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Drug Policy, Strategy and Regulation of Pharmaceutical Products along the Supply and Value Chain

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ABSTRACT

The healthcare system and the drug policy connected to it carry into effect certain social functions and form one of the most vital systems of society. At the same time, the realization of these functions can be carried out at several different levels - regional, national, European and global. Drug policy and pharmaceutical production are characterized by highly pronounced regulatory mechanisms. In the modern conditions of pandemic and geopolitical conflicts, the importance of processes related to the supply chain management in the context of ensuring the security and reliability of supplies, as well as in relation to the potential changes in the value chain, is increasing.

Keywords: drug policy, strategy, regulation, supply chain, chain of the value.

INTRODUCTION

The Treaty on the Functioning of the European Union (TFEU) reinforces the importance of a health policy by stating that „a high level of protection of human health shall be ensured in the development and implementation of all policies and activities of the Union“ (Article 168, paragraph 1 of TFEU) [1]. The main responsibility for the protection of health, and in particular for health systems, continues to be carried by the Member States. However, the EU plays an important role in improving public health, disease prevention and control, limiting the sources of danger to human health and harmonizing health strategies between Member States.

The availability of medications is a serious long-term problem on a global scale, which affects even leading communities in economic, political, social and health terms such as the European Union, which was reported in a resolution of the European Parliament, stating that in the last decade the problem of shortages of drugs becomes systemic [2], affecting, in addition, treatment regimens at planning level

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and/or during ongoing implementation. Such problems may turn out to be factors affecting the health of EU citizens in the short, medium and long term and ultimately have an impact on the sustainability of health systems in the Member States. The main causes of drug shortages are multifactorial, with challenges identified in the fields of the value chain within the pharmaceutical industry, and quality and production issues for industry competitiveness [3]. In particular, drug shortages can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components.

The COVID-19 pandemic has further heightened the importance of supply chain assurance in the context of ensuring uninterrupted supply of medications. This is especially true for the most critical medications, which are essential to ensuring continuity of care, providing quality healthcare and ensuring a high level of public health protection in Europe.

Security of supply has been identified as a central objective [4] of the Pharmaceutical Strategy for Europe („Pharmaceutical Strategy“) from November 2020. The Commission has announced several actions aimed at improving the availability of medications, in particular the need for the Pharmaceutical Strategy to initiate a structured dialogue on the security of drug supply [5].

The aim of this paper is to examine the current state of the policies, strategies and regulations related to the pharmaceutical market in the context of elements of the supply chain and the value chain, in order to highlight possible factors that affect the security of the supply chain, the effectiveness of drug policies and the mechanisms of value chain formation.

DRUG POLICY, SOCIAL AND MARKET ASPECTS

A series of intensifying problems require a serious consideration of the health reforms planned or currently being carried out, taking into account the specifics of the pharmaceutical market and the features of the drug policy. The nature of such problems can vary widely and is related to ongoing processes in society, such as: globalization; demographic changes in the structure of the population; deterioration of the health status of the population; restrictive policy of health insurance funds; the lack of sufficient programs for the prevention of certain diseases; public dissatisfaction with the quality and volume of health services covered by the patients‘ health insurance systems; increasing awareness of patients about new achievements in the field of medicine and their desire to apply them in the treatment process; established persistent stereotypes in the behavior of users of health services; and inequalities in access to high-quality health care. These serious and unsolved problems inevitably lead to ever-increasing healthcare costs, in which drug costs take a significant share.

The production, distribution and retailing of pharmaceutical goods, both individually and as a whole, are of significant socio-economic and public interest. The processes in these economic activities are characterized by a high degree of dynamism and ambiguity in their course. Therefore, their analysis should treat in a complex way the state and development trends of the three interrelated sectors of the pharmaceutical chain: drug production, drug wholesale (including imports) and drug retail.

The importance of all these factors was essentially assessed in a resolution of the World Health Assembly in 1975 [6] , which recommended that the World Health Organization establish a set of policies and activities to facilitate the development and implementation of comprehensive national drug policies by individual country members of the organization. The updated and supplemented document was prepared by the WHO in 2001 [6] to formulate and implement a comprehensive national drug

policy. By its very nature, the national drug policy is a document based on public consensus and includes the goals, priorities and main strategies and approaches to achieve these goals, while covering both the private and public sectors [7].

SPECIFICITY OF PHARMACEUTICAL MARKETS

Any analysis of the functioning of a market and any assessment of actions under competition law must take due account of the structure of supply and demand. In the context of pharmaceutical markets, different stakeholders pursue different interests. Patients are the end users of medicinal products, but in the context of a demand side, in addition to patients (end users of medicinal products), prescribers, pharmacies and health insurance systems should also be included. Depending on the nature of the treatment, patients can pay fully, partially or not pay for the prescribed medicinal products, and in the last two cases, the cost of the medicinal products is partially or fully covered by the health care system, as stated in Ordinance No. 10 of 24.03.2009 of the Ministry of Health [8]. Prescribers - usually doctors, decide which prescription drug a patient should use based on existing good practice guidelines and experience. Patients can also get advice from a doctor or pharmacist about which non-prescription medicinal products to use. The costs of the prescribed treatment in the context of the drugs used and the specifics of the treatment are usually at the expense of the patient or the health insurance fund or are shared between them, and not at the expense of the doctors who prescribed the respective treatment. Pharmacies can also influence the demand for medicinal products, for example where there are incentives for pharmacists to supply the cheapest available version of a medicinal product (e.g. a generic version or a parallel imported product). Pharmacists are also often the main source of advice for patients about over-the-counter medicines. Private and public health insurance systems are financed by their members (and/or the state) and cover patients‘ medical expenses on their behalf. A country‘s drug reimbursement scheme affects demand and influences the behavior of prescribers and pharmacists. The offer on the pharmaceutical markets can be carried out by: manufacturers using different business models (offer of original medicinal products, of generic medicinal products or, increasingly, of both types of products); wholesale merchants; different types of pharmacies (online pharmacies, mail order pharmacies, traditional pharmacies and hospital pharmacies). Original drug companies are actively involved in research, development, production, marketing and supply of innovative medicinal products. They usually compete „for the market“ by trying to be the first to discover, patent and market a new drug product, but they can also compete „on the market“ when different drug products are relatively substitutable in terms of similar symptoms. Generic drug manufacturers offer non-innovative - generic versions of the original drug product, usually at significantly lower prices, after the original drug manufacturer‘s exclusivity expires. A generic medicinal product has the same qualitative and quantitative composition in terms of active substance, as well as the same pharmaceutical form (e.g. tablet, injectable solution, aerosol) as an original product that has already received authorization („reference medicinal product“), and its bioequivalence with the reference medicinal product must be demonstrated through studies. Generic medicinal products are usually used to treat the same disease as the reference medicinal product. Thus, generic drug manufacturers compete with originator drug manufacturers (or with other generic drug manufacturers already on the market) to win markets. Some manufacturers offer both original and generic medicinal products. They develop different business strategies for each

type of product. Wholesalers, in turn, organize the distribution of pharmaceutical products by purchasing them from manufacturers and selling them to pharmacies and hospitals. The different types of pharmacies fulfill a dual role - giving advice to patients and providing the necessary medicinal products. Last but not least, the Member States of the European Union also play an important role in this highly regulated sector - various agencies manage the marketing, pricing, procurement and reimbursement of medicinal products. Through the use of regulations, governments within the EU seek to achieve several objectives, such as: maintaining a high quality of pharmaceutical products, safety, effectiveness and efficiency; ensuring the availability of pharmaceutical medicinal products by negotiating prices and creating public health insurance systems; promoting innovation and medical scientific research and others.

THE BULGARIAN PHARMACEUTICAL MARKET

The pharmaceutical market in our country, as well as abroad, is highly regulated. Along with the administrative-legal ones, there are also economic barriers to entering the market with their differences and specifics for the respective sectors, drug production, wholesale and retail trade in medicinal products. In the Republic of Bulgaria, market participants related to the pharmaceutical sector operate with a wide range of medicinal products, mainly ready-made products for human medicine in a variety of forms, including tablets, capsules, ampoules and others, and in more limited quantities are developed, produced and they also distribute medicinal substances. In the context of the supply chain, Bulgarian manufacturers perform the function of both a supplier of raw materials for medicinal products and a manufacturer of finished forms. The dynamics of changes in the supply chain that we observed during the COVID-19 pandemic, as well as the uncertainty of these supplies due to economic and geopolitical factors, create specific threats to the production and provision of medicinal products based on imported medicinal raw materials. This creates threats, not only to the life and health of patients in a country, but also a threat to its national security in terms of affected human resources, disrupted socio-economic relations, introduction or strengthening of inflationary processes and others. A change in the supply chain will also lead to a change in the value chain, as cheap but uncertain primary sources of medicinal raw materials must be replaced, as well as logistical routes of supply.

The Bulgarian pharmaceutical market includes both imported and Bulgarian medications - medicinal substances and products, and during the analyzed period the value ratio is in favor of imports. In the group of medicinal products covering all significant therapeutic classes, the production of generic pharmaceutical products dominates in our country, and the production of original products is insignificant. In conclusion, we can make the following generalization about the Bulgarian pharmaceutical market: the drug market is specific, since the market participants who operate on it are also in the role of related parties; merchants and manufacturers have fiduciary duties to customers; the trade in medicines on the Bulgarian market is divided into wholesale trade and retail trade, which predetermines the definition of two groups of participants in the respective markets.

DRUG POLICY AND REGULATORY FRAMEWORK

The pharmaceutical market is one of the most highly regulated sectors of any healthcare system, taking into account market defects on the one hand, and the combination of interests of patients, industry and funding institutions on the other. Drug market regulations are implemented

depending on the type of health care system in a given country. The National Drug Policy (NLP) determines the development of the pharmaceutical sector in the country being part of the government's health policy [7]. The drug market, by analogy with other types of markets, also needs specific regulations, since we have an exchange taking place. At the same time, the medicinal market has two characteristic features that distinguish it from the typical market, namely:

- Regulations imposed by the specifics of the product itself (medicinal product);
- Regulations related to investments.

The drug policy sets the framework by regulating and coordinating all activities of governmental and non-governmental organizations as well as all stakeholders in the pharmaceutical sector. Such a policy must combine the various components of drug legislation, the provision and reimbursement of drugs, their rational use, and the problems related to the pharmaceutical industry [9].

The pharmaceutical sector, on the other hand, is characterized by great dynamics of processes and in it are concentrated the responsibilities and expectations of a wide range of participants whose direct interests are multidirectional. With the Law on Medicinal Products in Human Medicine (ZLPHM) in force from 13.04.2007 [10], the procedures for mutual recognition of the issued authorizations for use are implemented, a decentralized procedure for authorizing the use of medicinal products, the specific requirements for homeopathic medicinal products and for traditional herbal medicinal products. A procedure has been developed for making changes to an issued authorization for the use of a medicinal product. The rights and obligations of the holder of authorizations for the use of a medicinal product are defined, a new participant is introduced - a qualified person who is responsible for quality control of manufactured or imported medicinal products and their compliance with the issued authorization for use. The regime of parallel import of medicinal products is also regulated. The requirements in relation to drug safety, inspections and control, clarity of information for patients and the provision for issuing the authorization for retail trade of drugs to the commercial entity have been completely renewed.

The regulatory framework refers to aspects of the implementation of control over the activities of retailers of medicinal products, as well as the imposition of relevant sanctions in case of violations. The mechanism for regulating the prices of medicinal products and the preparation of a positive medicinal list, as a unified and simplified system for their introduction into the national medicinal market and healthcare, with clarity and transparency of the procedures, has been determined. The competences and powers of the bodies exercising control over the activities under the law are regulated.

Despite the positive guidelines aimed at harmonizing our legislation with the European one, the specifics of our market such as volume and traditions must be taken into account. An example is the requirement for packaging - primary and secondary packaging in Bulgaria, which, given the limited volume of consumption of some medicinal products, makes the service provided by the foreign manufacturer unprofitable, and may lead to products dropping from the market. At the same time, if the representative office of a foreign pharmaceutical company refuses to import medicinal products with a valid authorization for use in the Republic of Bulgaria, this may lead to consequences related to ineffective treatment.

Accurate prioritization in the pharmaceutical sector is an important factor affecting both supply chain and value chain formation. The main goals and objectives are related to all government guidelines and actions regarding the pharmaceutical sector, and should be reflected

in the developed strategies and plans for their implementation. In a country with extremely limited budget funds for health care, the goals and objectives of the drug policy should be strictly defined in order to use the limited financial resources in an effective and rational way.

PRICING, REIMBURSEMENT AND COMPETITIVENESS

As pointed out by the Report from the Commission to the Council and the European Parliament Competition Enforcement in the Pharmaceutical Sector, national healthcare systems are under increasing pressure from high drug prices, as pharmaceuticals already account for a significant share of expenditure [11]. In this context, there is a growing need to strengthen the monitoring of competition law in the pharmaceutical sector. In most Member States, manufacturers must go through pricing and reimbursement procedures before placing prescription medicinal products on the market. The COVID-19 pandemic, the subsequent development of vaccines and their provision to health systems, has shown that pricing and reimbursement rules, while being the exclusive competence of Member States, can also be a priority and a unified policy for the whole European Union. Regulation, procurement and related negotiations have an impact on the price of the medicinal product, both for original and generic medicinal products. Member States have chosen different pricing schemes, which are usually based on negotiations between Member States‘ health authorities and manufacturers. These, in turn, can be combined with: reference to the price of the medicinal product in other member states; analysis of the additional benefit of the medicinal product, assessed as a result of health technology assessment; or a combination of the specified elements. The cost of medicinal products will generally only be reimbursed up to a certain amount, even where the original prices are not subject to specific mechanisms. Most Member States introduce measures to encourage price competition between equivalent medicinal products to take advantage of cost reductions. For example, the supply of cheaper generic drugs can be stimulated by rules that require a prescription for generic drugs (prescribing a molecule rather than a specific brand) and/or by allowing pharmacists to dispense the cheapest (generic) version of the medicinal product. In generic drug markets, health insurance companies can also organize tenders to select the cheapest supplier for a given drug product. The regulator can facilitate price competition between therapeutically interchangeable medicinal products, for example by reimbursing the cheapest product in a therapeutic class (i.e. groups of medicinal products that have different active substances but are used to treat the same disease) as well as cause a high degree of economic substitution. Such measures could profoundly transform the nature and intensity of competition for alternative medicines, as providers are no longer shielded from price-driven competition.

CONCLUSIONS

The study carried out showed that the production of medicinal products is highly dependent on the existing supply chains and the value chains formed on this basis, the functioning of which is highly threatened by factors such as: pandemics and the restrictions policies caused by them, including lockdowns, as it was in the case of COVID-19, which blocked the production and supply of medicinal products and raw materials; uncertainty or disruption caused to transport communications and supplies as a result of the alteration or blocking of traditional transport corridors, as in the case of the stranded container ship in the Suez Canal; geopolitical uncertainty and instability in countries that are sources of primary medicinal raw materials or manufacturers of generics; need to introduce restrictive policies

for customs and trade restrictions.

The analysis of the production of medicinal products and raw materials in Bulgaria shows that smaller countries and countries with insufficiently developed production, research and economic potential have a limited set of tools and opportunities to influence the value chain and the supply chain. Any disturbance in these chains can lead to a deterioration of the quality of healthcare, endangering the life and health of patients, shortage of medicines, problems of an economic and social nature, as well as, in general, endangering national security.

Outsourcing of the production of medicinal products and raw materials, including outside the European Union, is a profitable economic practice, but in the sphere of the pharmaceutical industry it can create significant problems that affect the economic, social and health potential, not only of the individual member country, but also of the union as a whole. In this regard, it is currently necessary to start processes aimed at the uniform stimulation of the production of medicinal products and raw materials within the framework and for the needs of the European Union, since this market has the potential and justifies the investments in this direction, which would otherwise not would be possible for the individual member state of the union or another country with a more limited market.

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