Abstract

This thesis deals with the conflict between the interest in the free movement of medical devices and the interest in the protection of health and safety. It is divided into two main parts, with the first part focusing on the *pre-market* phase, i.e. the phase before a medical device is placed on the market. The first part consists of two chapters describing the historical development of the regulation of medical devices and its separation from the regulation of medicinal products, as well as the way in which medical devices enter the market and what they must fulfil in order to be freely traded across the Member States. In particular, this part addresses the question of whether this separation (i.e. the move away from the *'old approach'* to the *'new approach'*) was a step in the right direction or a *'historical mistake'*. The system of CE certification of medical devices based on the participation of external auditors - Notified Bodies - is thoroughly discussed. The second part of the paper is devoted to the *post-market* phase (after the medical device has been placed on the market). The focus is on two *'knot problems'*, i.e. areas where the interest in free movement and the interest in protecting health and safety collide in practice, namely border products and parallel trade (specifically issues related to repackaging, relabelling and translation of information provided by the manufacturer). This section maps and analyses the CJEU case law on the free movement of medical devices.

The thesis compares the current European legislation on the regulation of medical devices (Directive 93/42/EEC, Directive 90/385/EC and Directive 98/79/EC) with the new European legislation (Regulation 2017/745 effective from 26 May 2021 and Regulation 2017/746 effective from 26 May 2022) and the regulation of medical devices with that of medicinal products. The conclusion of this comparison is that the new European regulations introduce a number of institutes that can have a positive impact on strengthening health and safety protection. At the same time, however, it is pointed out that the problem with the current regulation is not the lack of stringent requirements, but their ineffective control and enforcement, both in the *pre-market* and *post-market* phase. In view of the serious shortcomings of the current CE certification system, based on the participation of mostly private Notified Bodies, it is proposed *de lege ferenda* to abandon this system and to return to the principles of the old approach and to introduce *ex ante* registration of medical devices along the lines of the registration of medicinal products. As described in the thesis, this solution would, among other things, help to '*untangle*' the knot problems mentioned above.