

Regulation of the Pharmaceuticals Market in EU Countries

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Abstract: This article discusses the characteristics of pharmaceutical market regulation in the member states of the European Union. The author considers the correlation of EU regulation with national standards and reveals the characteristic features of regulation in Germany and France. The author focuses on the authorization procedure to place medicinal products for human use on the market of Member States, regulation of price of medicinal products and parallel importation issues. The article concludes that the EU pharmaceutical market is regulated at the EU and national levels. Despite the harmonization and unification of legislation in the EU member states, there is difference in legal regulation, which hinders the development of the common market.

1. Introduction

The common EU internal market was created on January 1, 1993; this another step toward the integration of European countries. The main tools for overcoming the obstacles to its formation, were the creation of market regulation common to all and the unification of legal regulation.

One of the most important segments of the EU internal market is pharmaceuticals, which is currently one of the most important sectors of the Union's economy. It contributes to the economic growth of the EU, creates a positive trade balance and new jobs, and also directly affects the health of citizens. In addition, among innovative industries, pharmaceuticals have long been in first place.

Speaking about the reasons for such a surge in the pharmaceutical industry, we should note that pharmaceuticals' goal is to ensure the health of citizens and the effective functioning of the healthcare system. Medicines today are as important as water, electricity and food. Given their importance and due to the specificity of the medicinal products and the principle of subsidiarity, the pharmaceutical market requires a special regulatory mechanism. This means that the Union does not provide detailed regulation of the pharmaceutical market, but create rules common to all Member States, which may specify and supplement these rules at the national level, thus implementing joint regulation.

2. Methodology

To analyze the existing regulatory mechanism of the pharmaceutical market, we consider the authorization procedure for placing medicinal products on the market within the EU, pricing, the parallel import using the example of one of the most developed countries in this industry – Germany and France.

3. Results and Discussion

Today, the European Union has a centralized authorization procedure for placing medicines on the market, which has been formed for a long time. The first step towards its creation was Council Directive 65/65/EEC [1]. According to it, each Member State had its own authorization procedure. The Directive also defined terms of authorization procedure, reasons for refusal to grant authorization and for its suspension or revocation.

Further, Council Directive 93/39/EEC [2] amended Council Directive 65/65/EEC: authorization was granted either by a Member State, or by the Community.

To control the authorization procedure, a European Medicines Agency was established, and the procedure became centralized. According to Regulation No. 726/2004/EC [3] (which replaced Regulation No 2309/93), the procedure should be based on the objective scientific criteria of quality, safety and efficacy of the medicinal product. The advantage of the procedure is that the authorization obtained is valid in all EU Member States.

EU Directives, which regulated the production, distribution, sale, labelling, classification, and advertising of medicines for human use, were assembled in Council Directive 2001/83/EC [5].

EU rules also pay special attention to labelling and package leaflet of pharmaceuticals [1, 4, 5].

The mentioned Directives were aimed at removing the obstacles to free trade in the EU imposed by national regulators by establishing national labeling and product packaging requirements. It is also possible to chronologically trace in these Directives how the Member States are increasingly restricted in setting standards for product labeling; this contributes to increased competitiveness in the EU market. So, the Member States no longer have the right to prohibit or to prevent the placement of medicines from other Member States on their market in connection with the labeling or package leaflet, if these medicines meet the requirements.

At the EU level, there is an exhaustive list of medicines labelling information. It is noticeable that one of the mandatory requirements for labeling is the placement of information in the official language of the Member States, where the medicinal product will be sold. Only if all of the requirements are met, medicines can be placed on the EU market. However, the national law may supplement the procedure due to the specificity of medicines.

In Germany, all aspects related to the placement of medicines on the market are regulated by the German Medicines Law [6]. In addition to the provisions of the EU Directives, it provides a list of terms related to products. So, a prerequisite for the authorization is quality and efficacy of a medicinal product, which its manufacturer is to confirm with the relevant documentation. At the same time, quality is defined as a property of a medicinal product characteristic, expressed through its composition, purity and contamination. Under the efficacy is understood the degree of influence of a medicinal product impact on the human body and health.

Particular attention in Germany is paid to the quality of pharmaceutical products, which is expressed in higher standards compared to other countries. The standards relate to products manufactured in Germany and pursue two important goals – to increase the competitiveness of domestic medicines in the EU market and to legally keep the products of other countries off their domestic market. The latter implies that only domestic medicines should be sold in Germany and that this can be achieved within the EU only by improving their quality.

In France, issues related to the marketing authorization of medicines are regulated by the French Public Health Code [8]. The first book of this code provides an exhaustive list of labeling information. In addition to the information listed in the EU Directives (to which there are references in the code), the manufacturer needs to describe in detail the side effects, contraindications and interactions with other drugs. This is a good example of supplementing EU standards: instead of introducing new criteria for evaluating a medicinal product, the existing criteria are described in more detail. As a result, only high-quality pharmaceuticals are placed on the French domestic market, and the ineffective ones are kept off without violating the EU rules.

The largest scope of powers for Member States with regard to the pharmaceutical market is pricing. This aspect is regulated mainly at the national level. At the EU level, Directive 89/105/EEC [9] specifies the transparency of measures for price regulation and fixed prices setting for medicines. In addition, pricing in the pharmaceutical market is indirectly regulated by the Treaty on the Functioning of the European Union [10] (Art. 34 and 35 relating to the freedom of movement of goods and services). In general, pricing issues fall within the competence of the Member States.

In Germany, the main price setting method is to introduce a sliding scale of margins. So, the level of wholesale and retail margins is defined by law: for wholesalers, it can be from 6 to 15%; for pharmacies – 3% of the highest possible price of the wholesaler plus 8.1 euros [11]. However, these rules apply only to prescription drugs.

Another method is the reimbursement system for medicines – the so-called fixed payment

system. When buying a medicine, the patient is reimbursed a certain amount, but if the price of the medicine exceeds this amount, then the patient must pay the difference. This system is a convenient guide for manufacturers, because with the help of fixed margins they can most accurately calculate the retail price of a medicine.

It should be emphasized that the use in Germany of a combination of the margins regulation and reimbursement system allows to cover the entire chain of pricing from manufacturer to retailer. Accordingly, in fact, it is the state that determines the price of a medicine.

Among the legal acts establishing the reimbursement system in Germany is the Social Code [12], which provides that the fixed payment system aims primarily to ensure the equality of every person in the market and to provide consumers with the most optimal price for medicinal products. Thus, a fixed payment for a particular medicine should be within the lower third of the entire spectrum of retail prices for this medicine. This means that manufacturers whose prices exceed the level of the lower third of retail prices are in a less favorable situation, which can only be corrected by lowering prices. It follows that the system of fixed payments can limit the prices of medicines.

Thus, in Germany, in the field of pharmaceuticals pricing, market mechanisms practically do not work. The freedom of action of market participants is severely limited; the entire price chain is regulated from manufacturer to retailer. However, this does not contradict EU standards, since the protection of health is within the competence of the Member States.

A different approach to pricing exists in France. One of the methods for setting prices for pharmaceuticals is to compare internal and external prices. When using this method, the cost of new medicines is established taking into account the prices of similar products that are present on the domestic market. As a result, prices for similar products from different manufacturers become approximately the same, which virtually eliminates price competition. In addition, in France it is allowed to set the price of a new medicine higher, but not more than a certain percentage compared to the price of an existing product on the market. With the appearance of fundamentally new medicines with undoubted advantages, prices should be adjusted accordingly.

Also, in France, the fixed retail margin method is used, which means a fixed compensation for each medicine sold, i.e. a pharmacy receives income not depending on the value of medicines sold, but depending on their quantity. This prevents pharmacists from cooperating with doctors to increase the number of prescribed and sold expensive medicines.

A characteristic feature of the pricing in the French pharmaceutical market is the promotion tax aiming at limiting the expenses of pharmaceutical companies on marketing their products in France, which are to be reimbursed by the French health system [13]. This helps to discourage the development of new pharmaceuticals that are similar in composition and effect to existing ones.

Another feature that is unique to France is the method of lowering prices based on the volume of medicines consumption. It concerns the most expensive pharmaceuticals that pose a threat to the state budget in reimbursing their costs. This method allows to reduce the price of medicines in case of exceeding the permissible sales volumes. Furthermore, the reduction is subject to negotiations with manufacturers, and is not established imperatively. This, in turn, stimulates manufacturers to organize research and promote their medicines in the domestic market.

Thus, in France, the regulation of pricing is more harmonious and market in nature. Prices are set objectively by comparing them; this contributes to the development of the EU common market. A characteristic feature is the introduction of higher prices for new medicines that already have analogues in the market.

One of the specific features of the pharmaceutical market is parallel import. In the EU, this phenomenon created many judicial precedents. In general, parallel import is the import of goods for which the intellectual property right is exhausted through channels that are not directly related to its owner and are an alternative to authorized distribution.

The practice of parallel importation of medicines has shown that sometimes the protection of intellectual property can become an obstacle to the functioning of the market. For example, the trademark owner has the exclusive right of primary placement of products on the market of a certain country; however, within the EU, this means simultaneous placement on its entire domestic market.

Thus, after the sale of products, for example, in Germany, the trademark owner cannot prevent its distribution in France. This rule aims to stop the abuse of exclusive rights and to ensure freedom of movement of goods in the EU internal market and has been repeatedly recognized by the EU Court [14].

The rules regarding parallel importation are defined in Directive 2004/48/EC [15]. In addition to it, there are other EU acts concerning trademarks. However, in the pharmaceutical field, parallel importation is complicated, for example, by different pricing in the EU countries, because the cost of the same medicines can vary depending on the methods used. Therefore, now share of parallel importation is not more than 6.5% of the pharmaceutical market turnover.

The EU Court of Justice rulings play a significant role in this area. On the basis of several cases, the importer received the right not to provide the entire list of documentation on the imported products, if this was already done by the manufacturer. Importers were also allowed to remove tablets medicines from original packaging to repack them in compliance with sanitary standards and always with the consent of the manufacturer.

The EU Court of Justice introduced a criterion of objective necessity [16], which means that if, without repackaging, access to the market can be considered as hindered as a result of resistance from a significant part of consumers to relabeled product, the parallel importer is authorized to place the product on the market.

However, despite all this, parallel import in the EU pharmaceutical market develops slowly. Both in Germany and France, there is no opposition in this area. In many respects, this is the result of many years of practice of the EU Court of Justice, which the companies of these countries unsuccessfully applied to. The benefits of parallel imports are significant for consumers. It gives them the opportunity to purchase medicines at lower prices, which, in turn, indirectly affects setting medicines prices in the domestic market. Negative aspect relates to companies, which suffer financial losses that reduces investment, and states: destabilization of their pricing policy threatens public health in general.

4. Conclusion

To conclude, we should note that the regulation of the pharmaceutical market in the European Union has a number of specific features. First of all, this market segment is regulated by a combination of both EU rules, which are common, and national law. However, with all the harmonization and unification of legislation in the EU member states, its legal regulation is different, which hinders the development of the common market as a whole.

Other features of the internal pharmaceutical market in the EU are a well-established system of uniform standards for the quality of pharmaceuticals, the growth of investment in research and development of new types of pharmaceuticals, as well as control over the production of medicinal products in the Member States. At the same time, the EU Court of Justice plays a significant role in the formation of regulatory rules, many its rulings influenced the EU Directives and Regulations, especially in the field of parallel importation.

When analyzing regulatory measures in Germany, we note that the state controls the entire pharmaceutical distribution chain, starting from production, to which high quality criteria are set, and ending with sale, where prices are essentially set “from above”. The ultimate goal is to legally keep foreign medicinal products off the German market and achieve their highest demand in the common EU market.

Analysis of regulatory mechanisms for the pharmaceutical market in France showed that there are the highest criteria applied to medicinal products; but their goal is to achieve maximum efficiency in the use of medicines. Prices for products are established by comparison with foreign medicines and in agreement with manufacturers. The ultimate goal is to establish optimal prices for pharmaceuticals, which will be most beneficial for citizens, and to oust medicines analogues by increasing their prices.

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