Retail trading of the medicinal products. Administrative aspects

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ABSTRACT

This paper presents issues regarding the administrative and legal aspects of retail trading of the medicinal products. Because one of the most important goods protected by law is health, the regulations included in the branch of administrative law are to serve its protection. Nor can one forget that public authorities must protect public health. The state carries out its tasks, among other things, by introducing restrictions on retail trade of the medicinal products. Such limitations have been inscribed into the essence of the social market economy, which is characterised by parallel economic and social goals. Although all kinds of restrictions on the issue are justified, they are somewhat restrictive.

Keywords: Retail trading, medicinal product, pharmaceutical law

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INTRODUCTION

All legal issues related to the medicinal product and their turnover were included in the 6 September 2001 Pharmaceutical Law Act (PLA) [1]. At the same time, the law implemented Directive 2001/82 / EC on the Community code relating to veterinary medicinal products. It is worth noting that the Act referred to above on the issue of medicinal product turnover applies to both medications intended for human and veterinary purposes [2]. In PLA, the following have been specified in detail: rules of admission to trading, conditions for manufacturing, advertising and marketing of medicinal products, as well as conducting clinical trials and requirements for pharmacies, pharmaceutical wholesalers and non-pharmacy sales outlets. It should also be noted that the Act of 11 March 2004 on the protection of animal health and combating infectious animal diseases [3] imposed on veterinarians the obligation to keep medical and veterinary documentation in relation to the performed therapeutic and prophylactic procedures as well as medicinal products and feeding stuffs [4].

REVIEW

As it has been indicated above, PLA regulates the principles of placing on the market, production and advertising of medicinal products intended for both humans and animals. The rules applicable to medicinal products for both humans and animals are very similar. Nevertheless, the present work focuses only on the discussion of the sphere of medicinal products intended exclusively for people.

In its current form, PLA complies with EU standards set by the Directive of the European Parliament and Council 2001/83/EC [5]. It contains a code on medicinal products for human use [6]. This regulation, being aimed at protecting the safety of final purchasers and users of medicinal products, is restrictive and, in principle, sets the framework for trading and producing them.

Medicinal products and medical devices are goods subject to the rules of the single market. Thanks to this, the EU has the competence to grant permits that are compatible with the assessment and supervision procedures. With a view to protecting public health, new medicinal products to be used in humans must have a permit, issued in accordance with the procedure, carried out by the European Medicines Agency (EMA) or by national agencies before being placed on the market. The admission of medical devices to the market is subject to a specific regulatory framework, and private sector organisations called 'notified bodies' verify that these frameworks are respected [7].

The basis of European Health Policy is the principle according to which good health of society determines the achievement of basic EU goals regarding prosperity, solidarity and security. That is why the European health strategy offers three objectives, i.e. [8]:

1. promoting health in an aging Europe;
2. protecting citizens against health threats and;
3. supporting dynamic health systems and new technologies.

In economic terms, the pharmaceutical sector is one of the most powerful economic activities that significantly improves living conditions in Europe. This is done by ensuring availability of medicinal products, and thus affects economic growth by employing employees [9].

In order to ensure the protection of public health, marketing authorisations are issued, the classification and labeling of medicinal products is determined. Such practices in the EU have been regulated since 1965. The multiplicity of differences between legal regulations in force in the Member States meant that trade in medicinal products on the EU internal market was difficult. Therefore, since 1993, EMA has become an institution responsible for evaluating medicinal products since its establishment. In order to guarantee the highest level of public health and ensure the availability of medicinal products, a centralised authorisation procedure was established in 1995. Directive 2001/83/EC [10] and Regulation No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [11], in which the rules for establishing a centralized and decentralized procedure are laid down are the basic legal documents in this field. However, it should be remembered that in 2008 the European Commission presented a plan to introduce the so-called pharmaceutical package. The Pharmaceutical Package is a new perspective for the pharmaceutical sector that focuses on << safe, innovative and accessible medicinal products >>. They were also three legislative proposals aimed at informing the public, monitoring its safety and combating falsified medicinal products. In view of the above, provisions have been introduced for orphan medicinal products [12], medicinal products for pediatric use [13] and advanced therapies [14].

When the medicinal product goes on the market, the EMA monitors it with the pharmacovigilance system. This system allows registration of side effects of the drug that were observed during clinical practice. It is worth noting that the pharmacovigilance issues were established

under the Regulation of 25 October 2012 1027/2012 and Directive 2012/26/EU [15].

The introduction of a given medicinal product on the market requires that attached documents containing the test results to which it has been subjected. Standards regarding the test results to be followed have been developed since 1990. They are ultimately defined in EU legislation and must be respected by the pharmaceutical industry. The legal basis for the proper conduct of clinical trials involving humans is the Helsinki Declaration of the World Association of Physicians - adopted by the 18th General Assembly of the World Association of Physicians (WMA) in Helsinki in June 1964 [16]. Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of the principle of good clinical practice in carrying out clinical trials on medicinal products for human use [17] has also been strengthened Directive 2005/28 / EC of the European Parliament and of the Council of 8 April 2005 fixing the principles and detailed guidelines of good clinical practice for investigational medicinal products for human use as well as requirements for the validation of the manufacture and importation of such products [18].

According to art. 2, 2c and 2d of the PLA medicinal product is "a substance or a mixture of substances that have been formulated into active pharmaceutical form or placebo, tested or used as a reference product in a clinical trial, including a product already authorised, but used or prepared in a different way. from a form admitted for free circulation or used in an indication not covered by the authorisation, or used to obtain additional information on characters already authorised [19]. In relation to animals, it is "a substance or mixture of substances that have been given pharmaceutical or biological form and which are used in veterinary clinical trials" [20].

However, it should be noted here that Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [21] contains a much clearer definition of a medicinal product than PLA. The above directive defines two groups of products that can be considered as medicinal products. The first one refers to products that have treatment or disease prevention properties. In turn, the second group are products given for a specific purpose - making a diagnosis or restoring, correcting or modifying the physiological functions of the body [22].

Generally, it can be considered that the drug is a substance or mixture of substances that has the property of preventing or treating diseases occurring in people or animals, or administered to a human or animal to diagnose the restoration, correction or modification of the physiological functions of the human body [23].

PLA distinguishes also a medicinal product intended for special nutritional purposes, which is intended for nutritional treatment, properly processed and produced, with a strictly defined composition, used on the order of people and under the supervision of a physician [24].

Other uses include a homeopathic medicinal product that is prepared from a variety of ingredients or mixtures thereof, according to a homeopathic procedure officially recognised by European Union (EU) Member States or European Free Trade Association (EFTA) Member States, i.e. contracting parties for the European Area Economic (EEA) [25]. Other medicinal products are [26]:

1. An immunological product - a medicinal product that is in particular a serum, a vaccine, an allergen or a toxin that acts primarily on the immune system.
2. Blood product - a medicinal product prepared from blood or blood components, in particular albumin, clotting factors, immunoglobulins that are industrially manufactured or processed.
3. Plant medicinal product - a medicinal product containing as active ingredients one or more vegetable substances or one or more herbal preparations or one or more herbal substances in combination with one or more vegetable products.

After defining the definition of a medicinal product at this point, it will be reasonable to define the definition of "marketing of a medicinal product".

Pursuant to art. 65 ust. 1 PLA marketing of medicinal products can be carried out only on the principles set out in pharmaceutical law, which is divided into wholesale and retail trade. However, it should be noted here that the legislation lacks a legal definition of these concepts. As the Act does not specify the general definition of marketing of a medicinal product, it is therefore appropriate to use the definition of wholesale trade to be able to define the definition in question.

Wholesaling is all activities that consist in sourcing, storing, supplying or exporting medicinal products or veterinary medicinal products with a marketing authorisation issued in a Member State of the European Union or a Member State of the European Free Trade Agreement - a party to the Agreement on the European Area Economic or a permit issued by the Council of the European Union or the European Commission, carried out with manufacturers or importers in the field of medicinal products manufactured or imported by them, or with wholesalers, or with pharmacies or animal treatment facilities, or with other authorised entities, excluding direct supply of people. It should

also be noted that wholesale trade is also the export of medicinal products from the territory of the Republic of Poland and the import of medicinal products from the territory of EU Member States or EFTA Member States. On the other hand, the entrepreneur is not regarded as marketing of medicinal products for the purposes of state reserves and imports from abroad of the medicinal product for advertising purposes within the meaning of the Act of 2 July 2004 on the freedom of economic activity [27] or an entity conducting economic activity in the state an EU Member State or an EFTA State which has applied for or obtained a marketing authorisation for a medicinal product [28].

The doctrine, however, is assumed that the marketing of medicinal products is considered as: "any form of transfer of ownership of a medicinal product, including free of charge within civil law transactions and by virtue of a legal transaction. The marketing of medicinal products depends on obtaining permission to perform such activities [29].

According to art. 68 § 4 and 4a PLA retail trade is not: direct application of the medicinal products and medicinal products included in the anti-shock kits, whose need for use results from the type of health service provided, direct use in the animal by the veterinarian of veterinary medicinal products or medicinal products, which the need for application results from the type of medical-veterinary service provided [30].

On the other hand, the list of medicinal products that can be provided on an ad-hoc basis, as well as the list of medicinal products included in life-saving shock-recovery sets are specified in the Ordinance of the Minister of Health on the list of medicinal products that may be provided on an ad-hoc basis. granted health care, and a list of medicinal products included in life-saving anti-shock kits [31].

Retail trade in medicinal products is carried out primarily through public pharmacies. Apart from them, retail trade may run pharmacy outlets (on the terms set out in the Regulation on criteria for classification of medicinal products that may be admitted to trading in non-pharmacy and pharmacy outlets [32] and in the regulation on the list of medicinal products that may be authorised for trading in non-pharmacy marketing and pharmacy outlets [33].

PLA enables non-pharmacy marketing establishments (herbal medical stores, specialised medical supply stores and mainstream stores) to conduct retail trade in medicinal products that have been issued without medical consultation, excluding veterinary medicinal products.

However, it should be borne in mind that pursuant to art. 68 para. 2 PLA, the retail sale of veterinary medicinal products purchased at the pharmaceutical wholesaler is conducted exclusively within the framework of the activities of an animal treatment facility [34].

Pursuant to the above mentioned regulation, non-prescription (OTC) and prescription (RX) medicinal products may be sold provided that they meet the criteria set out in Annex 1 of the Regulation [34].

In turn, in herbal medical stores, medicinal products may be sold if they meet the following criteria jointly, ie: "active substances included in medicinal products are admitted to trading on the territory of the Republic of Poland in medicinal products issued in pharmacies without a doctor's prescription for a period of at least 5 years old and are herbal medicinal products or traditional herbal medicinal products, or medicinal products, admitted to trading on the application referred to in art. 20 § 1 pkt. 4 PLA., or meet the criteria specified in Annex 1a to the above regulation and have an accessibility category without a doctor's prescription (OTC) [34]".

CONCLUSION

One of the most important goods protected by law is health. Therefore, the regulations included in the branch of administrative law are to serve this purpose. Health care is implemented in the aspect of public health. This is because protection in the gesture of an individual does not exhaust the essence of administrative law. This branch of law focuses on the implementation of the common good, and public health protection is not possible without the protection of individual health.

The Constitution of the Republic of Poland is the source of public authorities' obligations in the area of protection of public health. According to it, every citizen has the right to health protection and to equal access to health care services, which are financed from public funds.

The implementation of the right to health protection is carried out in two ways.

Firstly, it is a set of activities that are undertaken by the state, which is to eliminate all public health threats. That is why various legal norms are created, and pharmaceutical law is the crowning example.

Secondly, these are actions aimed at creating a health care system and ensuring equal access to a part of healthcare services. All this is aimed at guaranteeing the right to health protection. However, it should be borne in mind that the functioning of this system, without the use of medicinal products, will not bring the intended effect.

Conflicts of interest

The author declares that there is no conflicts of interest regarding the publication of this study.

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