The concept of the “Europeization of law”, including pharmaceutical law, may be assigned a variety of meanings (1). In this paper, the term “Europeization of law” applies to the process by which European law, understood as Community law under the First Pillar, impacts and shapes the law of Poland, including any changes thereto. Upon Poland’s accession to the structures of the European Union, there have also been radical changes to the Polish legal system. According to the concept of the sources of law accepted in the Constitution of the Republic of Poland and the body of judicial decisions of the European Court of Justice, Community law now takes priority over national law, even over acts of parliament. Pharmaceutical law represents one of the areas where the harmonization process has been taking place. It shapes the principles and the manner according to which medicinal products are approved for marketing, the conditions of clinical trials, as well as the conditions of drug manufacture and advertisement. It also determines the rules of trading in medicinal products, the running of pharmaceutical wholesalers and pharmacies, as well as the duties and rights of the Pharmaceutical Inspectorate. This paper provides a summary of research on the impact of Community law on Polish pharmaceutical law, i.e. on the europeization process, and on the consequences of this process for the Polish pharmaceutical market and for research and development.

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vant authorities in the Member States are being assigned specific duties with the aim of ensuring compliance with the requirements of Community law. The conditions determined by European standards make it easier, to a large extent, to withdraw faulty products from the market and enable an effective fight against counterfeit products. Therefore, enactment of laws in this area contributes to elimination of counterfeit, phoney or faulty drugs from the market.

The process of the europeization of pharmaceutical law may take place on the level of both law enactment and the application of law. The standards of European law may have a direct effect on the Polish legal order, without the need to be implemented or ratified (e.g. regulations). The process of approximation of Polish law to European law takes also place through the creation by Polish legislators of legal rules which ensure the implementation of the rules of Community law (e.g. directives), and also the elimination of those which do not comply with European law. European standards which result from the so called “soft law” are also taken into consideration, even though soft law does not represent binding legislation they should be obeyed. Another aspect which plays a significant role in the process of the application of domestic law is its interpretation, in line with European law and taking into account the body of judicial decisions of the European Court of Justice. The level of europeization is also influenced by the refusal of public authorities in a Member State to apply a domestic provision if it contravenes European law, in order to ensure the effectiveness of European law.

Here we provide a summary of research on the impact of Community law on the status of Polish pharmaceutical law and the consequences of this process for research, development and innovation, as well as for the Polish drug market and the safety and availability of medicinal products, both original and generics. The scope selected for the analysis of the legal situation covers only medicinal products for human use, while omitting the products for veterinary use, even though the latter are included in the Pharmaceutical Law Act (PhL).

The concept of a “medicinal product”

Without any doubt, the term “medicinal product” represents the key concept in pharmaceutical law, as the fact that a product has been defined as a medicinal product determines the application of the provisions of the PhL (2). Consequently, the definition of this term is of crucial importance. In the process of harmonization of pharmaceutical legislation, the provisions of the PhL which specify the scope of the term have been based on the guidelines provided in Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 (3), as amended by Directive 2004/27/EC (4). The regulations of Community law understand a medicinal product to be: any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Similarly, Article 2 point 32 of the PhL (2), includes among medicinal products those products which have medicinal properties or prevent diseases, or those presented in a way which suggests they are medicinal products, and/or those used for diseases diagnosis, restoring, improving, or modifying physiological functions of the human body through their pharmacological, immunological or metabolic action. This wording of the legal definition of a “medicinal product” should eliminate any doubts concerning which legal acts should apply, when a product, covered by the scope of the definition quoted above, also has other features which place it within the scope of the definitions of other regulated products.

In practice, differentiating a medicinal product from other products (such as cosmetics or dietary supplements) may raise doubts. The problem of so called “borderline products” has been regulated by Polish lawmakers in Article 3a of the PhL (2). According to the text of this article, if a product simultaneously meets the criteria of a medicinal product and those of another product type, the provisions of the PhL should apply. This approach reflects the position adopted by the European Court of Justice (5), according to which a definition of a medicinal product has been devised in such a way as to protect consumers with regard to public health requirements.

Placing a medicinal product on the market

In order to remove the barriers to trade within the Common Market, procedures have been established with a view to making it possible to obtain authorization for placement of a medicinal product on the market in more than one Member State (6). Currently, thanks to the europeization process, a medicine may be approved for placement on the market in Poland as a result of one of the following registration procedures: national procedure, central-
ized procedure, procedure of mutual recognition or decentralized procedure. This provides Polish patients with access to modern therapy.

There are two types of marketing authorization – either issued pursuant to national regulations and valid only within the country’s territory, or issued pursuant to Regulation (EC) 726/2004 (7) and valid throughout the entire Common Market. Under Article 3 Sections 1 and 3 of the PhL, marketing authorizations for placing a medicine on the market may be issued by the minister in charge of matters pertaining to health or – as a result of the europeization process – the European Commission or the Council.

A successful passage of the documentation for a medicinal product through the centralized procedure is a guarantee of simultaneous registration of the product in all Member States. The centralized procedure, which is obligatory for high-tech medicinal products, especially those resulting from biotechnological processes, has been developed in order to maintain a high level of scientific evaluation of those products in the EU and, by doing this, to preserve the trust of patients and members of medical professions. This procedure applies also to orphan products, anti-cancer, anti-diabetic and anti-HIV products.

The decentralized procedure is regulated under Article 18a of the PhL and it applies to a situation where the medicine is being registered for the first time in the territory of the Community and in several countries simultaneously. The procedure of mutual recognition (Article 19 of the PhL) concerns the registration of a drug in several countries, though this procedure applies to medicinal products which have already been registered in an EU Member State.

According to Article 4a of the PhL, a marketing authorization may also be granted to products which represent parallel imports. When introducing into the PhL the provisions concerning parallel imports, Polish legislators based these provisions on Communications from the European Commission, which represent soft law (8, 9), as well as on the extensive body of judicial decisions of the European Court of Justice (10). Even though non-binding, Communications play an essential role in practice. They publicize the main principles of the admissibility of parallel imports, as formulated by the ECJ, and give guidance on their practical application. Thus, Polish legal regulations concerning parallel imports represent the implementation, under the europeization process, of the solutions provided in European soft law, while being also influenced by the judicial decisions of the ECJ.

The process of adjustment of the registration dossier of a medicinal product to the EU requirements stipulated in the Accession Treaty

By signing the Accession Treaty, Poland undertook the obligation to adjust the registration dossiers of the medicinal products present on the domestic market to the EU regulations. At the same time, a four-year transitional period for the adjustment of registration dossiers was obtained. The harmonization process ended on December 31, 2008. One of the most important elements of this procedure was to supplement the registration dossier with information on bioequivalence research. This applied mainly to research concerning studies of generic drugs in comparison to reference products (mainly innovative ones). Bioequivalence studies are carried out on healthy subjects. These tests are planned, carried out and reported in accordance with Good Clinical Practice, and the procedures in place during the tests are in compliance with regulations on clinical tests.

The adjustment of registration dossiers was complicated and costly, yet it guaranteed the presence of medicinal products on the market. It should be noted that, similar to EU regulations, our law guarantees to manufacturers the so called “clearance sales clause”, which allows products placed on the market before December 31, 2008 to remain on the market and be legally traded until their expiry date. The process of adjusting the registration dossiers of medicinal products caused many changes in the Polish market on both wholesale and retail level, yet it also allowed unification of the principles which apply to newly registered drugs and those applicable to medicines which have been used in therapy for a long time.

Clinical trials of a medicinal product

The regulations concerning clinical trials were incorporated into the PhL by the amendment of April 20, 2004, which came into force on the day when Poland became a member of the EU, i.e. on May 1, 2004. The provisions of Directive 2001/20/EC (11) and Directive 2005/28/EC (12) have thus been implemented into Polish law.

The provisions of these Directives are aimed at simplifying and harmonizing the provisions of administrative law of the Member States relating to the conduct of clinical trials, by establishing clear and transparent procedures and by creating conditions conducive to effective coordination of clinical trials by competent authorities in the Member States. In order to justify the involvement of human subjects in clinical trials it is essential that compli-
of new drugs.

The reliability of the research process and the safety of drug trials are a result of the European standards and experience. At the same time, it provides assurance of the protection of risks, safety and well-being of trial subjects, and of credibility of the results of these trials.

The benefits resulting from placing a new drug on the market are determined, first of all, by the drug’s efficacy and safety profile. The fundamental measure of a drug’s clinical usefulness is the benefit-to-risk ratio. The point is to ensure that the expected effects of using the drug in a specific population outweigh the unfavorable effects. Therefore, the objective of every clinical trial of new medicinal products is to credibly estimate the benefit-to-risk ratio in the target population. In a clinical trial, the risk of adverse drug reactions is higher than it is when using an already approved drug. The burden of threat is related to the drug’s toxicity (non-modifiable risk), the way in which the drug is being used (modifiable risk) and, to some extent, to the experimental nature of the procedure (13). This is why pharmaceutical law is very restrictive with regard to the obligation to report any adverse drug reaction of the medicinal product tested (i.e. any unfavorable and unintended reaction occurring in response to any dosage) and the safety of test subjects represents a priority for the correctness of the trial.

The provisions of the Polish PhL (2) stipulate the general conditions for initiating, conducting and ending clinical trials, and the principles for the protection of trial subjects. They also provide the principles which apply when conducting clinical trials with specific groups of subjects, i.e., children and those who are legally incapacitated. The assumptions, objectives and detailed solutions provided for – both in the PhL and in numerous executive regulations thereto – are a result of the europeization of domestic law and prove that this process has reached a highly advanced stage. The harmonization of Polish pharmaceutical law with respect to clinical trails has guaranteed a wide scope of legal protection for Polish patients, based on European standards and experience. At the same time, it provides evidence of the pursuit of the objectives of ensuring the reliability of the research process and the safety of new drugs.

Monitoring adverse drug reactions

Community law contains, in the Pharmaceutical Code (3, 4), the provisions concerning the safety of pharmacotherapy. These provisions determine the principles of monitoring the adverse drug reactions (ADRs) of medicinal products approved for sale or distribution in order to protect public health.

In Poland, a pharmacovigilance system has been created based on the guidelines of Community law. The system is based on the collection, evaluation and analysis of data concerning ADRs. The Polish drug registration authority (the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) was instrumental in the creation of the system.

Data on adverse drug reactions reaching the Office come from spontaneous reports submitted by pharmacists, doctors, nurses and midwives, or are delivered by marketing authorization holders in current and periodical reports. These data can also come from pharmacovigilance authorities in other countries, from the professional literature, or from the WHO database. The marketing authorization holder is obliged by law (2) to monitor the adverse drug reactions to a specific medicinal product. The authorization holder must ensure that all suspected occurrences of adverse reactions in the territory of any Member State are promptly reported. It is also obliged to designate a qualified person who will be responsible for the monitoring of drug-related complications. Creation of system which is an element of the WHO Programme for International Drug Monitoring is the guarantee for the safety of product use on an international scale.

Mail-order sales of medicinal products

New legal regulations concerning mail-order sales of medicinal products in the PhL (2) prove in turn the influence of judicial decisions of the European Court of Justice on domestic law. This change has resulted primarily from the need for the uniform application of Community law throughout the Member States, which requires the national authorities and agencies to take into consideration the interpretation of Community law provided by the ECI.

Mail-order sale by pharmacies and pharmacy outlets of medicines classified as “over-the-counter” (OTC) is currently legal. Prior to the amendment to the PhL which came into force on May 1, 2007, such operations were prohibited. The basis for changing the rules applicable to this matter was the ECI’s judgment of December 11, 2003 (14), which ruled...
that: “a national prohibition on the sale by mail order of medicinal products, the sale of which is restricted to pharmacies in the Member State concerned, is a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 TEC (15).” This means that on the issue of mail-order sale of medicinal products, the europeization of pharmaceutical law expressed itself by the transposition of the guidelines resulting from the ECJ’s judicial decisions into the Polish legal system.

Advertising of medicinal products

The rules of advertising of medicinal products introduced into the Polish legal order reflect the principles resulting from Community law directives. Advertising of medicines has been regulated, first of all, in the PhL (2) and in the regulation of the Minister of Health of November 21, 2008 on advertising of medicinal products (16).

The PhL has implemented into the Polish legal system the provisions concerning advertising included in Directives 2001/83/EC (3) and 2004/27/EC (4), called the “Pharmaceutical Code”. As of May 1, 2007, legislation to amend the PhL (“the large amendment”) came into force, which implemented the provisions of the new Directive into domestic regulations. The changes in domestic law, caused by changes in Community law, represent the effect of the europeization process.

Promotion of medicines is subject to legal restrictions whose objective is to ensure access to reliable information on the efficacy of various treatment methods and to eliminate any irregularities which might have a negative impact on public health. Advertising of medicinal products should meet criteria which guarantee the neutrality, truthfulness and objectivity of the presented messages, and should also ensure safety with regard to using the drugs.

The PhL defines advertising as activities which take the form of providing information or encouraging the use of a medicinal product, with the aim of increasing the number of prescriptions or the quantity of deliveries, sale or consumption of medicinal products. This is a broad definition which covers many forms of advertising. According to experts in the field (17), the Polish definition is less precise than the definition resulting from the directives, where advertising of medicinal products includes any form of door-to-door information, or other canvassing activity or inducement, designed to promote the prescription, supply, sale or consumption of medicinal products. In this way, the objective of advertising – which is to increase interest in the product – has been emphasized.

Advertising activities are treated separately from information concerning the medicinal product, which is in compliance with the provisions of the two directives. The clear differentiation between advertising and information is indicated by the fact that the amending Directive (4) added a new Title VIII: “Information and advertising”. The restrictions concerning advertising of medicinal products feature the prohibitions and demands originating in the Directive, which take a specific shape in subsequent provisions of the PhL and of the Ministerial regulation.

CONCLUSIONS

The europeization of Polish pharmaceutical law is an evolutionary process and it has caused a far-reaching change in the operation of the drug market in Poland. The impact of this process can be specifically seen within the area of the principles of defining a medicinal product in the Polish legal system, and the principles of drug registration, advertising, and clinical trials. It has also affected the legal regulations concerning mail-order retail sale. Another effect of europeization is the access to the pan-European system of reporting adverse drug reactions. Thus, europeanization has, in consequence, re-shaped Polish pharmaceutical law, in order to achieve compliance with the requirements of Community law. The direction of these changes indicates increased protection of the patient as a subject of clinical trials, strengthened pharmacovigilance in the area of the safety of use of medicinal products, and more restrictive drug advertising rules aimed at ensuring neutrality of the presented data and, thus, protection of public health. On the other hand, there has been some liberalization, in the form of allowing mail-order sale, aimed at ensuring that the Community principle of the free movement of goods is guaranteed.

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