Abstract

Registration and distribution of medicines from the administrative point of view

This diploma thesis focuses on two major areas of the pharmaceutical law – a registration and a distribution of medicaments. The main goal is to explain how the medicinal products are registered and distributed to parmacies and other facilities, considering an activity of administrative authorities, or more precisely administrave offices. The thesis is mainly focused on a Czech law regulation of the given issue.

In an introduction, the pharmaceutical law is systematically classified into a law area, there is briefly discussed its historical development in a territory of the Czech Republic, basic terms that are used throughout the thesis are mentioned, as well as a basic characteristic of administrative authorities.

Then follows the first major segment that is dedicated to the registration of the medicinal products. It is divided into three smaller parts, that are successively focused on a national registration, then a specific procedure of mutual recognition and a centralized registration, where the most significant attention is paid to the national registration. In this section, the reader learns not only about the registration procedure, but also about some issues of a modification, an assumption and a transfer of the registration, then about a usage of the unregistered medicinal products or a planned amendment to the Act no. 378/2007 Sb. about medicinal products and changes of some related laws.

The second major segment is dedicated to the distribution of the medicines. There are described the procedure of the distribution permit, obligations of the distributor, his activities and also an issue of an export of the medicines abroad, that is supplemented with a brief description of where and how the medicinal products disappear from the Czech Republic. In connection with this, there are also mentioned tools that are used by the Ministry of Health to limit or prohibit the export of medicines abroad.

The last part of the thesis is rather supplementary and it describes an activity of administrative authorities in an area of a control and an administrative penalization of the distributors and holders of registration decisions.

The entire diploma thesis is complemented by some practical examples and works with available data from the previous year 2022, that are published by the State Institute for

Drug Control. After a reading, the reader should have a basic knowledge about a process of the registration and the distribution of the medicines in the administrative law and then better to understand the issue of the unavailability of the medicinal product or an importance of generic medicines.

Key words: marketing authorisation, distribution of pharmaceuticals, administrative law