The System of Medicines Safety Supervision

The dissertation in the field of: legal sciences, written under the scientific supervision of dr hab. Jan Olszewski, prof. UR.

The aim of the study was to demonstrate the main institutions constituting The System of Medicines Safety Supervision, the scope of which goes beyond the international organisation of adverse reaction reporting - also known as pharmacovigilance. The main research thesis is to show the impact of the law on the drug safety surveillance system. The legal institutions categorised as *System of Medicines Safety Supervision* demand supervising on the part of the health care system policymakers. The theoretical model of the work falls within the scope of business law, which justify the intervention of public administration bodies in the economic activity of private business. The author tried to show how, on the grounds of the law in force, the indicated entities interact without interfering with constitutional rights - the freedom to conduct business (Article 20 of the Constitution of the Republic of Poland) and the right to health protection (Article 68 of the Constitution of the Republic of Poland). The Supervision System described in the work operates within the framework of a social market economy, and the effectiveness of supervision depends on the degree of implementation of the law by entities operating in the health care system.

The *System* refers to pharmacies and pharmacists, whose role in ensuring the safety and quality of a medicinal product was indicated in the explanatory to the draft amendment to the Pharmaceutical Law (named pharmacy for pharmacist). The enforcement of the obligations specified in the Acts by the pharmaceutical supervision authorities ensures the constitutional right to health protection. The system of supervision over the safety of use of medicinal products includes legal institutions that can be grouped into: a) those constituting the activity of pharmacies open to the public, b) those related to the organisation and functioning of public administration bodies, c) those dealing with the availability of medicinal products (state actions aimed at guaranteeing universal availability of medicinal products within the adopted health care system).

The research issues of the Pharmacovigilance System include issues that have been grouped into five chapters. The structure of the work leads to the presentation of the legal institutions affecting the safety of use of medicinal products, and the last chapter is an indication of the functioning of the supervisory authorities and the supervisory measures

available to them. The inclusion of the Polish and EU supervisory authorities in one chapter is primarily justified by the fact that the primary role of the EU medicines safety authorities is the reporting of adverse reactions and the registration of medicinal products in a centralised procedure.

The issues of The System of Medicines Safety Supervision are described in the following chapters:

1) Basic concepts - analyses made on the basis of the legal acts included in The System of Medicines Safety Supervision showed the following: terminological inconsistencies arising from the subject of the work and the commonly understood pharmacovigilance system; differences in the categorisation of patient versus consumer of medicinal products; definition of medicinal products and attention to the legal aspect of the classification of borderline products;

2) *The Genesis of* The System of Medicines Safety Supervision - the chapter helped to show the dynamics and direction of organisational and legal changes for the safe use of medicinal products. It was shown that the roots of patient rights and pharmacovigilance derive from human rights;

3) Sources of law - legal acts containing legal instruments that concern The System of Medicines Safety Supervision, which are important for ensuring the constitutional right of health protection (Article 68 of the Constitution of the Republic of Poland), have been indicated. The chapter highlights the role of soft law in creating appropriate standards for the protection of patients' rights in access to medicinal products. This is done by presenting entrepreneurs with the way to perform their statutory duties;

4) Legal institutions which regulate the market of medicinal products in The System of Medicines Safety Supervision - the chapter points legal institutions which are designed to achieve an adequate standard of protection for consumers of medicinal products. *De lege* ferenda postulates in the field of safety in the use of medicinal products include the way in which ICT systems are used to supervise the safety of the use of medicinal products as part of their pharmaceutical care. An evolutionary model for the use of pharmacists for the creation of pharmacovigilance standards is indicated.

5) Pharmacovigilance authorities in the European Union and in Poland - the chapter analyses the organisational structure of pharmacovigilance authorities, with particular emphasis on the State Pharmaceutical Inspectorate. The study showed that the scope of competence of the

State Pharmaceutical Inspectorate structure and does not warrant the issuing of decisions that are binding for the safety of medicinal products.

The research conducted was dominated by the formal-dogmatic method. Particularly useful for the formulation of final conclusions was the juxtaposition of legal regulations with the analysis of articles for the pharmaceutical market. The author also carried out comparative studies for selected legal institutions affecting the safety of pharmacotherapy. The analysis of the legislation concerned the safety of access to medicinal products in three aspects: access to safe medicinal products (the paper presents the aspect of adverse effect reporting), the economic aspect of safety of access to medicinal products (with particular emphasis on generic medicines and pharmacy substitution) and access to medicinal products per se (with particular emphasis on the role of the pharmacist as the person responsible for assisting in the selection of pharmacotherapy). The research carried out showed that achieving a high level of the health system in the area of pharmaceutical safety requires the medicines safety supervision system to be an interaction between private business and public administrations. The study shows that the clarification of supervisory institutions for the *System* guarantees the efficiency and safety of pharmacotherapy in the current healthcare system.