure 3. The shape of the AR curve distinguishes from the Figures 1 and 2, drawn above. The main difference is given by the major thrive of this theory, which is imitation of the competition, unlike the previous schemes, which were mostly based on the total revenues and sales (Hawkins 1954).

Another reason why the marketers are using the model of pricing at the market, is to avoid price competition and price wars. But for such reasons we need to modify the chart to be able to make a basis calculation of the competitors. First of all, we have to estimate the AR curve, after all competitors have responded to the moves on the market, and have set their prices. Responding to certain market and then to estimate AR, average revenues, which is crucial for the purpose of the model. In figure 4, the response of AR to competitors is shown as AR₂. A simple AR poses the customary curve based on assumption that everything else stays the same. Essential is the fact that it might be very difficult for the seller to guess the incentives and the responses of the competitors, but the

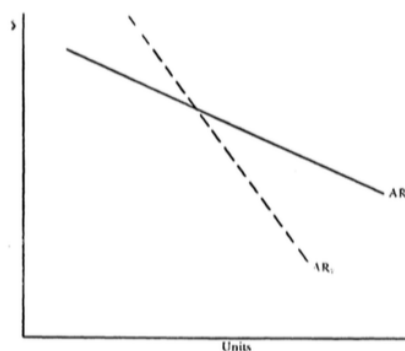
theory of the correct oligopoly pricing, with an explanation of the AR_2 curve, is clear (Hawkins 1954).

Figure 3 Imitation of competitors while setting the price



Source: Hawkins, 1954

Figure 4 Responses of competitors



Source: Hawkins, 1954

We can notice the interaction between economists and people working within the field of marketing. While these two fields seem to be separated from each other, they need a help to understand certain action within market, by spreading and sharing their ideas. From the economists' point of view, they need people working in marketing to be able to detect sudden customer's decision, which are influenced by changing prices. In the field of marketing, it is called consumer behaviour. It is crucial to understand why and under which circumstances, they are reluctant to make the purchase. It is also clear, that the economists need to know more about the pricing policies to be able to react and explain the possible price and market fluctuations in their economic theories.

On the other hand, the side of marketing has to have a basic economic knowledge to be able to understand certain models and charts in order to develop a new marketing strategy.

After examining certain ways and means how the prices are formed, we could move to another step to incline the classical functions of the price.

The decisions of consumers are mainly described by the price mechanism as well as circumstances under which their decisions about purchasing are made. Partially, the price mechanism even determines the allocation of resources. There are three important functions, that help us to understand the consumer's behaviour.

First of those is a signalling function. The price sends signals to the consumers and suppliers. If the price is rising due to high demand, it is a sign for the suppliers to extend production to meet the higher demand. In case of excessive supply in the market, the price mechanism should help to eliminate a surplus of a good by conceding the market price to fall. In another words, the signalling function coordinate the changes in market conditions by providing the information to producers and consumers.

Another function is the transmission of preferences. There is a constant hunt between consumers and producers on the market. Through the choices of consumers and their changing natures of needs and wants, the information to led to producers, who try to adapt their technologies or services to please their customers as much as they can. When the high prices occur within the market, the producers have an incentive to increase output in order to make a better profit.

The last function is significant for both the demand and supply side. It is a rationing function. When there is a scarcity of the product, naturally the price will rise, which might deter some consumers from buying the product. But on the other hand, this is an opportunity for the producers to provide another kind of good, a substitute. The demand of the good with increasing price may be reduced, but the market that offers a similar commodity is experiencing increasing demand. Almost all the goods are fungible, once the price of certain products is too high for the consumers. This shows the infinite cycle. The demand of one good is decreasing, because of the high price, while the demand of another commodity is increasing. Once the producers see the customers buying their goods, they increase the price for better profits. This takes us back to the first market. The demand was decreasing because of the unwillingness of consumers to buy the good for a high price, the producers react to that with certain discounts or even setting the price as low as it was at the very beginning, to get their customers back (Geoff Riley 2018).

With regard to prices, we can again mention Friedrich August Hayek, who's approach "Knowledge and Prices" explains the simplicity of the reactions to price changes.

We must look at the price system as such a mechanism for communicating information if we want to understand its real function. The most significant fact about this system is the

economy with which it operates, or how little the individual participants need to know in order to be able to take the right action (Hayek 1945).

The core of his claim is based on the consumer not knowing all the details about the price change. The information about the product is not important for the consumers. They do not need to know anything about the costs behind it. The only thing they care about is the price. Consumers are not aware of the circumstances that lead to an increase in prices, whether it was caused of a lack of natural resources or because of a weather disaster. All they know is, that the price increased.

Hayek interprets an interesting pattern. Even though the consumers have a lack of information why the price changed, they come to the decision based on their observations. If they had known the circumstances by which the price went up, they would have made the same decision (Komrska and Hudík 2016).

2. Pharmaceutical markets

The pharmaceutical industry has a significant meaning for the entire economy of a given country, not only regarding GDP but also as an important part of socio-demographic determinants. Import of pharmaceuticals is crucial for the prosperity of the country especially because of the endogeneity of citizens.

Pharmaceutical markets offer an interesting area to explore. Not only by different social groups and nations, but also by different markets and market rules, which provide a wide sphere of different products. **An interesting fact about pharmaceuticals is their ratio to the whole import of the entire country, which distinguish significantly.** Taken an example of United States, that have an average of three drugs classified as a therapeutic class compared to Italy, that has approximately five drugs per therapeutic class and Switzerland has an average of four drugs per class. Here we can observe certain patterns, in terms of the location of the country and its size (Lee et al. 2016).

Only one third of prescript pharmaceuticals is marketed in one of the seven largest drug markets. These markets are based in the United States, Canada, France, Germany, Italy, United Kingdom and Japan. As the pharmaceutical companies have lots of possibilities to trade, there should be incentives to spread their sunk costs of drug development over as many markets as possible (Kyle 2007).

We have to understand the patterns of entry to pharmaceutical markets, to be able to detect its functioning. There are monopoly and duopoly markets. The competition between companies, which participate on the pharmaceutical market thrives price not only the price settings but also a cost fluctuation. The cost structure within the pharmaceutical market is without any doubts the most important for every company, which is about to enter the market. To choose a precise and accurate entry strategy, the companies need all the information to be able to compete and acquire customers. It is also clear, that the firms are influenced by certain level of regulations. Particularly price controls. Especially in terms of pharmaceutical markets the government has a widespread possibility to interfere. Therefore, it is unnecessary to determine all the factors influencing pharmaceutical markets, to be able to examine the level of state intervention and its purpose (Lee et al. 2016).

For example, as *an annex* we can mention here the fact, that **certain companies even delay the launch of new drug into price-controlled markets and then, after launching the new drug into regulated market, it is disproportionately likely that they introduce their products in additional markets.** Which basically means, that the use of price controls, has a substantial effect on entry into that market, within the country, that imposed the price regulation (Kyle 2007).

Another interesting fact worth to mention is the fragmentation of pharmaceutical market. The various sizes of firms play a crucial role. According to certain studies only several hundreds of companies with good innovative technologies, advanced R&D strategies have introduced drugs on the market. The rest are comprised by such fragmentation, because they have a shortage of financial resources and innovative technologies (Kyle 2007).

Another example of fragmentation we can take national markets, which are distinguished to each other by the number of dimensions and the kind of regulation that is imposed. Normally each nation is supposed to have agencies or ministries, which are in charge of evaluation and assessment of pharmaceuticals with a purpose to assure safety and effectiveness of a new drug. The agencies and ministries vary within countries significantly. Some countries require clinical trials on domestic patients and have a dismissive attitude towards foreign data. Other countries call for the proof of cost-effectiveness (Ekelund and Persson 2003).

There have been certain trials to mitigate the diversity within the agencies and harmonize the regulatory standards for the major markets, in particular within the European Union (hereafter abbreviated with EU). One of the options of a drug evaluation is the Centralized Procedure, which is based on the drug submission to the European Medicines Evaluation Agency. The main role of this agency would be the marketing approval in all EU nations. It is worth mentioning, that it is a drug's manufacturer, who negotiates with individual countries over prices and conditions under the Centralized Procedure (Kyle 2007).

2.1. Price regulation of pharmaceutical markets and competition between pharmaceutical companies

As mentioned in section 2, the specification of pharmaceutical markets is their fragmentation and diversity. This fact does not change even in terms of pricing. Even the price regulation itself has many variants, that are distinguished by the country of origin. However, most of the countries have shared some common forms over the last years. Normally the price controls advert either the ex-manufacturer price or the amount of national health service pays for a pharmaceutical product. In pharmaceutical terminology it is called the reimbursement price (OECD 2008).

Normally, the price of the drug is based on the ratio of therapeutic value, additionally it is necessary to set off the cost of comparable treatments, manufacturing costs, and the level of contribution of the drug's manufacturer to the domestic economy. Always consider these factors when setting the accurate price. However, they can choose different levels of comparison. Many countries refer to the actual price of the drug when setting the price. By such actions they can even affect the price of the drug on other markets. This case is called **international reference**. The pharmaceutical firms and the government interact with each other. This process can be slow and long lasting. Many companies blame the government for their loss of possible revenue, because of the delay of the launch of a new drug. The firms under the pressure of government have to postpone the launch, and by imposing more restrictions on the price settings, it might even happen that a new product is not brought on the market after all (Kyle 2007).

According to Kyle (2007) the price of pharmaceuticals is mostly lower in countries who use price controls unlike to countries who do not use price controls. Nevertheless, there are even cases where countries use so called demand-side controls. This kind of control is typically determined by the total cost of drugs a physician prescribes (Kyle 2007). As the result doctors are encouraged to prescribe less expensive products. Another way that can be used, is a **reference-pricing scheme**. It is characterized by a patient's responsibility for paying the price difference between the drug he chose and a reference drug defined by government. In some countries there are more disadvantages for pharmaceutical companies, because governments can control the profits of

pharmaceutical firms on the sold drugs. This is a case where the firm is penalized for providing new pharmaceutical products. There are two parties of negotiators, the government and the manufacturers. Normally the government sets a price according to formulas which evaluate operating costs, the expenditures of promotions and research and development spending (Brekke et al. 2014).

Pharmaceutical markets are characterized for its diversity, especially because of the different cultural environments, legislation and rules of certain countries. Significant are also no regulatory aspects, as size or number of pharmacies, apportion and distributions of margins. The attitude of a patients towards doctors, prescriptions and drug dispensing differ geographically. Physicians in Japan are used to prescribe drugs in lower doses than elsewhere in the world. Besides this, the compliance and trust of patients towards doctors is high. Companies in Japan can lose their profits because the patients will be most likely to take the prescription with a lower dose from their doctors. They will not be interested in buying more than prescribed. On the contrary, in Europe many people are trying to find an alternative way of treatment (Brekke et al. 2014).

Regular drugs are mostly used as a last aid. Here we see the space on the market for companies, which brings to the market an innovative and green technology, based on more gentle medicines and herbs. Even though we still speak about drugs here, the consumers see it differently, since the composition of drug is consisted of natural substances. Unlike to Europe, the United States have completely different situation. The alternative therapies and drugs are less favourable; however, the popularity has increased last years. One of the reasons can be attributed to the high price of regular drugs, which is for most of the citizens too expensive. The American pharmaceutical companies can benefit not only from high prices but also from the increasing amount of customers who are interested in less chemical drugs, opening possibilities for green technologies (Brekke et al. 2014).

Once we mention a space for various pharmaceutical companies, the case of competition comes into the scene. The pharmaceutical market is highly competitive and volatile. There is a widespread distribution of different chemicals that treat the same conditions.

There are new generics² entering the market almost every month and this segment gathers considerably high market share. As a reason of such situation we can mention an example of a temporary monopoly. This firm gets a monopoly, which lasts around 20 years and becomes the only producer of this drug among the pharmaceutical companies. It works as an incentive for innovations, which does not cross the line between the law and monopoly rules. The firm is allowed to provide various medicines with the same healing effects, only under different names. That is a trick used by non-monopoly companies to squeeze the most from the market as they can. The public ideology says, that during the years a firm has a monopoly position on the market they do not require more profits, since they gained a sufficient amount (OECD 2008).

On the contrary, OECD studies have shown that 20 years is time enough for other companies to invent and develop new drugs and generics (OECD 2008). This may further lead to the disadvantage of the company, which used to own the monopoly. To be able to compete with other companies out of the market it is necessary to continuously innovate and enhance research and development. Unlike other companies, which have enough time to converge and catch up, the monopoly company put all the efforts, financial resources and technologies, for the one specific drug production, which has taken away the possibility to invent something new, which would be competitive to other products from other companies. The competition itself can be enhanced even by the regulatory environment (Kyle 2007).

Some therapeutic studies have shown, that pharmaceutical companies have incentives to launch a new product in foreign countries first, where they have wider sphere of setting higher prices, than in non-foreign countries. Therefore, they compete with each other by developing more efficient technologies to get there first and gain the most profits. However, this can have a side effect and significantly influence and **depress global revenues**. Since the parallel imports are allowable within 15 EU member states, it enables the wholesalers to arbitrage the price difference. The launch of new drug on price

² generic drugs: do not have a trade mark and are sold normally for lower price with the same healing effects

controlled markets can trigger the sale between countries, where the price is set high. Basically, if wholesalers purchase the drugs from price controlled markets and sell them on other markets, where the prices are higher with a view of greater profits. This would affect the markets (OECD 2008).

Related to the pharmaceutical market, regulation is also an example of a mechanism of price setting. The government has in this case power to promote domestic producers, by for example ignoring the therapeutic value in setting price or use some subventions or donations to help the domestic firm gain the main share of the pharmaceutical market. It is for sure significantly profitable for the domestic firm to produce medicines only on the home market instead of developing new drug for export. In contrary, since the foreign firms are disadvantaged, they are not really motivated to offer their products on such protected market (Santerre et al. 2005). Unlike to foreign firms, that are in this case disadvantaged and not really motivated to offer their products on such markets, where the most power is acquired mostly for the domestic firms. Some of the negative outcomes caused by this government intervention are based around low quality drugs provided by domestic firm. On the other hand, the pharmaceutical companies, try to launch drugs with the highest quality possible to assure they dominate their position towards their competitors. Clearly, high quality drugs have even more possibilities to succeed (Santerre et al. 2005).

Price controls can have an internal response to some other factors. They can be captured in omitted variables such as a drug safety conditions, industrial growth and policies. All these together can significantly affect social welfare. Starting with low drugs quality, passing through delayed research and development and end as the reduction of incentives for innovative technologies. The examination of the nature of competition should be highly recommended to avoid those unfavourable factors (Ekelund and Persson 2003).

3. The determination of basic terms used within pharmaceutical institutions and pharmaceutical regulation

3.1. The definition of pharmaceutical law

In general, the pharmaceutical law represents itself as a subset of health laws. The health law can be determined as a summary of all legislations regulating the emergence, change and extinction of legal relations within healthcare (Král 2014, p. 22).

The term of pharmaceutical law is mostly understood as a regulation of pharmaceuticals, respectively of subjects, which are dealing with pharmaceutical products, specified as distributors, holders of regulation's decision, merchandisers, pharmacists, doctors, patients and insurance funds. Some talk about the pharmaceutical law in closer relation as a field of law, dealing with facts, emerging by a development, assessment, production and distribution of pharmaceutical products (Král 2014, p. 22)..

A significant part of pharmaceutical law is a medical law. Medical law is focused on a regulation of employees working in the healthcare sector and it is focused on a problematic or individual providers of healthcare services. The regulation of public health insurance, creating and protection of healthy life conditions goes along with the pharmaceutical law as well (Šustek and Holčápek 2016, p. 32).

Whereas there are no apprehensions about the dominate administrative measures in terms or pharmaceutical law, such as public law focus, the medicinal law significantly tends to private law sphere, for instance the provision of the healthcare.

The method of a regulation is a law jurisprudence based and it is consisted of two groups of subjects, which are unequally divided. On the one hand are the executors of public administration, primarily administrative authorities. On the other hand, there are addressees, persons, who exerts the regulation Here we speak about producers, distributors, dispensing parties. Another criterion is used for internal System- wide coherence of legislation of specific area. By the pharmaceutical law, this criterion is implied specifically by the existence of basic codex, which is a law of pharmaceuticals and a law of pharmaceutical products (Král 2014, p. 23).

3.2. Exercise of public administration on pharmaceutical space

In the field of pharmaceuticals, we encounter not only with pharmaceutical products, medical devices and another subjects related to such topics, but also a widespread palette of regulatory authorities of public administration. One of those institutions, which significantly contributes to our problematic, is a ministry of health (Král 2014, p. 24).

The ministry of health is an enforcement authority of the public administration for health services, protection of public health, pharmaceutical scientific research, providers of health services, health insurance and health information and many other, which is depending on the pharmaceutical law of the individual country (Král 2014, p. 24).

3.3. The definition of main terms in the pharmaceutical space

3.3.1. The medicinal product

Since the main topic of this research is the regulation of pharmaceuticals, it is worth to clearly define the term “medicinal product”. This term is crucial for the whole field of the pharmaceutical law and for the pharmaceutical industry itself.

The definition of medicinal product involved in a legislation of the EU, as in national legislation, where it is described as follows:

- I. The substance or the combination of substances is presented as it has either medical or preventive features in a case of human diseases.
- II. The substance or the combination of substances, which can be used by humans or administrated to humans, and so be as a recovery purpose, the purpose or the influence of psychological functions through pharmacological, immunological or metabolic effect, or for the purpose of the determination of a medical diagnosis (Král 2014, p. 30).

Since we have the main overview of the term “medicinal products”, we will proceed with an analysis of the definition which is described above. This definition consists of two separated parts, where the achievement among these two leads to the qualification and assessment certain product named “Medicinal Product” (Král 2014, p. 30).

Firstly, we take the definition according the performance of the medicinal product.

In this case there is a crucial the way the product is presented, respectively what features are attributed (Král 2014, p.31).

According to the existing case law of the Court of Justice of the EU, the term “presentation of product” should be extensively interpreted. In that regard it is important to remind the Directive of medicinal products, which is based on criterion of the product presentation with an aim to involve not only medicinal products, which have a real therapeutic or medicinal effect, but also products, which are not effective enough (Král 2014, p.31).

This directive, leads to the protection of consumers. Not only against harmful substances or toxic medicinal products, but also against some products who do not use appropriate medicinal products.

The product itself is presented as a bound for previous disease or a healing process only if it is expressly mentioned or recommended either orally, or specified on the labelling or leaflet (Král 2004, p.31).

Due to the fact that every medicinal product has to be registered is obligatory, the definition of medicinal product aims to one thing in particular. This is to clean the market from products, which objectively do not include the features of medicinal products (Král 2004, p.31).

Secondly, we define the definition of medicinal products according to its functions. Such products consist of substances of which the pharmacological, immunological or metabolic features have been proven scientifically, subsequently the real determination for diagnosis or recovery is required and lastly adjustment or influence of physiological functions. Whereas the presentation function is based on subjective assessment of the health's intensity claims of a competent authority, state concerned, the function definition stands to objective proof of certain features. Each case has to be examined individually, where the case law of the EU's Court of Justice requires the pharmacological, immunological or metabolic features of products to ensure a significant effect for metabolism (Král 2014, p.32).

The assessment itself consist of a wide sphere of partial parameters, along such belongs the consistency, pharmacological features, the conditions of use, the ratio of the product extension, the consumers' knowledge of certain products, or the risks involved with using the product.

3.3.2. The Healing substance

Within the definition of medicinal product, a healing substance plays a crucial role. In context of pharmaceutical regulations, we distinguish two basic types of substances; a healing substance and excipients.

The healing substance is any substance or the mix of substances intended for the use of production or preparation of a medicinal product, which becomes an effective component of medicinal product intended for the development of pharmacological, immunological or metabolic effects which are aimed for recovery, change or influence of physiological functions or to determine diagnosis.

The origin of healing substance can be either human based, toxins, extracts or preparations from the animal blood as well as plant and chemical based (Král 2014, p. 34).

In contrary, an excipient is determined as a component of medicinal product, which is not a healing substance or covering packaging material (Král 2014, p. 34).

3.3.3. The medical device

We have discussed the similarity of the legislation of the EU in terms of healing substance and medicinal product. However, with the term "Medical Device", it is very problematic to construct a definition, due to different descriptions in various applicable laws (Král 2014, p.34).

The medical devices are on the level of the EU determined by three directives, which are:

I. The Directive about medical devices (hereafter abbreviated as the Directive about MD).

II. The Directive about active implantable medical devices (hereafter abbreviated as the Directive about AIMD).

III. The Directive about diagnostic medical devices in vitro (hereafter abbreviated as the Directive about IVD) (Král 2014, p.34).

The definition of medical devices can be analysed in detail, just like the analysis of the medicinal product.

With the analysis of the definition can be concluded, that it consists of two individual substances, where the first one has its characteristic as a subjective and the other one as an objective.

If we take the subjective substance definition of the medical device, we can use a general explanation ;*The Medical device is a tool, device, determined by its producer for the use by a human for a purpose.* (Král 2014, p. 37).

The objective definition of the medical device is necessary for the product to be marked as a medical device. This definition contains an objective assessment or the entire proof of its partial aspects. Firstly, there is a verification that the specified purpose of declared producer is actually reached. By fulfilling such aspects, it should eliminate the cases where the producer is presenting certain purposes of the medical device in such way, where it gets the impression that it falls under the definition. However, by regular use of this product the purpose reported by the producer is not fulfilled at all (Král 2014, p. 37).

3.3.4. The Court of Justice of the EU as the conclusion

For the deep understanding it is necessary to analyse the related judicial jurisprudence, which has to deal with the incoherence of administrative law practice along the individual member states. It is clear, that the Court of Justice of the EU has to permanently measure the principle of the free movement of goods on single internal market towards the principle of the public health protection. The situation is even more complicated, since the protection of public health is determined on the national base, while the rule of the free movement of goods are harmonized or unified. The fact, that the Court of Justice of the EU in such cases must prefer the health of the citizens of the EU is also clear.

Here comes the question if the member state has at least the right on its territory to change the category of the product. The argumentation of the industry has been based on the principle of the single internal market. The producers required all member states, to be obligated to respect the qualification, which has been made by a competent authority in the country of origin of the product (Král 2014, p. 45).

The member states on contrary have been dismissive to such action with a reference to their obligation to ensure the protection of the health of physical persons on its territory, which represents higher value than the free movement of goods. The EU's Court of Justice has admitted the argumentation of the member states, that by current situation of the law of the EU is still possible, there are some persistent differences between the member states in terms of qualification of such products as the medicinal ones or the groceries. The circumstance, that the product is in one-member state qualified as a grocery, hence can't prohibit to the other member state as an importer, to possible admit the feature of the medicinal product, if all the features and requirements are met (Král 2014, p. 42).

3.4. Theoretical dimension of pharmaceutical law

It is crucial to have a deep overview about the pharmaceutical law itself as well as its components. There is no better way how to acquire deeper knowledge about pharmaceutical law than to be focused on its systematization and closeness (Šustek and Holčápek 2016, p. 58).

3.4.1. The international and European sources of the pharmaceutical law

In terms of the international sources of the pharmaceutical law it is important to mention several international treaties. Especially the ones that are relevant for the legislature regarding the regulation of the medicinal products as well as for the medical devices. Specifically, the directives ensuring the elementary harmonization of the legislation within the whole EU through the process of transposition to the national legal forms and then directly to the effective regulations (Král 2004, p. 45).

3.4.1.1. The international treaties

The international treaties represent a collection of international laws, as it is necessary to examine their relations towards the national law. From the law theory there are two general approaches, **One-Tier System**, which is based on the assumption that the international law and the national law creates the only legal system, and, **Two-Tier System**, which comes out of the theory of co-existence of two interconnected legal systems. Neither of these systems has fully implemented applications. The most common is as called **Mixed approach**, which is based on the combination of both systems. one-tier system and two-tier system conception, where Traditionally, it is focussed more on the two-tier system. Nowadays, it is noted that the one-tier system is implied more for presidential treaties, whereas two-tier system is noted for the governmental and resort treaties (Král 2014, p. 47).

One of the most significant documents has become the **Convention of the Council of Europe**. The Convention itself is a general document of the Council of Europe and is compiled by all the member states. The Council of Europe exercises several activities in the field of pharmaceuticals. The example of the Convention against the counterfeiting of the medicinal products and medical devices is important. Such action is a big step towards crime harming the public health. This document represents a crucial reinforcement of the protection of the legal producers as well as legal distributive chain. Another action of the Council of Europe which is related to this Convention, is the acceptance of the Convention about the human rights and biomedicine (Král 2014, p. 48).

Connected to the regulation through the pharmaceutical law we can encounter the term “**Directive of the new approach**”. This is suitable to determine what the new approach is about the field of the technological harmonization. Generally said, the aim of the technological harmonization is the maximal possible correlation of all the legal forms contained technical standards, as well as the assessment’s rules of the products’ conformity. The main aim of the harmonization is to remove the trade obstacles and enforce the principal of the free movement of goods on the single internal market. The trial of a continuous elimination of the technical obstacles can find within one of the treaties of Rome (Šustek and Holčápek 2016, p. 245).

The cornerstone of the European legislation based on the new approach was the directive about general security of products and the directive about providing the information for the field of standards and technical legislature regulation. For the individual categories of products, had been decided, to imply the new approach. There have been progressively implied specific directives, which had to be fulfilled before the launch said products to the launch said products to the market (Král 2014, p. 55).

3.4.2. The European legislation of medicinal products

The procedure of the harmonization of the European legislation in the field of medicinal products is slow paced. The main goal of any rules for the production, distribution and use of the medicinal products is the protection of the public health. Such goals should be accomplished through the resources, which will not oppose the development of the pharmaceutical industry and the trade with medicinal products. To mitigate the differences of regulation between individual member states, the rules for the control of medicinal products should be specified as well as duties inclined to the appropriate organs of the member state with a purpose of compliance of the legislation (Král 2014, p. 61).

The standards and protocols to test and assess the medicinal products, could facilitate the movements, by establishing certain rules for the tests and assessments, in order to reach compilation documentation's registration and assessment of the request.

According to Král (2014) it is crucial to make sure that the innovative businesses is not disadvantaged. In order to ensure better protection of health and the abolition of replicate effort to assess the registration's request for the medicinal products, the member states should systematically prepare the reports about the assessment of each medicinal product, which they are registering. For the purpose movements' facilitating in terms of medicinal products and to prevent the repetition of similar controls carried out by individual member states, minimal requirements for the production and import from the third world countries should be established (Král 2014, p. 63.).

Another aspect, which enforces the individual approach towards the regulation of the medicinal products through the member states, is the high degree of probability of the actual legislation implied as well as wealth of the case law of the EU's Court of Justice.,

This has removed several application problems and uniformity by the interpretation of the Directive about MD (Král 2014, p. 63.).

The Directive about the MD now involves the problematic of the definition of the production, registration, distribution, labelling, classification, import, advertisement, pharmacovigilance and sanctions. However, even over the effort to make only one legislation, there are still some measures which deal with a specific aspects of the regulation of the medicinal products. The directives about the right laboratory practice are covered within these legislations, just like the right production and the clinical practices (Král 2014, p. 64.).

3.4.3. The European legislation of the medical devices

Whereas by medicinal products it is possible to talk about a practical complex harmonization of the legislation through the directive about the MD, by medicinal products it is a state of European legislation more destitute. The majority of the legislation about the medicinal products is on the level of the EU included within the three general directives has been mentioned in previous sub-chapter. The directive about MD, the directive about IVD and the directive about AIMD (Šustek and Holčápek 2016, p. 31).

The main purpose of the acceptance of the directive about MD is especially about the anchoring the basic principles and measures in the area of the single internal market by which's framework it should be effectively ensured the free movement of goods.

An important fact is also a significant disunity and incompatibility existing legislation of the individual member states. Especially important is to point out the necessity of the determination such rules of the field of regulation of medical devices, which will reflect the requirements for the assurance of the security and a high degree of the protection of patients (Král 2014, p. 64.).

Pegged to the directives mentioned above follow up another legislation, which are specific and its focus is very tight. Under such belong for example the directive about detailed specifications for the medical devices made by using a tissue of animal origin, the legislation about electronic instructions for the use of medical devices or the legislation the appointment of notified persons (Král 2014, p. 65).

II. Practical Part

Once we got through all the theories, which have helped us to understand better the market functioning in general, we should have a better overview in terms of the pharmaceutical market specifics, to know the term of regulation and what are the main instruments used within such area.

After examining all the factors mentioned above the thesis will now deal with the most crucial part and it is the comparison of the Czech Republic and Switzerland. At the very beginning the thesis will point out some legislative forms, which significantly influence the rights of firms participating on the markets, consumers, patients and lastly doctors.

4. Legislation related to the pharmaceutical industry

4.1. Overview of the constitutional order related to healthcare in the Czech Republic

Czech Republic belongs under the countries of the continental legislation therefore the main objectives of its law forms are normative legal acts, so called constitutional laws, laws, legal measures and relevant bylaws. The main focus of this section will be devoted to the wide-spread legal framework as well as to certain decrees and Legislative decrees.

The Constitution of the Czech Republic does not bring a significant contribution in terms of pharmaceutical law, in contrary the Convention of Human Rights and Freedoms is in relation to pharmaceutical law crucial. Article 6 guarantees all the individuals the right for the life and its protection (Vrubel 2011). As next article 31 claims, that every person has the right for the health protection. The citizens have to pursuant of the public health insurance the right to have free healthcare and medical equipment under the conditions determined by law (Šustek and Holčápek, p. 647, 2016).

As the most important for the thesis seems to be the problematic of the free healthcare. The objective of this provision is divided into two aspects. **Free of charge and partial delegation on the law degree** (Král, 2014, p.69).

The problem about free of charge is more sociological ranged. The majority of the population thinks, that a provision of **healthcare is for free**. Which can be sometimes misleading because medicinal products as well as medical devices have their own value, which has to at least reflect the minimum input costs, reasonable profit and eventually tax input. Now here comes the institute of the public health insurance, which should in an ideal case cover the whole price. However, the term “free of charge” does not really mean there would be no participation from the patient’s side in terms of payment (Král, 2014, p.69).

The question of payment is divided into two separated subsets. The first is represented as a standard additional payment, in a case that the price exceeded the reimbursement, which

the patient got from the insurance company. The second one is represented by so called “regulative charges” (Šustek and Holčápek 2016, p. 668).

In a case of additional payments, the rules for the reimbursement of medical devices and medicinal products are made by legislative authority, which does not exclude the possibility, that at the end of the day in certain cases the price will be higher than the reimbursement, which requires logically the financial contribution of patients. The system of public health insurance is clearly limited by its financial resources, which are acquired by the obligation to pay the insurance for public health insurance (Šustek and Holčápek 2016, p. 668).

Act. No 48/1997 of the public health insurance, change and the adjustment some of existing laws, in § 15 paragraph 5 determines, that in all groups of healing substances mentioned in **the annex 2** of the health insurance, always fully reimbursed one healing product the least or a grocery for a specific medical purposes (Vrubel 2011).

From the health insurance by provision of institutional care are the medicinal products and groceries for a specific medical purposes, individually prepared medicinal products, radiopharmaceuticals and transfusion preparation, fully reimbursed.

Of course there have been many complainers who wished for a such legislation adjustment, which would ensure him not only fully reimbursed (Král 2014, p.70)

With regard to regulatory charges, which have been established since 1st January 2008, there were some emotional and argumentative political and law discussions ongoing (Vrubel 2011). To be more specific about the amounts, the patients were obligated to pay 30 CZK for the visit at a doctor, 60 CZK for one day spent in the hospital and 90 CZK to be treated on the hospital emergency. Based on many complains and the contradiction with a term “free of charge” the Constitutional court of the Czech Republic had to deal with that. Subsequent political and legislative development led to the adjustment of the charges. The regulatory charges have been the 1st January 2015 dismissed with an exception of a charge for visit on the emergency (Šustek and Holčápek 2016, p. 580)

4.1.1. The statutory and secondary legislative adjustments of medicinal products

In the Czech Republic most of the aspects related to the pharmaceuticals are mentioned within the law of Pharmaceuticals. However, the regulation of pharmaceuticals itself is covered only partially. For example, by human medicinal products, such legislation regulates the majority of life stage of such products, nevertheless a big part of regulation is divided into different laws.

What makes it even more difficult is according to Král (2014) the fact, that unlike the legislation on the level of the EU, the law on Pharmaceuticals in the Czech Republic includes also the law about the regulation of veterinary medicinal products (Král 2014, p. 71).

Some of subsequent aspects of pharmaceutical law are adjusted in the law of narcotics.

From the implementing legislation is worth mentioning at least the decree about production and distribution of medicines, the decree about registration of medicinal products and the decree about an appropriate ways of clinical practice (Šustek and Holčápek 2016, p. 670).

4.1.2. The statutory and secondary legislative adjustments of medical devices

For the field of regulation of medical devices there are actually valid within the Czech legislation two crucial legislative measures. Firstly, is the law of technical requirements to the products, which deals with a problematic of assessment of similarities and technical questions related to the launching of medical devices on market. Secondly, there is a law about MD, which should include above the framework of the law of technical requirements to the products, also the adjustment of all other fields generally connected to the regulation of market with medical devices (Král 2014, p. 73).

As by the medicinal products, the price regulation of medical devices is contained within the law of authorities of the Czech Republic in the area of prices, the law of prices, the law of public insurance. The reimbursement regulation is generally adjusted by the law of public health insurance (Vrubel 2011).

4.2. Overview of the constitutional order related to healthcare in Switzerland

Switzerland is well known for its diversity especially because of cantonal organization. It is implied even in terms of health care. **Cantons of Switzerland have a share responsibility over the health system functioning.** Therefore, the decision made on the cantonal level have led to a bit different health system over the entire Switzerland. However, the confederation over the years has been trying to take more actions and improve the system as much as possible. The establishment of Swissmedic, which is mainly responsible for the registration and authorising market entry for pharmaceuticals and medical devices (OECD 2011).

Although cantons have their own health departments for the purpose of better co-operation and co-ordination there have been established various institutions on the federal level. As for example the Federal Office of Public Health and the Federal Office of Statistics. Both of these offices belong under the Federal Department of Home Affairs. The main responsibilities for health on federal level are the legislative and supervisory role in the following areas:

1. Sickness and accident insurance
2. Control and eradication of communicable diseases
3. Promotion of exercise and sport
4. Social insurance
5. Oversight of professional medical examinations and recognition of doctor's qualification
6. Promotion of science, research and tertiary education
7. Genetic engineering, assisted reproduction, transplant medicine and medical research
8. Protection of the health and safety of the workforce
9. Protection of the environment
10. Quality and safety control of medicines and medical devices
11. Food safety
12. Substance abuse
13. Health profession training

14. Provision of health statistics

On the other side stay cantons of Switzerland, which are in charge of:

1. Provision of health care and partial finance of hospital costs
2. Authorisation to open medical practice of pharmacy
3. Disease prevention and health education
4. Implementation of federal laws delegated by the federal government (Schweizerische Eidgenossenschaft 2016).

In Switzerland is high competition between agencies, who are offering a health insurance. The person, living in Switzerland is obligated to have a health insurance from one of the authorised insurers. The mandatory Swiss insurance is set in the Insurance Law (Loi Fédérale sur l'Assurance Maladie),(hereafter abbreviated as LAMal) (Schweizerische Eidgenossenschaft 2016).

As an interesting fact is worth to mention, that all the insurance providers, authorized by Federal Department of Home Affairs are not allowed to profit from providing basic health insurance. The basic cover is separated from an additional insurance, which is always offered to customers. Nevertheless, even the basic, mandatory insurance might be a financial burden for low-income people, therefore the confederation offers a certain subsidy, which are distributed across the cantons based on the amount of citizens, living in said canton. Each canton is obligated to reduce at least 50% of insurance premium for children and young people living in families with low or middle income (OECD 2011).

The cantons are also empowered to monitor, whether the individuals hold a basic insurance and enforce them, if needed, to enrol themselves. On the top of mandatory health insurance, there is a possibility for the Swiss citizen to enrol in so called supplementary insurance, which is also covered under the legal framework but promises additional services such as accommodation in private or semi -private rooms and dental care (OECD 2011).

4.3. Health insurance and its influence on payments of patients

Since the thesis is comparing two completely different political systems, it is clear there are differences even in terms of health insurance and the rules related to that. Health insurance is crucial for us to start understand the price regulation of pharmaceuticals itself. Some insurers offer special prices for meds as well as full reimbursement of the price of medical devices or medicinal products. Therefore, it is very significant to know the differences between those two systems to examine the real amount paid for pharmaceuticals by Swiss citizens and by Czech citizens. Well known is also the fact, that Switzerland is costlier than Czech Republic so the amount paid for the insurance by Swiss citizens seems by the naked eye incomparable. However, following examples based on real amount and percentages will show us, that the comparison of two different economies is possible.

4.3.1. Health insurance problematic in Switzerland

As mentioned many times here, Switzerland is special in terms of its cantonal distribution. The specificity does not change either when it comes to the health insurance. Every Swiss citizen, who lives in Switzerland pays a premium, deductible and a retention fee. The amount they pay for the premiums depends on canton, insurer. Children under age 18 pay a reduced amount and people from low income families have the right to get a premium reduction 50% (Maienfisch 2018).

Basic health insurance is compulsory in Switzerland. There are two types of cover. The first is **basic compulsory cover**. This breaks down into cover for illness and accidents. Standard policies cover both. Those with accident insurance as part of their employment are able to opt out the accident element and reduce their premium. This is called Franchise.

The second type is **complementary or supplementary cover**. This is optional and includes optional coverage for range of treatments not covered by basic insurance. It can also cover risks not covered by basic policies (Maienfisch 2018).

Basic healthcare covers basic healthcare and hospitalisation in your canton of residence.

Complementary insurance covers a wide range of care not covered by basic insurance, including dentistry, alternative medicine, prenatal care, travel insurance, enhanced hospital care, loss of earnings and lump sum payments if you are unable to work. Complementary insurance is separate from basic insurance even when bought with basic cover (Maienfisch 2018).

The decision on the franchise influences the amount you need to pay on a monthly basis, premium. Yet, the amount of franchise that you choose equals the amount you need to pay for health costs. In that sense, for people going not often to see a doctor, it is more attractive to choose the highest franchise possible in order to reduce costs to the minimum.

There are different possibilities for adults to pay the annual franchise (300, 500, 1500 and 2500 CHF). For children the amounts are lower, (0, 100, 200, 300, 400, 500 and 600 CHF) (Maienfisch 2018).

The mechanism works the way, if a customer decides to pay **the lowest possible option of the franchise, 300 CHF, then the monthly premium is higher.** The explanation is simple, if there is an illness or sickness, the customer, patient is only obligated to pay treatment up to 300 and the rest is covered by insurers. To make the expenditures fair, therefore he has to pay more monthly to make it equal. This possibility is often used by people with high odds to accidents. Normally, as mentioned above, if the odds of illness or sickness are rare, people try to set the franchise as high as possible to reduce their monthly premium, as mentioned above.

The mechanism of such system is quite complex. The meaning is, all the patients pay all the additional payments, if they get sick up to agreed franchise amount. However, regardless which premium you chose to pay monthly, there are subsequently other expenditures Swiss citizens have to pay when they receive a treatment. Normally they pay share of the costs, retention fee, even though the treatment exceeded their franchise, they are still obligated to pay 10 per cent of any other costs exceeding the costs above your franchise, so called coinsurance. **Maximum amount of coinsurance is 700 CHF per year,** which corresponds to the annual amount of 7000 CHF you chose to pay as a franchise. A maximum annual coinsurance applied for children is 350 CHF per year

taken from the franchise set up on 3500 CHF per year (Schweizerische Eidgenossenschaft 2016).

For better understanding a short example is provided.

Let's say you have a deductible 300 CHF, 500 CHF, 1500 CHF and 2500 CHF. You got sick and have received treatment valued at CHF 5500 in a single calendar year. The deductible chosen by you must be paid out of your own pocket. Taking cost sharing in account you have to pay 10 % on top of the remaining CHF. Then the rest is paid by your insurer (See Table 1.)

Table 1 Bill received for treatment CH 5,500

Chosen franchise per year CHF	300	500	1500	2500
Monthly payments CHF	600	500	400	300
Remaining CHF after deductible is taken in account	5,200	5,000	4,000	3,000
Costs sharing- 10 % of remaining CHF	520	500	400	300
The amount paid by the insurers CHF	4,680	4,500	3,600	2,700
The amount paid by patients CHF	820	1,000	1,900	2,800

Source: public survey, self- illustration

From this example we can observe certain patterns. Even though the patient with the highest franchise determined pays at the end of the day, even more than his insurers, his monthly payments are two times lower than the ones, set up by a patient with a franchise on the lowest amount as possible.³

³ The used data are based on the statements of some Swiss citizens with different franchises

The payments distinguish from the insurance agency to insurance agency and it even **depends on the rules of said canton**. Certain agencies offer special packages, where certain meds are covered by such insurance. Always depends on agreement and on what said agency offers. But the principle stays the same. In Switzerland to spend one day at the hospital costs 15 CHF (Schweizerische Eidgenossenschaft 2016). Especially this amount distinguishes to Czech Republic significantly. Since the payments for staying at the hospital have been dismissed in the Czech Republic, Czech citizens do not pay for such service.

4.3.2. Health insurance in the Czech Republic

In the Czech Republic is obligatory to have health insurance as well. Each citizen must have one, according to legislation. In many cases the state pays for the said health insurance. Here we speak for example about dependent children up to 26 years, seniors, women on maternity, students, individuals seeking for a job registered on Town Council (Ministry of Health Czech Republic 2012).

The legislation in the Czech Republic determines three main types of payers of the premium. The employer, then the state which pays the insurance for certain groups of individuals, explained above, the latter one the insured ones as a self-worked employee. By employees, the premium is enumerated from gross wage. Then it is divided to **4,5 %** taken directly from gross wage of employee and **9 %** is the amount the employer pays to state for the employee. With entrepreneurs and self-worked employees, the calculation of the premium is taken from a half of their revenues from the previous year, divided into 12 months and then 13,5% from that amount is sent to state for the health insurance. However, if the amount which is used for the calculation of premium is lower than the minimum wage of Czech Republic, which is 12,200 CZK, the person is obligated to pay for the health insurance 13,5% from the said minimum wage (Ministry of Health Czech Republic 2012).

4.3.3. The comparison of the amount paid for the health insurance based on percentages

Compared to Switzerland is clearly the amount the Czech citizens pay for the insurance lower, however we must take in account the percentage of income Swiss and Czech citizens give away to finance the insurance. We already know that in the Czech Republic the percentage is 13,5 % from the minimum wage and then it is applied to any other highs of wages. This is determined by legislation (Ministry of Health Czech Republic 2012). However, in Switzerland the situation changes, since the payments are individual and always depend on the agreement with the insurance company.

To make it clearer the thesis provides an example taking in account the average wages in the Czech Republic and Switzerland.

The average wage of hair dresser in the Czech Republic is approximately 27, 800 CZK (Eurostat, 2015). In Switzerland the average wage of hair dresser is approximately 92, 225 CZK (CHF4,375) (lohncomputer.ch 2016) (See Table 2).⁴

Table 2 The percentage of the health insurance expenditures

Switzerland		
Monthly payments of premium CHF	Monthly payments of premium CZK in thousands	The percentage related to the average wage
300	6,324	6,86%
400	8,432	9,14%
500	10,540	11,43%
600	12,640	13,71%

Source: public survey, self-illustration

The data has been taken according the statements of 10 Swiss citizens, who had different agreements with their insurers. The numbers can distinguish from the insurance agency to insurance agency.

⁴ Based on the exchange rate of Central National Bank 2018 - 1CHF=21,080

If we compare the percentages in Switzerland in terms of the total amount paid for the insurance, we see that Czech Republic has set its percentage for health insurance in approximately $\frac{3}{4}$ of cases higher. However, what is worth mentioning is the fact, that the compulsory Swiss insurance does not cover dental expenditures. Then the case of accidents where the patients are obligated to pay the amount which corresponds to their agreement with the insurer plays also a crucial role in terms of total expenditures on healthcare. Summa summarum, the exact percentage taken out of Swiss salaries is hard to determine, because it always depends on the individuals. What kind of franchise they chose, how risky their life is and moreover on the final agreement with their insurers.

5. Pricing policies of pharmaceutical and reimbursement of medicines

Drug prices are regulated in many countries. Some want to make sure that the prices are reasonable. Related to such problematic is even the launch of new drugs to market and their examination and testing. The main reason of such assessment is to provide the patients the most efficient and affordable products. However, when innovative medical products come to scene, the situation changes, because such products need specific clinical testing and special technologies to invent a drug, which can extend life of some individuals even for years. This chapter will provide the information about pricing and reimbursement policies in the Czech Republic and Switzerland with a comparison, which will follow.

5.1. Pharmaceutical pricing policies and reimbursement in Switzerland

In Switzerland, the basic health insurance finance all the drugs included in the positive list. In the 2015 the list contained 3,700 drugs (6,815 presentations), which represents more than 57% of available drugs (Interpharma 2015).

Which means that all pharmaceuticals, which are reimbursed by basic health insurance must be listed in this document so called “*Liste des spécialités*”, which has been established by Federal Office of Public Health. As mentioned above, in terms of ambulatory care, the patients normally pay 10% of the costs of medicines, after the expenditures exceeded the chosen deductible. However, once the positive list has been mentioned, there is necessary to provide an overview, what kind of drugs has the right to be reimbursed and what is the process like in order to get certain drugs reimbursed. Table 3. shows the pattern of pricing of a new drug, that is about to be launched on the market. To understand better such scheme, the thesis will provide the detailed explanation of such process (OECD 2007).

There are certain conditions, that must be fulfilled in order to be listed in the positive list. The outcome of the assessment must be always approved by authorities, either Swissmedic, which is mainly responsible for the registration and authorising market entry for pharmaceuticals and medical devices or General Office of Public Health. The

effectiveness, appropriateness and value-for money are the criteria, which must be taken on board while testing a new drug. In the Figure 5 such step is described as quality, safety and efficacy criteria. Especially effectiveness has a specific examination (Interpharma 2015).

The pharmaceuticals, which are about to be listed on the positive list have to go through controlled clinical trials. Once the medicine was found out as an effective enough, second steps comes on the scene, **value-for-money**. This terms have its name for certain reason. The medicine is considered to be value-for-money means, when it produces a given therapeutic effect at the lowest possible cost. Now even another country is included in order to assess said medicine as best as possible. General Office of Public Health reflects to the price proposed by the manufacturers compared to its manufacturer price abroad. Exactly the manufacturers are the ones, requesting the drug being listed on a positive list. Additionally, the therapeutic effectiveness of said drug is compared to other medications with an identical indications or similar effects. Daily cost or cost per cure are compared the same way as well.

The case of medical devices is taken in account too. Assessment of these is sometimes provided on request of providers of health, health insurers, health authorities or patients. In practice, usually drugs which are candidates for the reimbursement are then also listed, it is really rare for drug being a candidate for reimbursement and not being put on the list (OECD 2007).

After authorisation and classification comes finally the question about pricing. Firstly, The General Office of Public Health in consultation with Federal Medicines Committee, (see Table 3.) consider the main elements to set a framework for price regulation. To be considered are facts as: relative effectiveness of the new drug with a comparison to the existing ones and prices of the new drug in foreign countries. Of course the prices are compared only with countries with a similar or comparable economic structure. In terms of Switzerland, such countries are Germany, Denmark, the United Kingdom and Netherlands, as first ones to be considered. The main essential for such comparison is a rule that the **ex-factory price**, which is a term for price of the products taken directly from a factory, can't exceed the average ex-factory price. There are some exceptions in

comparing the prices with said countries, if the price in one of these countries is either too high or low, such data are not taken in account for the average considered. Then Switzerland seeks for another country, which can play a role of a substitute (OECD 2011).

Sometimes can even happen, that said drug is not yet available in other countries, because Switzerland is a first country to launch such medicine on the market, so then some parts of assessing will not be available for the benchmarking. If the effectiveness of a new drug happens to have a similar effect as the existing ones or not have anything more effective, to be put on the list, such drug must be priced at a lower level.

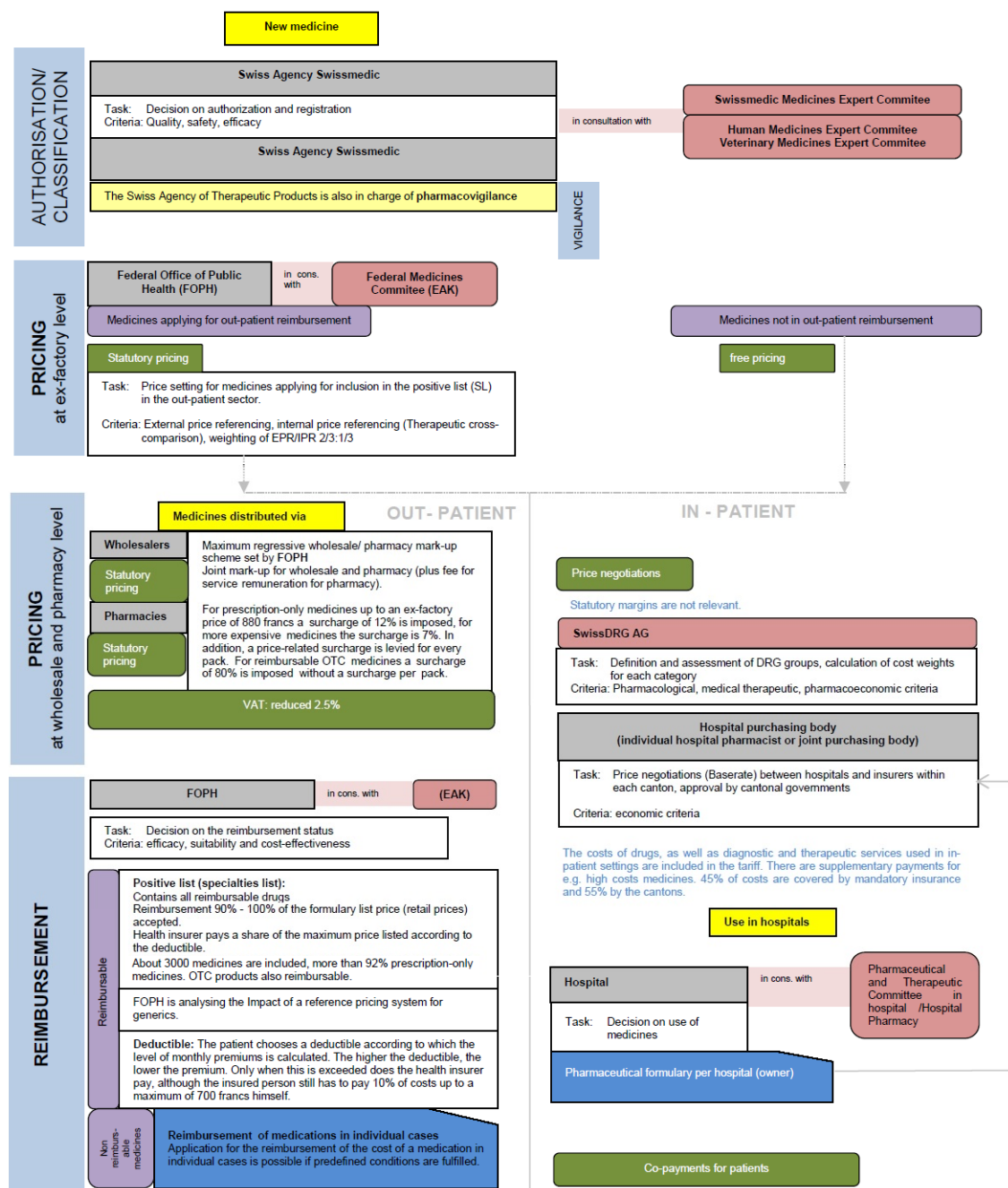
The Drug Commission classifies new drugs in certain categories according to their level of innovation. Clearly, when a new drug is highly innovative R&D costs must be taken in account. For such drugs are prices set higher than for drugs, that need less innovative technologies and R&D to be invented (OECD 2007).

Worth mentioning, that drugs listed within the positive list are regularly subjects to periodic assessments to make sure they still offer value-for-money. First assessment takes place after 24 months of the inclusion to check if the entry price was accurate and appropriate. If the price happens to be too high, then the General Office of Public Health lower the price. Then after 7 years from inclusion in the list, drugs must complete the assessment of effectiveness.

Maximum price of the drug is set in the positive list after the inclusion and cannot be increased without another authorisation from the General Office of Public Health's side.

The positive list contains the maximum reimbursement price. The calculation of such price is taken as the price of manufacturer and the distribution's percentage of mark-up (wholesale and pharmacy) (see Table 3.) All the costs of transportation, dispensation and of capital are taken in account (OECD 2007).

Figure 5 The mechanism of pricing and reimbursement of pharmaceuticals in Switzerland



Source: Schweizerische Eidgenossenschaft

5.1.1. Public price and reimbursement of listed medicines

Public prices are understood as prices, that are paid by basic health insurance. It is distinguished to at-ex factory level by the margin of wholesalers and pharmacists. In the positive list is the final, maximal reimbursement price contained of all the elements,

which is ex-factory price set in the positive list, distribution margin, payment for pharmacist's services and valued added tax 2,5%. However, this counts only for reimbursed pharmaceuticals. Pharmaceuticals, which are not listed in the positive list have so called "Market price" and the payments go out of the pockets of patients (Schweizerische Eidgenossenschaft 2016).

Important is also to identify, when have the patients the right to get their drugs reimbursed. In Switzerland it works a bit differently than in the Czech Republic.

The thesis has mentioned the deductible several times, so the mechanism of such health system is clear. Nevertheless, worth mentioning the fact, regardless the prescription of doctor or not, patients always have to pay for their meds and then they send the bill to their insurers to get some repayment. However, such action can be taken only, if they have already exceeded their deductible set and have the right to ask for the reimbursement from their insurance agency. The amounts always distinguish according the type of deductible, as described in previous chapter. Again, they can only get their money back for the drugs, listed within the positive list. Such action does not imply for the regular drugs available in pharmacies, which are not included in the positive list (Schweizerische Eidgenossenschaft 2016).

According to statements of asked Swiss citizens, the majority mostly does not even require the reimbursement from the insurers after the exceeded deductible, as long as it is not about thousands Swiss francs. The mechanism of reimbursements is not control automatically. If the patients don't send the bill of the meds to the insurance agency, the reimbursement of pharmaceutical costs does not have to eventually take place.

5.2. Pharmaceutical pricing policies and reimbursement in the Czech Republic

Czech Republic has adopted a new reimbursement system of medicinal products in 2008. The main adjustments have been imposed mostly to the law of public health insurance. The Ministry of Health used this chance to reform reimbursement mechanism and the new regulative principles of pharmaceuticals followed. The main decisions about price and reimbursement

belong under the responsibility of State Drug Control Authority and Ministry of Health. New system of reimbursement brought a new mechanism of reference groups. The term “reference groups” is a term for generally therapeutic similar medicinal devices, which have the same determination of basic reimbursement (Synek 2018).

The final price of meds in pharmacies is determined by the compliance of several substances. Czech Republic distinguishes the **price of the producer and the margins**. Firstly, the margins are regulated by setting the maximal price, which can't be exceeded. The margins are common for all the distributors and pharmacies. The maximal price is the amount, which all the subjects can add in total. The collaboration in terms of anticipation is necessary. The previous distributors must set such margin to leave some space for the distributors, who come after. Normally in praxis, the pharmacies are the ones, who get the majority of margin. The margin is basically the only revenue of pharmacies from the reimbursed mass production of drugs, beyond the mark-up the pharmacies do not get any other funds from the health insurers. The maximal price of margin is depending on the producer's price and has a degressive character. The higher the price of producer, the lower margin the pharmacies can get (Král 2014).

Secondly, the price of a producer is mainly based on the factory price tracking, known from previous subchapter 5. 1 as an ex-factory price. As discussed in the mechanism of price setting in Switzerland, Czech Republic follows the same principle. First of all is the product's price compared to the prices of the same product to countries with close economic standards, market functioning and purchasing power parity. Such group of countries is so called “**Reference basket**”. Czech Republic compares the prices with Estonia, France, Italy, Latvia, Hungary, Portugal, Greece and Spain (Vrubel 2011). The maximal price of the medicinal product's producer is then set according to average prices in these countries. The procedure of tracking the price is similar to Switzerland.

5.2.1. The price regulation of medicinal products and medical devices

In the Czech Republic, all the medicinal products, which do not require a prescription (free sold drugs), are not reimbursed from the public health insurance.

Therefore, for such products, there is no regulation of producer's price neither margins. Although the Ministry of Health still observe an unwarranted eventual excessive price increase of unregulated medicinal products, and take an action if necessary (Synek 2018).

However, there are some exceptions, even for the set of reimbursed drugs, for which the regulation of producer's price does not imply. Normally such case occurs, when the product is highly competitive. This is based on the rule, if a certain healing substance is included in at least four medicinal products of at least four mutually independent producers, then is not necessary to regulate such products by setting the maximal producer's price. For instance, the healing substance *paracetamol* is included in a medicinal products so called Acifein (Herbacos company), Ataralgin (Glenmark), Coldrex (GlaxoSmithKline), Daleron (Krka), Efferalgan (Bristol-Myers Squibb), Daleron (Nycomed), Panadol (GlaxoSmithKline) or Paralen (Zentiva). We can then say, that the market with a healing substance *paracetamol* is competitive enough, hence there is no need to regulate the producer's price, since the regulation is made a natural way, by competition. Nevertheless, regardless if the regulation of producer's price is implied or not, all the medicinal products are regulated by maximal margin united for the entire distribution chain and pharmacies (Synek 2018).

Nowadays the system of health insurance registers over 9 000 reimbursed medicines and approximately 3 000 is fully reimbursed. Almost half of these belongs under the healing substances, where is no need to set a maximal producer's price, because of the high competition. Approximately 54% of reimbursed drugs is regulated by the maximal producer's price and margin (Synek 2018).

5.2.2. Reimbursement regulation of pharmaceuticals

We have already mentioned a positive list, under which have certain drugs the right to be reimbursed. Czech Republic has established a new reimbursement system the 1st January 2008. Such system is based on the reference groups, which belong under positive list. Each reference group contains certain drugs, which are basically therapeutically interchangeable. The assessment of medicines, which share the same healing substance is based on the comparison, with all the drugs, already classified under certain reference group. As an outcome of this kind of system, is taken a fact, that only medicinal products,

which's pharmacotherapy has demonstrable and qualified results and the usage is cost effective, safe and efficient (Kaslová 2018).

The amount of reimbursement itself is firstly set according to **the cheapest foreign prices**. Secondly is the reimbursement of concrete medicinal product compared within the whole **reference group** and lastly, with a respect availability of fully reimbursed medicinal products within groups **of annex 2**, the law of public health insurance, which will be more describe below.

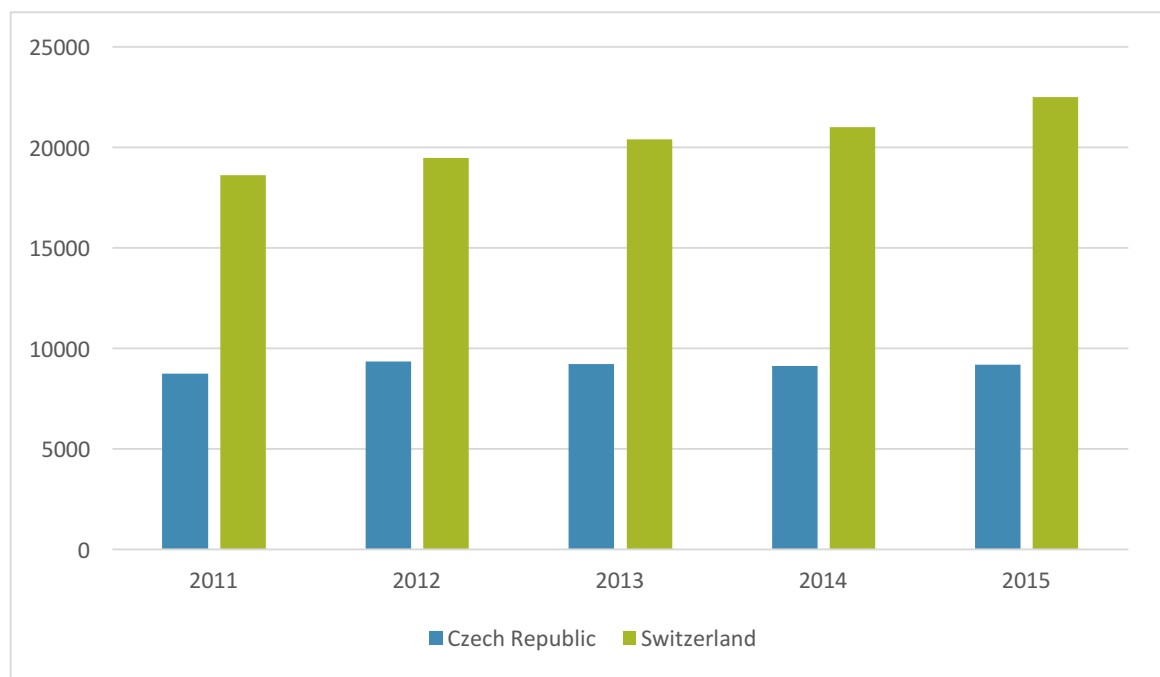
By groups determined within the *annex 2*, the law of public health insurance, the patient of Czech Republic must **have fully reimbursed** at least one medicinal product from groups of medicines included *in annex 2*. For example, for patients with blood clotting disorders, there are several medicines determined for the treatment. However, only one medicine out of the whole group *annex 2* of the drugs specialized for the blood clotting disorders is fully reimbursed, so called *Warfarin Orion 5mg*, where the healing substance is *warfarinum natricum*. In contrary, under the same reference group belongs for example *Pradaxa 110 mg*, with a healing substance *dabigatran etexilate mesylate*, which is not reimbursed at all (Kaslová 2018).

The reimbursement of groups classified in *annex 2* of the law of public health insurance leads to such mechanism, where all the medicinal products belonging under this group, get per unit of daily therapeutic dose, the same reimbursement. The amount of per unit of daily therapeutic dose is compared to countries with the same reference basket (Kaslová 2018).

5.3. The comparison of pharmaceutical spending between 2011-2015

Pharmaceutical spending contains the expenditures on prescription medicines as well as self-medication. However, medicines consumed in hospitals are excluded. The final amount of expenditures includes wholesale and retail margins as well as value-added tax. Following graph shows the difference between the total annual amount paid by consumers in Switzerland and Czech Republic between 2011-2015.

Graph 1 Pharmaceutical spending CZK per capita 2011-2015



Source: OECD data, self-illustration

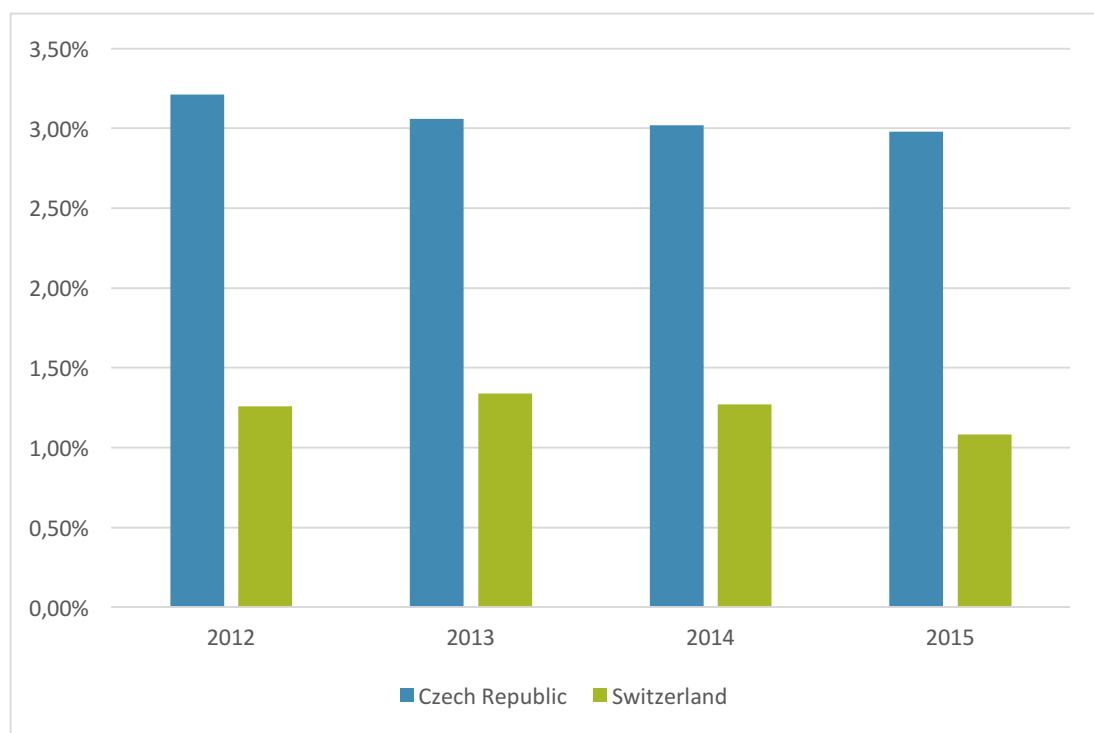
The difference between the expenditures is observable. While in the Czech Republic the total expenditures of pharmaceuticals have mostly stable or partially decreasing character, the total expenditures of pharmaceuticals in Switzerland have increased significantly since 2011. As one of the reasons, the thesis sees the fact, that since 2011 the major pharmaceutical company in Switzerland Novartis, Roche introduced highly innovative drugs against cancer and multiple sclerosis. Such treatment requires higher expenses, due to costly technologies for the R&D (Novartis 2011) .

Unfortunately, the data for 2016 from OECD report are not available yet, however we can assume an increase in total pharmaceutical spending in following years as well (OECD data 2015).⁵

⁵ Based on the exchange rate of Central National Bank Czech Republic, valid 4.5.2018 USD1=21.310 CZK

To show the annual total expenditures on pharmaceuticals more accurate following Graph 2 depicts the ratio of annual pharmaceutical spending and average income between 2011-2015 in Switzerland and Czech Republic.⁶

Graph 2 Total pharmaceutical spending of average annual income in the Czech Republic and Switzerland



Source: Eurostat, self-illustration

From the Graph 2 the percentages of expenditures show, that Czech citizens spend in total higher percentage of their annual income for pharmaceuticals. In both countries certain pattern is observable. Although, the average income has increased in the Czech Republic as well as in Switzerland, the percentages of total expenditures on pharmaceuticals remain stable.

⁶ Based on the exchange rates of Central National Bank, 2011-CHF 1=22.4 CZK, 2012- CHF 1 =18.6 CZK, 2013-CHF 1=21.09, 2014- CHF 1= 20,6 CZK, 2015- CHF 1=22.3 CZK, 2016- CHF1=24.6 CZK

6. Pharmaceutical trade in Switzerland and Czech Republic

6.1. Pharmaceutical trade in Switzerland

Switzerland belongs to the largest trade leaders in terms of pharmaceutical products. In Europe is Switzerland behind Germany the second largest pharmaceutical producer. In 2014 the Swiss export reached CHF55.13bn and the forecast for the following years seems very promising for Switzerland, in terms of enhancing the export (See Table 4.). The top export destinations for Switzerland are Germany, United States, France, United Kingdom and China (Business Monitor International 2011).

Novartis, Roche and Actelion, which are the major drug makers in Switzerland, celebrate a huge success especially with a production of immunological drugs, and their profits increase the year by year. Especially Novartis, that keeps its first position within the worldwide ranking of drug sales with the total sales USD 48 billion in 2016 ⁷(OECD 2016). The glory of Switzerland in terms of pharmaceutical exports is attributed to a high-value production of pharmaceutical products and great efficiency of drugs. However, nowadays, where the industry requires cost reductions to maximise profit margins, there has been a new trend established, to outsource the production of drugs to low-cost locations such as India or China. Nevertheless, such expansion needs a general increase in manufacturing standards and implementation of standards for bioequivalent production, therefore this is most likely to remain restricted to simple small-molecule drugs (Business Monitor International 2011).

The Swiss pharmaceutical imports did reach in 2015 EUR 20,688 mil. (527,544 mil CZK) (see Table 3) and is expected to rise steadily as the pharmaceutical market is dependent on imported products provided by major multinationals from the US, as well as several smaller companies.

The country has approximately a 9.5% share of the world pharmaceutical market, and it is expected to increase as the generic market expands. Prominent international producers

⁷ Based on the exchange rate of Central National Bank, 2015- USD 1=21.31CZK

and distributors in Europe will try to increase their trade with Switzerland as the generic market expands.

In order to ensure a good functioning trade between Switzerland and other countries, the EU validated an international agreement that is removing customs duties on all pharmaceuticals imported from (Business Monitor International 2011). The Table 3 provides an overview about Swiss pharmaceutical import, export, turnover, trade balance and change over previous years between 2011-2015.

Table 3 International trade with pharmaceutical and medicinal products in Switzerland

Time period	Turnover	Export	Import	Trade balance	Change over previous year in %	
	in mil. CZK				Export	Import
2011	1765,977	1245,573	520,404	725,169		
2012	1934,354	1359,66	574,694	784,967	9,159	10,432
2013	1657,041	1196,817	460,224	736,593	-11,977	-19,918
2014	1778,294	1292,162	486,132	806,03	7,967	5,629
2015	2009,783	1482,239	527,544	954,695	14,71	8,519

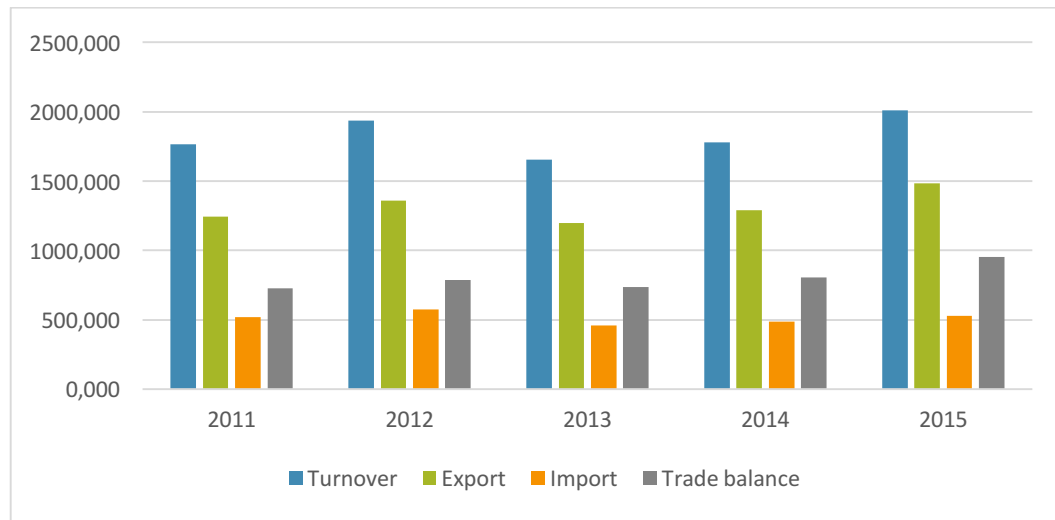
Source: Efpia, self-illustration

The most significant contribution of exports to the Swiss revenues has been calculated in **2015 to 1482,239 mil. CZK**. The same year also the highest trade balance is observable, **954,695 mil. CZK**. In 2013 the change over previous year got into **negative numbers** since imports and exports decreased.⁸

Following graphs depicture the trend between imports and exports of pharmaceuticals using the values from the Table 3.

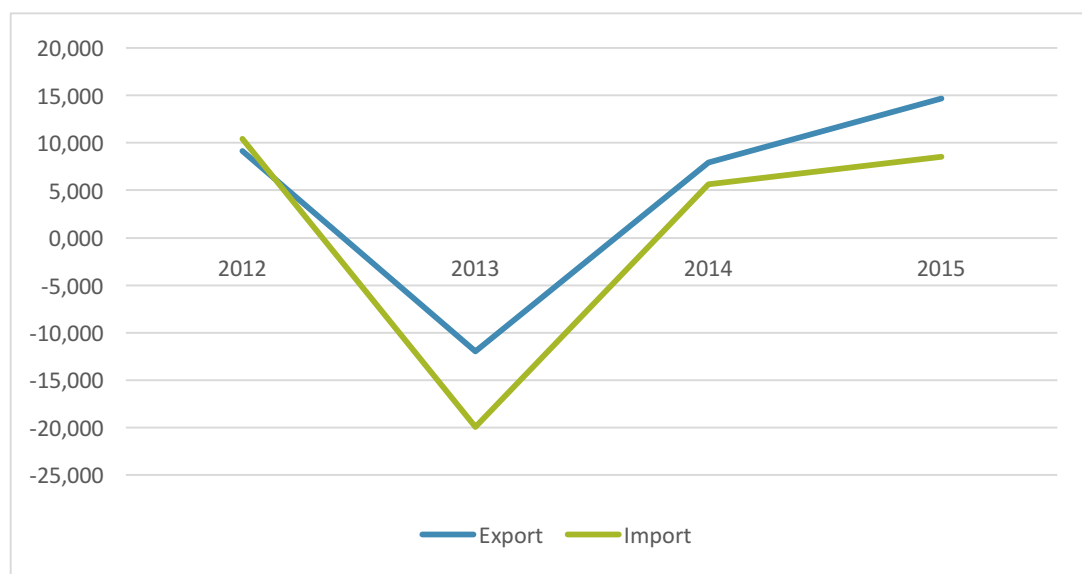
⁸ Based on the exchange rate of Central National Bank Czech Republic, valid 4.5.2018, EUR 1= 25.5 CZK

Graph 3 International trade with Pharmaceuticals and Medicinal products in Switzerland 2011-2015



Source: Efpia, self-illustration

Graph 4 The percentage of change over previous year in %



Source: Efpia, self-illustration

6.1.1. The landscape of competition between Swiss pharmaceutical companies

Despite its small geographical size and population is Switzerland one of the largest pharmaceutical player in Europe, there is surely enough space for the competition between drug makers. As mentioned on the beginning of chapter 6. the domestic manufacturing Swiss sector is led by the major multinational companies, Novartis and

Roche. These two companies own more than 60% of the domestic production of pharmaceuticals in Switzerland and are well known especially for their innovative technologies and enhancing pharmaceutical development (Business Monitor International 2011). Nevertheless, the left 40% of pharmaceutical industry is fulfilled by international drug producers, multinational companies, which are present either directly or indirectly. There are many ways how to participate on the market as importers, through partnerships or similar collaborative deals with another companies (Business Monitor International 2011).

However, nowadays as the trade with generics is highly demanded there is even more space opening for multinational companies. Such growing potential of expanding trade with generics starts to attract the competitors from all around the world, by advanced patent expirations. Especially from the low-cost countries as **India the market with generics presents a great opportunity to increase the profits**. However, the Swiss market with generics lags behind those of Germany and the UK and so far it remains that way. The forecasts of expanding market with generics in Switzerland does not seem to be changing in following years. One of the reason is the dominant position of domestic-based firms as Novartis and Roche (Business Monitor International 2011).

Despite a big success of Swiss pharmaceutical industry, in the meantime parallel trades remain a threat due to high prices of medicines within the Swiss market compared to European averages. In the 2008 the Swiss parliament voted in favour of parallel import for specifically patent-protected goods with the exception of pharmaceutical goods, where the protection still remains (Business Monitor International 2011).

6.2. Pharmaceutical trade in the Czech Republic

Czech Republic is a strong competitor in terms of generic production, which has even increased significantly by the merger of one of the major countries' pharmaceutical manufacturer, Leciva with one of the Slovakia's leading pharmaceutical companies, Slovakofarma. As a result of this merger, well known Zentiva has been established (CBI market survey 2010).

Despite this important merger, Czech pharmaceutical industry characterizes itself as a country with a high degree of foreign ownership. However, the foreign companies must face an extremely strict regulatory environment as explained below.

Czech Republic does not have really big production of branded pharmaceuticals, we could even say, the production is minimal. One of the reasons is the easiness to obtain these from neighbouring countries, (Germany, Austria). Due to the parallel-low priced patented pharmaceutical products is Czech Republic forbidden by the EU's accession treaty to high-price EU markets (e.g. the UK), which limits the Czech distributors and drug makers to extent their production to some of high-price foreign countries (CBI market survey 2010).

The major leading pharmaceutical companies in the Czech Republic are Zentiva, Ivax, Pliva Lachema and Farmak. Additionally, on the Czech pharmaceutical market are active even some multinational companies as Roche, Merck and GlaxoSmithKline. As an interesting fact, worth to mention, that exactly these three multinational companies have even indicated an increase in sales, while financial crisis (CBI market survey 2010).

Czech Republic has become very popular especially for its R&D. Together with Hungary belongs to the profitable spots for pharmaceutical research in Central and Eastern Europe. Such research is even supported by suitable environment in terms of the amount of universities and research institutes which are focused on life science. Czech Republic tries to keep up with its competitors from the entire Europe exactly by enhancing the R&D and trying to support universities, focusing on the pharmaceutical problematic. Despite, the enhancing R&D and support the pharmaceutical research is being given from the state, there is a different issue with a regulatory environment. The strict regulations started to discourage innovative pharmaceutical companies. The Ministry of Health has implemented new rules, where it requires doctors to prescribe drugs by active substance rather than brand, which basically means that the patients will get the cheapest version of drug prescribed, even regardless the better efficiency of more expensive drug (CBI market survey, 2010).

Czech Republic's exports of medicinal and pharmaceutical products have been calculated to **33,354 mil CZK** in the beginning of the year 2011 (see Table 4.). By the year 2015

the numbers have significantly increased. Nevertheless, the trade balance between exports and imports is still in negative numbers. The most significant year in terms of revenues from exports was 2015 where the exports have been calculated to **54,774 mil. CZK**. However, the lowest negative trade balance we can observe in 2014, when the exports were 52,760 mil. CZK and imports 88,051 mil.CZK (Efpia 2016).⁹

Table 4 International trade with Pharmaceutical and Medicinal products in the Czech Republic

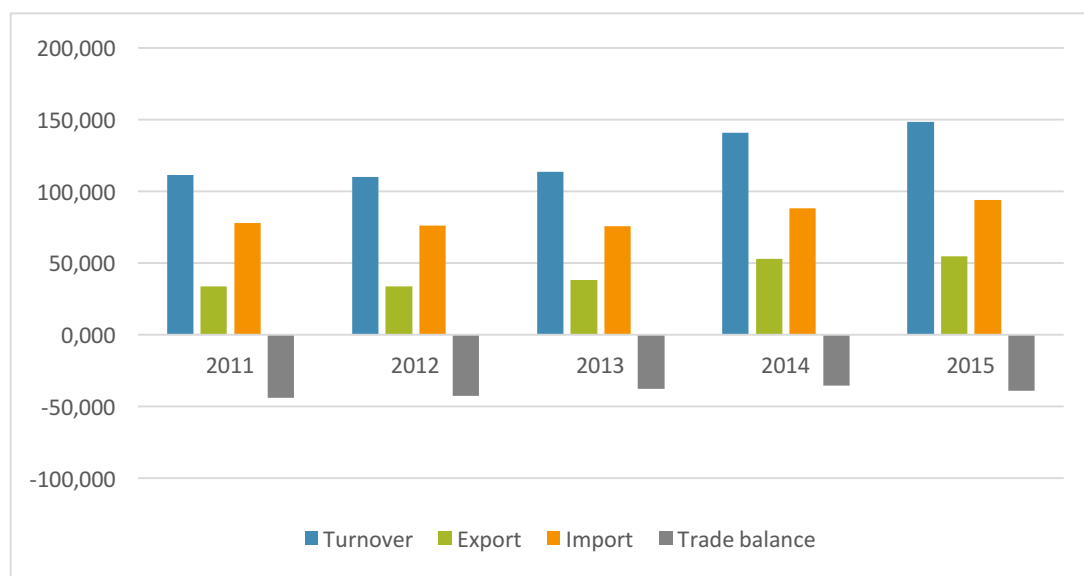
Time period	Turnover	Export	Import	Trade balance	Change over previous year in %	
	in mil. CZK				Export	Import
2011	111,257	33,584	77,673	-44,09	.	.
2012	110,058	33,762	76,296	-42,534	0,532	-1,773
2013	113,475	37,995	75,48	-37,485	12,538	-1,07
2014	140,811	52,76	88,051	-35,292	38,859	16,655
2015	148,563	54,774	93,789	-39,015	3,818	6,517

Source: Efpia, self-illustration

Following graphs depicture the trend between imports and exports of pharmaceuticals using the values from the Table 3.

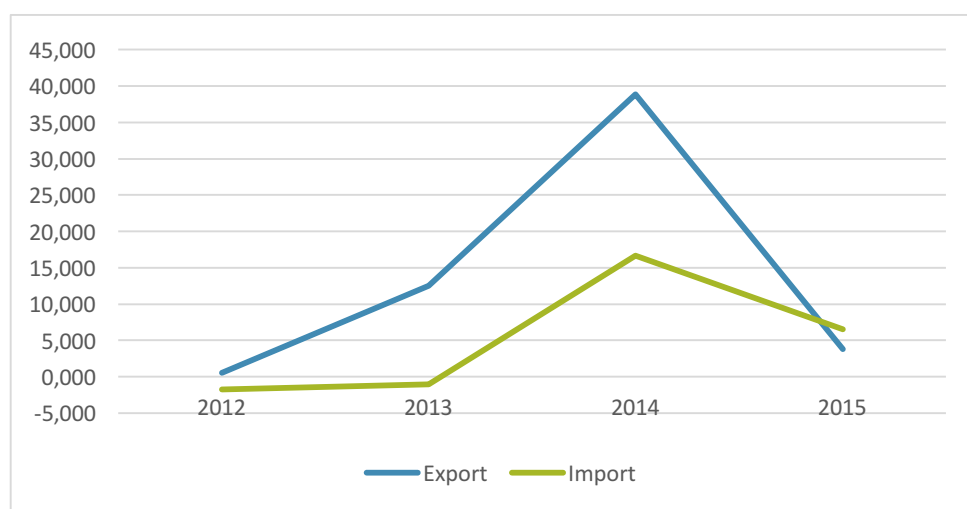
⁹ Based on the exchange rate of Central National Bank Czech Republic, valid 4.5.2018, EUR 1= 25.5 CZK

Graph 5 International trade with Pharmaceutical and Medicinal products in the Czech Republic 2011-2015



Source: Efpi, self-illustration

Graph 6 The percentage change over previous year in %



Source: Efpi, self-illustration

7. The comparison of socio-economic consequences of the pharmaceutical price regulation in the Czech Republic and Switzerland

After examining the functioning of the both health systems and reimbursement mechanisms, we can finally focus on the main consequences that come out of it. This section will provide the comparison of the both health systems with some examples as well as the main differences between the reimbursement mechanisms. Socio-economic indicators of pharmaceutical prices will follow.

7.1. The comparison of the health systems in the Czech Republic and Switzerland

As the main difference between these two health systems can be taken the fact, that in the Czech Republic works a state based health system, unlike Switzerland, where the private institutions have the main word. Czech citizens can't choose from as many insurance opportunities as the Swiss ones. Czech Republic has only a few insurance companies, which do not distinguish to each other significantly. Although, all the Czech citizens are obligated to have a health insurance they can't pay for better service neither for better facilities. The thesis found disadvantageous, that the conditions in terms of health system are the same for everyone, regardless the will to pay more. This implies also for the maternity service in maternity hospital, where the mums to be have no chance to pay for a single room to have some privacy (Majerová 2018).

As mentioned at the beginning of this chapter, in the Czech Republic is only few insurance companies, which do offer basically the same service. Therefore, the citizens can't really choose exactly what they want according their needs. In Switzerland with a wide-spread possibilities of insurers the citizens can basically pay for any better service they require. Even if the basic health insurance is obligated to everyone, it is up to individuals what agency they choose and what amount they want to pay monthly. The insurance agencies may not differ significantly in terms of monthly payments and the price of franchise, but what services they offer differs significantly (Maienfisch 2018).

According to statements of some Swiss citizens what is the biggest difference between the individual insurance agencies are the various products and services they offer on the top of your deductible. Basically it works the way, that the insureds choose the company that suits them the most, according to their jobs, diseases and life style. Some insurance companies offer reimbursed contact lenses, for the ones with vision problems, some companies offer an alternative treatment for allergies, always depending on the needs of the insured. The state itself, as the Ministry of Health intervenes very little to the health system. Only when there is a need to reimburse the deductibles for low-income families and students or when it is necessary to observe any new patterns in terms of new drug launched, clinical testing and putting the new drug on the positive list. Then the action is taken by the collaboration with Swissmedic (Maienfisch 2018).

In contrary, since the Czech Republic has a state in the main role, there is not enough space for individuals to choose. Sometimes the insurance companies, as for example Military insurance agency or General insurance agency, offer vouchers for certain activities for their insured, e.g. one free entry to the public pool or the possibility to try to shoot from the gun.

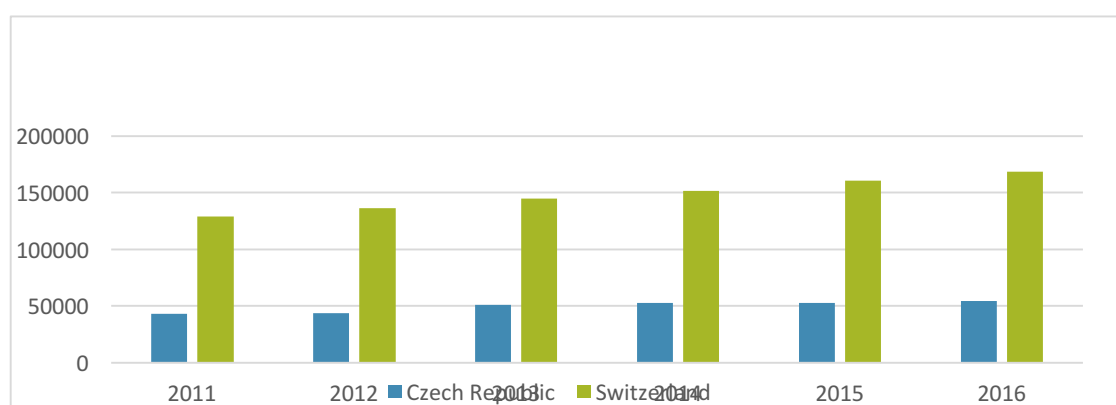
However, what the thesis finds useful is the state's aid for those, who can't afford to pay health insurance out of their own pockets. On the other hand, Czech Republic has experienced many cases, where such financial relief has been used many times. Since some individuals get the health insurance for free, they do not value enough such financial support and try to squeeze out of the system as much as they can, by pretending several diseases to get fully or partially reimbursed drugs. According to MUDr. Kotík, situations, where the drugs have been acquired for free and sold for very expensive prices in abroad, are not rare. So here comes the question, whether the state full support in terms of health insurance is really that positive and should not be restricted for some groups.

In Switzerland, where everyone is responsible for his own insurance, all the contracts and deals are made independently on the state, abuse of the system is not common. Because everyone is well aware of the amount he pays monthly, and there is not much space for the abuse (Kotík 2018).

7.2. Health spending in Switzerland and Czech Republic 2011-2016

Health spending indicates the final consumption of health care goods and services. The following graph represents the total annual health expenditures per capita between 2011-2015 in Switzerland and Czech Republic. Compulsory health insurance, voluntary health insurance, private financing such as household's out-of-pocket payments and government spending are involved in the total amount, since the health care is financed through these (OECD data 2016).¹⁰

Graph 7 Health spending per capita in Switzerland and Czech Republic 2011-2016



Source: OECD data, self-illustration

As in previous graph from the chapter 5, we can observe an increase in terms of health spending in Switzerland. The thesis sees a possible effect of highly innovative drug's launch on the total expenditures. The Swiss citizens might have agreed on new conditions with their insurance companies, due to higher availability of highly innovative drugs since 2011. **The amount of health spending changed since 2011 from 128,883 CZK to 168,675 CZK in 2016.** The situation in the Czech Republic in terms of health spending remains stable, since the amount of insurance is not negotiable with insurance companies and the amount paid monthly is determined by State. **The Swiss franc has been fixed in 2015 by Swiss Central Bank**, therefore the exchange rate has no impact to the graph and

¹⁰ Based on the exchange rate of Central National Bank Czech Republic, valid 4.5.2018 USD1=21.310 CZK

the change of variables is depending on the individual preferences during the year 2011-2016.

7.3. Pharmaceutical's reimbursement, inequality and the negative consequences of the price regulation in the Czech Republic compared to the Swiss health system functioning

The thesis has discussed the principles of reimbursement's mechanism for the Czech citizens. Now we should understand what kind of drugs are contained in the list with reimbursed pharmaceuticals and how is the final price set. However, what has not been examined so far, are the negative consequences of the pharmaceutical's price regulation and inequality between treated individuals.

As the chapter about reimbursement of the listed drug in the Czech Republic explains, nowadays the list contains 9,000 of reimbursed drugs and approximately 3,000 drugs from the list are fully reimbursed. However, although the number of fully reimbursed drugs seems to be high, there are another aspect, which should be taken in account. Starting from the beginning with the reference groups. We already know, that each reference group is supposed to be specified for certain diseases, e.g. skin cancer, blood clotting disorders and many others (Kotík 2018).

Always, at least one drug from the reference group must be fully reimbursed, which means that the patients pay nothing for the medication. Take an example about the individuals for blood clotting disorders. The drug, which is fully reimbursed and contains the substance which should help people to cure such disease is called *warfarin Orion 5mg*, (see the subchapter 5.2.3.). The majority of patients is able to take this medicinal product without any problems, however for the ones, who are allergic to certain substances within this product, is this drug unacceptable. Therefore, they have to get a different drug described, which cures the same disease, blood clotting disorder, but it is not fully reimbursed, e.g. *Pradaxa 110 mg* pay (Kotík 2018). They are forced to pay for the medicine, regardless the fact, that they should have one drug for their disease fully reimbursed. The State Drug Control Authority takes in account the fact, that some patients might be allergic to the fully reimbursed drugs and has a solution for it. First of all, the allergy of the patient must be proven by the experts, which contains a special clinical

testing for allergies and the conference of medical consilium (Kotík 2018). If the allergy happens to be true, then the patient has a right to get another fully reimbursed drug from the reference groups. However, such actions can take months until the doctors and experts decide, that the concerns about the allergy have proven to be right. The patient who has the blood clotting disorder would not survive a day without taking the cure drug, hence he has to buy a different one, for such he has to pay (Kotík 2018).

Compared to the situation in Switzerland. Swiss pharmaceutical market does not sell *Warfarin Orion 5 mg*, however there is another similar medicinal product called *Sintrom and Pradaxa*, (see chapter 5). Both of these drugs are reimbursable and listed on the positive Swiss list. Which means, that once the patient fulfilled the yearly franchise he has the right to get all the drugs listed on the Swiss positive list reimbursed, only with a co-sharing 10% (Maienfisch 2018). Here we can clearly observe the inequality between the individuals in the Czech Republic and Switzerland. The Swiss positive list contains approximately 3,700 drugs (6,815 presentations). All those drugs can be fully reimbursed after fulfilling the franchise. Unlike the Czech Republic, where the number of fully reimbursed drugs is approximately 3,000. Although, here can be claimed the argument, that the Swiss citizens have to pay the franchise first and then they can receive fully reimbursed drugs with 10% co-sharing, it does not imply to the fact about inequality. Swiss patients have more possibilities to get prescribed the drug, that suits their health conditions and everyone has the same rights. The patients with allergies are not disadvantaged under the ones who can get any kind of the medical product.

What should be taken in account is the degree of self-realization within the health system in general. Since the Swiss citizens can choose from various insurance agencies, they can influence by themselves how much they pay monthly, what kind of service they get and choose the medicinal products, that help them the most, without considering the amount of reimbursement (Maienfisch 2018).

In the Czech Republic, there is not so much space for the individuals to influence somehow the service they are getting, neither the quality of pharmaceuticals. Since the major intervenor is the state Czech citizens can't really take the responsibility over their own health insurance neither of the disease's cure.

The medicinal products, listed on the reimbursable drugs have certain money-value and always the cheapest one is supposed to be fully reimbursed (see chapter 5.). However, sometimes the cheapest drug is not the most efficient one. Being specific with an example of oncological drugs. In the Czech Republic the cure for the cancer in general is implied as a chemotherapy, such treatment is fully reimbursed from the public health insurance, nevertheless, the efficiency of chemotherapy is much lower than by another innovative drugs, which has been invented last years. Surely, such highly innovative drugs are more expensive and need higher expenditures to finance the treatment, however, it goes on the whole patient's responsibility pay (Kotík 2018).

The system of public health insurance in the Czech Republic does not reimburse such innovative cures for the oncological patients, because of its high costs. Some of the treatments are listed in the positive list, but the reimbursement is only partial and the left amount to pay is for some patients very high and almost unpayable (Kotík 2018). In contrary, in Switzerland the oncological patients have nowadays more possibilities to be treated by highly innovative medicines which are contained in the positive list of reimbursable drugs. Thanks to the Swiss R&D for medicines against cancer and multiple sclerosis the volume of reimbursable medicines increased about 2.0% last year's (Interpharma 2016).

7.4. Recommendation for possible improvement in the Czech Republic and additional information found out during the research

The thesis pointed out the main differences between the reimbursement systems in Switzerland and Czech Republic. Since in the Czech Republic the state primarily intervenes to health system, Czech citizens **do not have much possibilities to involve themselves in the health system functioning and influence certain conditions for them**. Based on the information found out during the research, the thesis would recommend the **adjustment of the legislation and increase the involvement of public in the health system functioning**. Such recommendation is related to the possibility of choosing higher quality service in certain facilities like maternity hospitals, seniors' sanatorium. As a big advantage of this recommendation the thesis sees that fact, that the citizens will be able to take care of their own health the way they want with a possibility

to negotiate individual conditions of their health insurance. The higher involvement of public to health system functioning would lead to better awareness of patients about all the services and reimbursable medicinal products, which are provided by health agencies.

According to MUDr., Mgr. Michal Synek, (who works for the Ministry of Health at the department of the drug reimbursement and price regulation), the main problem in the Czech Republic is unavailability of highly innovative medicines for the patients. However, last years the production of highly innovative drugs has significantly increased and so has the price. The pharmaceutical companies are now more focused on the production of highly innovative drugs and set a high price, since such medicines are costlier. Highly innovative drugs mean increasing profits for the producers. Since the technologies used for the invention requires higher costs, the companies demand higher prices.

In the Czech Republic, the producers of highly innovative drugs are trying to get their medicines listed on the list with reimbursable drugs, which would ensure them permanent reimbursements. The incentives of the public to put such innovative drug to reimbursable list as fast as possible, are constantly increasing. Since 2010-2015 from total 90 highly innovative drugs, that have been launched globally, only one half of these drugs has fulfilled the main criteria (Synek 2018). For drug to be labelled as highly innovative, the effects must distinguish from the drugs previously listed within the list of reimbursable list. The main criterion is, to prove the life extension of oncological patients at least about half a year. However, as mentioned above, only half of drugs, which have been labelled as highly innovative ones, proved to have such effects.

The State Drug Control Authority of Czech Republic accepted the provided assessment by the pharmaceutical companies and listed certain drugs to the reimbursable list. Such pharmaceuticals have only partial reimbursement, so the patients have to still pay a significant part of the price.

The another examination after drugs have been already available on the Czech market, the State Drug Control Authority found out, that effects have not been fulfilled and removed 7 drugs for oncological patients out of the list, last year. Nevertheless, patients

and insurance companies already paid for these drugs, that have been on market for couple of years, with a vision of life extension.

On one hand side, there are incentives of putting highly innovative drugs to the reimbursable list as fast as possible to provide the patients a quick access to consumption. However, since the pressure on fastness, the examination for efficiency is disregard.

The Ministry of Health wants to get highly innovative drugs listed as soon as possible even with concerns, the information provided by pharmaceutical firm, might not be accurate. The State Drug Control Authority requires more precise assessment of drugs being labelled as highly innovative ones, to avoid unnecessary expenditures for oncological patients.

Conclusion

The thesis has examined the economic consequences of the pharmaceutical price regulation in the Czech Republic and Switzerland. Since the pharmaceutical industry itself is expanding over last years by innovating new medicines against serious diseases, the regulative policies in individual states are changing as well. Launching new drug on the pharmaceutical market is connected with new restrictions, assessing and certain requirements for reimbursement. All those mechanisms are connected to the main topic of the thesis, since the pharmaceutical price regulation plays a crucial role for reimbursement. Furthermore, the unavailability of certain medicines in the Czech Republic has been topic for several discussions many times. Since several medicines are not available on pharmaceutical market, it has an impact to the entire economy of state in general. For instance, highly innovative drugs present significant revenues for the economy, therefore I find advantageous to compare Czech Republic to Switzerland. Health system in Switzerland and pharmaceutical industry is well functioning and to point out the main differences shows possible room for improvement of the Czech System. For me personally, the thesis uncovered several patterns in pharmaceutical industry functioning. Interesting I find a big difference between individual states not only in terms of health system but also in pharmaceutical pricing. For me personally has the thesis significant contribution. As a Czech citizen I find useful to know all details about health system functioning and price regulation of pharmaceutical. Since I gained new knowledge during the research for my thesis I am able to critically assess certain situations when it comes to pharmaceuticals. The comparison with Switzerland helped me to understand better the health system in another country and make my own opinion on the situation in the Czech Republic

The main contribution of the theoretical part to the topic of thesis I see the claims of Milton Friedman and Friedrich August Hayek. Both of economists stay dismissive towards the government intervention to market which can be implied to price regulation as well. The Chicago school of economics, where the main representative is Milton Friedman, states, that the high competition between individual market works as a protection of customers. The individual firms are competing with each other by setting

various prices, which would attract the consumers the most. Such situation can be implied also to the topic of the thesis. In many cases the government intervention in terms of setting the maximal price of drugs can be disadvantageous not only for companies, but also for the customers, who are then influenced by the shortage of highly innovative pharmaceuticals, since the pharmaceutical companies are not interested in launching their products on the Czech pharmaceutical market. If the state intervened a bit less it would open new opportunities. High competition would adjust the price for them anyways. As Milton Friedman claims the customer's satisfaction is in the best interest of businessmen; therefore, the state intervention does not really make sense in this case. I personally agree with Milton Friedman that a government should not intervene significantly to market functioning, however I would point out one exception. The state control is necessary in terms of assessing certain goods to protect the customers against buying inferior or not efficient products. With regard to statements of Hayek and the Austrian school of economics, I find relevant, especially the claims about competition itself. Sometimes the protection of domestic market leads to negative consequences to customers. For the market to function properly the competition is exactly the fuel that thrives it. Customers should have wide-spread opportunities to choose what commodity they prefer to consume over others. When I point out the example with pharmaceuticals, the relevance of Austrian ideas seems even clearer. If Czech Republic wants to mitigate the financial burden to its citizens by setting certain restrictions on foreign pharmaceutical companies, it gives away the possibility for citizens to choose anything they want. If there is a shortage of very efficient oncological drugs, because of their price, lots of patients are disadvantaged by competitive restrictions. I must say, that both of the economic schools I chose to mention within my thesis give a solid overview about the market situation in general, and these theories can be implied also on pharmaceutical industry.

Since the health system in both countries distinguishes to each other significantly, the thesis had to point out the main differences between basic health insurance cover, which influences then the pharmaceutical spending of individuals. The citizens in the Czech Republic can't choose the conditions of their health insurance, since the health system is primarily determined by the state. Unlike to Switzerland Czech citizens get the same service, regardless their income, needs, jobs. It seems like all the individuals living in the

Czech Republic have the equal conditions in terms of medication, health care and medicinal services. However, when it comes to certain drugs, like the ones against blood clotting disorders, the inequality shows significantly. Under such topic belongs the problematic about reimbursement mechanism. As the chapter number 5 describes, the reimbursement system in the Czech Republic works the way, that group of drugs with the same healing substance as listed to the reference groups. All the drugs include in certain reference groups have the same conditions for the amount of reimbursement. The reference groups are completed by mechanism annex 2 of the law of public health insurance. The groups of medicinal products, that are involved in annex 2, must have at least one medicinal product fully reimbursed. When I come back to the medicines against blood clotting disorders, in the Czech Republic there is only one medicine against this disease, which is fully reimbursed, so called Warfarin Orion 5mg. However, some patients might be allergic to the substances, which are contained within Warfarin Orion. Therefore, they need another medicinal product prescribed, for instance Pradaxa 110 mg. This medicine is used also for the blood clotting disorders, however, is not fully reimbursed. Here comes the problem with inequality, regardless the same level of disease some patients with allergies are disadvantaged. The patients, who are not able to take Warfarin Orion, have to pay out of their pockets for medicine, which should be fully reimbursed for them. State Drug Control Authority of Czech Republic provides special clinical testing and medical consilium in a case, when patient needs a different prescription of certain drug, since the one fully reimbursed is not acceptable for him. However, such action takes months to prove the allergy. Here I would like to mention the situation in Switzerland, where the reimbursement system works equally for everyone, regardless any allergies. Swiss citizens as the Czech citizens are obligated to have a basic health insurance. Unlike Czech Republic, all the individuals can choose from wide sphere of insurance agencies according to their needs, jobs, requirements. The amount, they pay monthly is negotiable and so is the franchise deductible. The possible amounts of monthly premium are described within chapter 4. Once the franchise deductible is exceeded, the insurers pay 90% of all the expenditures on pharmaceuticals, that are listed within positive drug list. The left 10% is co-sharing participation of the Swiss citizens. The Swiss positive list includes in total 9,000 medicinal products, which are reimbursed once the franchise is exceeded. As we mentioned here the drugs against the blood clotting disorders, there

are several medicines like Sintrom and Pradaxa 110 mg, which are included and therefore, fully reimbursed. Although the reimbursement is implied only after the exceedance of franchise, I still find it more advantageous compared to the Czech system. Aside the medicinal products against the blood clotting disorders, there are also oncological drugs and drugs against multiple sclerosis. Swiss citizens have easier access to such treatment not only because of wide-spread reimbursable drugs, but also due to higher availability of highly innovative drugs in general. Starting with the reimbursement, since the list of fully reimbursed medicines, with 10% of co-sharing, is wider than in the Czech Republic, the Swiss citizens have more possibilities to choose what kind of treatment they prefer if they happen to have a serious disease. Sometimes it also depends individually on the agreement with their insurance agencies, whether some oncological medicines will be reimbursed or not, however summa summarum the possibilities for Swiss citizens to get very efficient and highly innovative drugs are higher than for the Czech citizens. Such topic is related to price regulation in several ways.

As in the Czech Republic the most attention is paid to prices of drugs, the doctors are sometimes forced to prescribe the medicine, which may not be as efficient as the other ones, but is the cheapest one or fully reimbursed. Such situation is disadvantageous for many foreign pharmaceutical companies. They might offer more efficient products but also more expensive, therefore such pharmaceuticals are not sold in the Czech Republic and foreign companies start leaving the Czech pharmaceutical market, because of possible loss of profits. Some of foreign companies even do not try to enter the Czech Pharmaceutical market, from such reasons. Then we can see the consequences for the Czech citizens, who have then lower availability of highly innovative drugs, since some of them are not even sold in the Czech Republic.

Nevertheless, what I find promising are numbers of pharmaceutical export in the Czech Republic. Since 2011 the export has increased significantly. The assumption can be concluded by the fact, that Czech Republic became over years one of the major generic producers for Eastern and Central Europe. Such situation can improve the entire state's economy by earnings which have the impact on GDP. However, the trade balance between imports and exports still remains in negative numbers. Nevertheless, Czech

Czech Republic has, in my opinion, a great potential to turn it over and get itself to positive numbers with enhanced R&D of generics in general.

Switzerland as one of the major pharmaceutical markets worldwide has the trade balance between imports and exports sustainable in positive numbers. We can assume even higher increase in exports due to highly innovative drugs, that have been launched in 2011 and the demand for such medicines is still increasing.

The chapter 7 speaks about pharmaceutical companies in general, as one of the major pharmaceutical companies is mentioned Novartis and Roche. These two companies have launched new highly innovative drugs on the pharmaceutical market in 2011 so as showed in chapter 6 on the graphs, even the total health spending and pharmaceutical spending of Swiss citizens have increased. The oncological patients and individuals with multiple sclerosis have now more opportunities for treatment, which is costlier. I find this as a reason why the pharmaceutical spending is still increasing.

As I described at the beginning of conclusion, some patients are being disadvantaged when they happen to have allergies on fully reimbursed medicines. Such situation has not been found out in Switzerland, since the total amount of reimbursable drugs is higher and the patients have more room to adjust their needs. What I am the most surprised about, is the conflict of interest between the Ministry of Health Czech Republic and the State Drug Control Authority. The statement of the Minister of Health, that was made public is about helping the patients to decrease the financial burden of pharmaceuticals as fast as possible, on the other hand the Ministry of Health rejected the suggestion of the State Drug Control authority about additional assessing highly innovative drugs to provide the patients efficient medicines. In my opinion this brings us to misleading information about cost savings and general financial help for patients. When they pay months, or even years for medicines, which are being labelled as highly innovative ones, with a vision of life extension, we can't speak here about the cost savings, in contrary they are paying high price for the drugs, which do not differ from the cheaper ones.

The main aim of the thesis was to analyse and critically assess the economic consequences of the pharmaceutical price regulation in Switzerland and Czech Republic. In my opinion

the main aim of thesis was met by synthetic analysis of individual health systems. The examining showed the main differences between reimbursement system and pharmaceutical pricing the impact on citizens, patients and pharmaceutical companies. The comparison of both countries has led to the detection, that in the Czech Republic there is still a room for improvement not only regarding health system functioning but also pharmaceutical pricing and additional reimbursement. The observation of change in pharmaceutical and health spending between 2011-2016 has shown the pattern of different health policies, additionally the impact of new invented medicines, that have been launched on the pharmaceutical market.

As one part of the aim was to find out a presence of black market, unfortunately there was not enough data available to show the possible impact of the price regulation on black market. However, what I found during the analysis of individual health systems is a possible start of a black trade with pharmaceuticals based on abuse of the health system in the Czech Republic. Since the state pays for lots of individuals, citizens registered on the there is a possibility, when the people do not appreciate enough the financial help, they might want to use it by pretending certain sicknesses to get the antibiotics or another fully reimbursed medicines for free. Furthermore, they can sell such medicines abroad for higher price or even trade with such pharmaceuticals within the country. However, such thoughts are primarily based on my personal opinion, which I made according to information I found out during several interviews.

Some graphs do not include time-lag 2016, the data needed for including also the year 2016 has not been published yet, therefore in some fields the statistical analysis ends by year 2015. From my personal point of view there is still room for improvement in terms of health system functioning and reimbursement mechanism. As I mention in chapter 7 one of the most important improvement's possibilities I see the better collaboration between the main authorities which deal with pharmaceutical pricing and reimbursement system.

My recommendations and assumptions for subsequent examining and assessing are connected to the gaps in the Czech health system functioning. Such topic is beyond the problematic of my thesis, however I think the patterns, that set the price of

pharmaceuticals and additional reimbursement should be definitely examined more to the depth. I found out several information e.g. conflict of interest between the State Drug Control Authority and the Ministry of Health and from my point of view the current situation with reimbursement should be assessed further. As another suggestion for further research I see the pricing and availability of highly innovative drugs and the whole mechanism of assessing by unavailability of certain medicines, which could significantly influence or improve the life of patients with such diseases.

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