Abstract

The issue of launching medical devices on the market became more intense in the last few decades in connection to the expansion of the pharmaceutical industry and legal area. This legal area is still mostly undescribed and it stands in the shadow of known and more discussed medical products. Proper legal theoretical analysis is often completely absent.

This master thesis aims to complexly describe and analyse theoretical bases of current legislative regulating the launching of the medical devices on the market, including other processes related to this issue. Emphasis is places on the concept of medical device, the responsibility of the manufacturer and the nature of notified body. The author focuses on the subsequent conformity assessment process and process of registration. The process of notification and exemption from this obligation and administrative nature of selected documents.

The thesis is divided into eleven chapters and the introductory chapter focuses on a general introduction to the field of pharmaceutical law, namely the regulation of medical devices, including the definition of basic questions in the work under study.

The second chapter deals with the analysis of sources of legal regulation of medical devices. The chapter is divided into sources of the law of the Czech Republic and the sources of the European Union law, including the non-binding recommendations of MEDDEV. The next chapter deals with the relevant state administration authorities. The two most important administrative bodies, the Ministry of Health and the State Institute for Drug Control contain a brief analysis of their scope and competencies.

The fourth chapter, entitled "Introduction to Medical Devices", focuses primarily on the explanation of the concepts and processes that are necessary for further orientation in the issue or issues detailed in the following chapters. It is primarily about the very notion of a medical device, its individual concepts and the types of medical devices. Next, placement on the market, including the individual possibilities of understanding this concept. The chapter is concluded by the qualification procedures used to classify products into specific groups and the reasons for errors in the qualifications and classification of medical devices followed by classification into classes

according to the degree of health risk or other groups. Another chapter describes the border products and their individual types. These include medicines, medical devices, cosmetics, supplements and more.

The sixth chapter deals with those involved in the marketing of medical devices. Special emphasis is placed on the manufacturer, the notified body, the authorized representative, the importer and the distributor. The beginning of the chapter is devoted to the registration of these persons - a description of this procedure and its subsequent analysis including determination of its nature. At the same time, the notified body includes an analysis of its nature - in view of the significant impact on the conformity assessment process itself.

The seventh chapter deals with processes related to marketing itself - such as clinical assessment, functional assessment, and the conformity assessment process (including a detailed analysis of the nature of the process) mentioned above. The following chapter is devoted to some of the selected documents that are being created during the marketing process. They are the certificate issued by the Notified Body, the Declaration of Conformity and the Instructions for Use (both documents are issued by the manufacturer of the medical device). All the documents presented include their description and correct legal analysis.

The ninth chapter deals with the issues of notifying the medical device. Emphasis is placed on its nature as an administrative procedure, as well as on the persons present as well as the elements necessary for the fulfilment of the notification obligation. In the conclusion of the chapter, there are individual exemptions from the notification obligation, including the outline of their main features.

The next, tenth, chapter is focused on special proceedings under the Medical Device Act. These procedures are basically used to correct qualification errors or classification and related problems. It concerns the procedure for the unauthorized affixing of the CE marking, the procedure for classification of the medical device and the decision on the border product.

At the end of the thesis the main goals and knowledge of regulation of medical devices are summarized. Emphasis is placed on the position of the manufacturer as the primary responsible person and the criticism of the absence of a correct legal theoretical examination of all the reported problems. At the same time, there is a reminder of the forthcoming new regulation under European Union law on medical devices.

Key words:
pharmaceutical law; medical device; launching on the market; conformity assessment