Medical devices

Abstract

The subject of this master thesis is the issue of medical devices. This thesis focuses on its reimbursement regulation. The work is divided into six chapters. The introductory explanation is devoted to the concept of medical device and it analyzes both the European definition of medical device and the national legal definition. The next part of the chapter emphasizes various division of these products, namely its variants, types and also classification of medical devices according to risk classes.

The second chapter describes legal sources. The attention is paid to international sources of law, then furthermore to European law, from current directives to new regulations, which will come into force in 2020. In this chapter is generally discussed what changes this new regulations bring, as it is further elaborated in the next chapter. Last but not least, the national sources of law are analyzed. The legal regulation enriched by the outline of the future legal regulation awaiting the area of medical devices is widely mentioned.

The next chapter defines institutions. The Ministry of Health and the State Institute for Drug Control are the key institutions in the field of medical devices, however, they are not the only authorities to carry out state administration in the field of medical devices. On the one hand, they can be viewed as major authorities, on the other hand, there are other important authorities, each with a significant role. This chapter provides further information of Czech Office For Standards, Metrology and Testing as well as regional trade offices.

The fourth chapter presents some entities who operate with medical devices. They are the manufacturer, importer or distributor. Moreover, the notified body or authorized representative is also analyzed.

Basic specific institutes of the law of medical devices are introduced and discussed in the fifth chapter. The basis is to clarify the concept of registration of persons handling medical devices and notification of medical devices. Furthermore, this part is focused on databases and a unique identification system. The conformity assessment process, the CE marking, the clinical evaluation, the service and the revision of the medical devices cannot be omitted. The conclusion of this chapter is dedicated to vigilance.

The following chapter discusses the issue of reimbursement regulation of medical devices. After the introduction of the previous reimbursement system, the Constitutional Court's position was mentioned and the new regulation of reimbursement regulation from the categorization tree to non-categorized medical devices was discussed in detail.

The conclusion of the thesis draws attention to the approaching effectiveness of the new European legislation, which tightens the legislation and brings a lot of innovations and rules for entities working with medical devices. It also anticipates future national legislation. Last but not least, the knowledge about the new system of payment regulation is summarized

Key words:

medical devices; pharmaceutical law; reimbursement regulation