doi: 10.36689/uhk/hed/2019-02-012

The Launching of Medical Devices - the Conformity Assessment and Registration Process in the Czech Republic

Hana MOHELSKÁ[1], Blanka KLÍMOVÁ[1], Petra MAREŠOVÁ[1], Ladislav HÁJEK[1], Michal NOVOTNÝ[2], Lukáš PETER[3]

[1] University of Hradec Kralove, Hradec Kralove, Czech Republic
{hana.mohelska,blanka.klimova, petra.maresova, ladislav.hajek}@uhk.com
[2] University Hospital, Hradec Kralove, Czech Republic
michal.novotny@fnhk.cz
[3] Technical University of Ostrava, Ostrava, Czech Republic
lukas.peter@vsb.cz

Abstract. The issue of launching medical devices is very topical. This is an area that is little described because more attention is paid to medicinal products. This paper aims to comprehensively describe and analyze the theoretical background of current legislation regulating the marketing of medical devices, including other processes related to this issue. The article discusses the concept of medical device, the manufacturer's responsibility and the nature of the notified body. In addition, it describes processes of conformity assessment and registration. Finally, the findings of regulation of medical devices are summarized. Emphasis is placed on the position of the manufacturer as a primary person and the criticism of the absence of a proper legal theoretical examination of all the problems mentioned.

Keywords: Pharmaceutical Law, Medical Device, Launching, Conformity Assessment.

1 Introduction

The issue of launching medical devices is only a little described in theory, as evidenced by the literary research conducted within the Czech Republic. Medical devices represent a significant and rapidly growing market within the European Union, employing more than 575,000 people, 25,000 companies do business in this field, and total annual sales of medical devices are over 100 billion euros. This is also a very sensitive issue, given the possible effects on the lives and health of not only patients, but also other people [8].

The regulation of medical devices belongs to the field of pharmaceutical law, respectively, to the pharmaceutical law in a wider sense - together with the treatment

of medicinal products or other medicinal products needed, e.g. blood, tissues, or cells [2, 11]. The pharmaceutical law itself is understood as part of medical law. The medical law then focuses mainly on the issue of healthcare workers and the provision of health services or the regulation of public health insurance and other similar areas [16, 12]. It is obvious that while the medical law has, in particular thanks to the current Civil Code, a considerable private overlap and a considerable part of the problem is solved by private law institutes, the pharmaceutical law has retained its distinctly public character. The basis of the relationships within the framework of the pharmaceutical law is the obvious superior relationship of public authorities on the one hand, and basically subordinate physical or legal persons on the other [2].

Due to the large number of types of medical devices, this article focuses only on general medical devices. In the paper, the emphasis is mainly put on the regulation of the launching of medical devices and on the differentiation of the basic differences between the legal regulation of human medicinal products and medical devices.

2 Czech and European Legal Framework

The basis of the Czech legal regulation is Act No. 268/2014 Coll., on Medical Devices. It includes a comprehensive regulation of medical devices, with the exception of conformity assessment and advertising regulation. These include in particular clinical trials or similar processes, documentation of medical devices, production, distribution and import requirements, vigilance and administrative offenses relating to all of these areas.

The current legal base of the European Union is primarily regulated in the field of medical devices by a number of directives dating back to the 1990s. The current Czech legislation is based on these directives, but in some respects it is more advanced than the already outdated European Union directive. The most important directive regulating the issue of medical devices is Council Directive 93/42/EEC, on medical devices, in a consolidated version [1]. Furthermore, Council Directive 90/385/EEC (1990) on the approximation of the laws of the Member States relating to active implantable medical devices in a consolidated version and Directive 98/79/EC of the European Parliament and of the Council in 1998, on in vitro diagnostic medical devices. In addition to the directives, the regulation of medical devices is currently included in Commission Decision 2010/227/EU [4] of 19 April 2010 on the European Databank for Medical Devices (EUDAMED). However, one major deficiency can be found in the European regulation as a whole - each of the directives contains its own definition of the term medical device, which in practice gives rise to considerable terminological confusion. This leads to potentially serious problems in transferring directives - the inconsistency of the definition, the various other definitions of definitions in different countries [11]. In the case of the Czech legislation, for example, these three definitions were fundamentally merged into one, as it can be found in Act No. 268/2014 on Medical Devices and on Amendment to Act No. 634/2004 Coll., on Administrative Fees, as amended [15].

However, the substance of the European legislation on medical devices is currently based on non-binding guidelines and recommendations issued by the European

Commission under the title MEDDEV [4]. The MEDDEVs promote a common approach to be followed by manufacturers and Notified Bodies that are involved in conformity assessment procedures. There are a number of these documents that are narrowly specialized - from the definition of the term medical device to the question of border products or the vigilance process. Unfortunately, in practice, it creates a number of contradictions in the approach to legal regulation of medical devices by the individual EU Member States and divides them. Most countries in Western Europe, including the Czech Republic, have respected MEDDEV so much that they actually took the rules into their national regulations. Some MEDDEV Member States do not take part in their legislation. There is a situation where part of the Member States requires compliance with these documents and others do not. This creates inequality and considerable disparity in terms of requirements and standards within the single market of the European Union as well.

3 Government Bodies Operating in the Field of Medical Devices

The Act on Medical Devices contains only two relevant state administration bodies, specifically the Ministry of Health of the Czech Republic and the State Institute for Drug Control of the Czech Republic. Other bodies of state administration acting in the field of medical devices are the State Office for Nuclear Safety, the Office for Technical Standardization, Metrology and State Testing and the Regional Trade Licensing Offices.

3.1 Ministry of Health

The Ministry of Health (hereinafter referred to as "the Ministry") is the central public administration body for medical devices. Pursuant to the Act on Medical Devices [15], the Ministry issues a binding opinion on the person's request for authorization to participate in the process of conformity assessment of medical devices (as well as its modification, suspension, or revocation). It also decides to temporarily withdraw a medical device from the market in case it may endanger the health or safety of persons. The Ministry also grants exemptions for the use of a medical device if it does not meet the statutory conditions for use at the request of the health service provider.

The Ministry is also responsible for the administration of the Medical Devices Register (hereinafter referred to as RZPRO). The key area activities of the Ministry are to ensure co-operation with the competent authorities of the member states and the European Union and cooperation with relevant authorities of the third countries and the World Health Organization. The Ministry together with the Institute is the representative of the Czech Republic among the competent authorities of the member states for medical devices. The Ministry also has a decision on appeals for administrative proceedings conducted by the Institute at first instance.

3.2 The State Institute for Drug Control of the Czech Republic

The Institute is the office and organizational component of the state; in the case of medical devices the administrative authority exercising most of the powers. Its scope and authority are based on a number of international treaties and national laws. In the first instance, the special administrative procedure under the Medical Devices Act - decides whether the product is a medical device, the classification of the medical device and whether the CE marking has been unlawfully affixed. The Institute also conducts the process of registration of persons participating in the activities regulated by the Act on ZP (manufacturer, authorized representative, importer, or distributor) and notification of medical devices. The Institute also provides the technical transfer of some data to the Eudamed database.

3.3 Other Bodies of State Administration

The other administrative authorities that deal with medical devices are as follows:

1. The State Office for Nuclear Safety,
2. The Office for Standardization, Metrology and Testing,
3. Regional Trade Licensing Offices.

The State Office for Nuclear Safety (https://www.sujb.cz/) is subject to those medical devices that are the source of ionizing radiation. In this case, medical devices are subject to both the Act on Medical Devices and the Law on the Peaceful Use of Nuclear Energy and Ionizing Radiation.

The Office for Technical Standards, Metrology and Testing (http://www.unmz.cz/urad/unmz) publishes Czech technical standards - these set out basic factual, not legal, requirements for products (including medical devices). However, the technical standards are not publicly available and their purchase price is relatively high. This office publishes the Bulletin of the ÚNMZ where it publishes information on the new technical standards, but no longer the standards themselves. It is also possible to find information on notified persons (i.e., authorized persons authorized to the conformity assessment process) on the territory of the Czech Republic. This administrative body is subject to the Ministry of Industry and Trade and not to the Ministry of Health.

The competence of regional licensing offices is to supervise the advertising of medical devices. The legislator planned to move this agenda to the Institute, mainly because of the need for a considerable degree of specialization and the associated complexity of staffing. Regional authorities have no longer the capacity for this task. However, this did not happen in the end [20, 17].

4 Medical Device

Any instrument, tool, device, software, implant, reagent, material, or other product intended by the manufacturer to be used, alone or in combination, for one or more particular healing purposes, is to be considered a medical device [9]:

1. setting a diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of the disease,

2. setting a diagnosis, monitoring, treatment, mitigation, or compensation of injury or disability,

3. examination, replacement, or modification of anatomical structure or physiological or pathological process or condition,

4. provision of information through in vitro screening of samples from the human body, including donated organs, blood and tissues.

The medical device must not achieve its principal intended effect in the human body or on its surface pharmacologically, immunologically or metabolically but its function may be supported by such effects. Medical devices also include products specially designed for the cleaning, disinfection, or sterilization of medical devices and means intended to control or promote conception [6].
The accessory of a medical device is an accessory which, although not a medical device, is intended by the manufacturer to be used together with one or more medical devices to specifically enable the use of the device or devices in accordance with their intended purpose or purpose to specifically and directly support the medical functionality of the medical device or devices with respect to their intended purpose [9].

4.1 Basic Terms – Registration, Notification, Conformity Assessment Process

The basic concepts which the entire Medical Device Act works with are the registration and notification. The obligation of the registration is restricted only to persons handling medical devices. In the case of the notification, on the other hand, it is a process that applies to the process focused on medical devices, not people. In this, administrative discrepancies can be seen. The registration and notification are also done with RZPRO. Significant concepts include the import and distribution of medical devices. The imports differ essentially from the distribution only in one thing - when imported, the medical device is transported across the borders of the member states. Thus, the object of importation is a medical device acquired outside the territory of the member states. A key concept in the case of imports is launching on the market. The object of the distribution is a medical device which is not imported across the border of the member states, that is, it was acquired in that territory. The notion of delivery to the market is decisive [2].

The conformity assessment process in the Medical Devices Act is not much described. One can only find the statement that it is "a process performed under another legal regulation regulating technical requirements for products." This issue is more precisely regulated in the law on technical requirements for products and further specified by implementing legislation. The conformity assessment is based on demonstrating the safety and efficacy of the manufactured medical device before it is launching on the market. Simplified verification is that the manufacturer has met the essential requirements.

4.2 RZPRO and Eudamed

The Register of Medical Devices is a public administration information system for the collection of data on medical devices that are launched in the Czech Republic. The RZPRO itself is managed by the Ministry - the Ministry's administration is limited to the processes and management carried out through RZPRO (and the Ministry can further delegate these powers to the Institute). However, the technical report is carried out by the Coordination Center for Sectoral Health Information Systems. Because of this, regulated entities must always consistently distinguish the nature of their problem in RZPRO's operation - whether the problem is technical or legal in nature (i.e., it is the object of an agenda that is managed by RZPRO or RZPRO itself). The contact places are in fact two - the Institute and the Coordination Center for Sectoral Health Information Systems (https://www.uzis.cz/link/ksrzis-koordinacni-stredisko-pro-resortni-zdravotnicke-informacni-systemy). For obligated persons, it is problematic in borderline cases to choose the right institution and procedure.

The data in the system is collected for the purpose of passing information from the Eudamed database and, at the same time, because of the possibility of providing (certain part) of information to the public.

The European Databank for Medical Devices (Eudamed) [3] was established by the European Commission by decision of April 2010. As early as in May 2011, this decision was binding on the member states. Eudamed is authorized to handle data that is essential for medical devices - such as product or authorized representative information. The Eudamed feature is particularly noticeable in terms of vigilance, clinical assessment, functional assessment, and conformity assessment. However, the system by which individual member states transmit the information to the Eudamed database differs - the Czech Republic, thanks to the effective law on medical devices, collects information electronically and can share it more easily and efficiently. However, some of the countries that have the obligation to pass on information do not still use the fully electronic system. Therefore, exchanging information is lengthy, complicated, and often incomplete.

5 Launching – Legal Concept and Related Processes

Only the manufacturer or importer can therefore launch the medical device. The distributor himself can never be the one who launches a medical device - the law stipulates that he can only deliver it, i.e., dispose of it only in the territory of the member states - and whether within one or more of them. At the same time, the regulation applies only to the medical devices that may be present on the market – i.e., the medical devices that have successfully undergone clinical evaluation or functional assessment, and have been assessed for compliance. The issue is rather a question of defining the market because it is not in line with the definition of the member state market which is commonly used in literature and practice but it is significantly extended in comparison with this definition. Not only the member states of the European Union but also other countries of the European Economic Area are considered to be member states. Switzerland and Turkey are also covered by international treaties.

5.1 The Process of Launching and Processes Related to this

According to Honce [9], a device may only be launched or put into effect if it meets the requirements of the regulation and is properly delivered and properly installed, maintained and used in accordance with its intended purpose. The device must meet the general safety and performance requirements set out in the regulation. Proof of compliance with the general safety and fitness requirements must be a clinical assessment. The launching of medical devices does not require the state to approve it as it is the case with medicinal products. The state gets involved in the process of notification, which takes place within the statutory period, only after the physical launch.

6 Conclusion

Thus, the whole process of the introduction of a new medical device on the market can be described as a system of successive processes that is carried out by the manufacturer himself (possibly followed by an importer, a distributor, and an authorized representative) culminating in the marketing of the medical device. The system begins with the manufacturer's assessment of whether or not the medical device is a medical device. Furthermore, the manufacturer determines, according to the legal criteria, the degree of the health risk of the medical device. However, the determination that it is a medical device or the determination of its class is not final at this stage since the notified body may assess whether it is going to be in the process or an administrative body during the notification process (when the notification is not approved and the medical device cannot be left on the market).

The article attempted to highlight the fact that the new EU legislation will bring down the number of the so-called notified bodies, which are testing centers to control the safety and effectiveness of medical devices. This will mean slowing down the entry of new technologies and limiting the availability of older resources. In the Czech environment, it will be a major obstacle to the implementation of the regulation, the lack of professional capacities - both on the part of the notified persons or producers and on the part of the supervising authority, which is the Institute [10].

Acknowledgements. The paper is supported by the project GAČR 2017 No. 15330/16/AGR Investment evaluation of medical device development run at the Faculty of Informatics and Management of the University of Hradec Kralove, Czech Republic.

References

1. European Parliament. On concerning medical devices, Pub. L. No. 93/42/EEC, council directive (1993). https://www.emergobyul.com/sites/default/files/file/europe-consolidated-mdd-93-42-eec.pdf, last accessed 2018/11/26.

2. Dvořáková, J.: Uvádění zdravotnických prostředků na trh. Univerzita Karlova, Praha (2017).
3. EUDAMED, http://ec.europa.eu/health/medical-devices/market-surveillance-vigilance/eudamed/index_en.htm, last accessed 2017/1/6.
4. European Commission. On the European Databank on Medical Devices (Eudamed), Pub. L. No. 2010/227/EU, commission decision (2010). https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:102:0045:0048:EN:PDF, last accessed 2018/11/25.
5. European Commission. MEDICAL DEVICES (MEDDEV) (1994). http://ec.europa.eu/growth/sectors/medical-devices/guidance_en, last accessed 2018/11/20.
6. European Parliament. On the approximation of the laws of the Member States relating to active implantable medical devices., Pub. L. No. 90/385/EEC, Council Directive (1990). https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31990L0385, last accessed 2018/11/21.
7. European Parliament. On in vitro diagnostic medical devices, Pub. L. No. 98/79/EC, Directive (1998). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31998L0079, last accessed 2018/11/21.
8. European Council and European Union Council. (2018, November 21). Modernizing EU rules on medical devices. https://www.consilium.europa.eu/cs/policies/new-rules-medical-in-vitro-diagnostic-devices/, last accessed 2018/11/19.
9. Honc, T.: Evropské nařízení pro zdravotnické prostředky - krok za krokem. Standardy Léčebných Postupů a Kvalita ve Zdravotní Péči (2017).
10. Koubová, M.: Naplnit evropská nařízení ohledně zdravotních prostředků zkomplikuje v Česku nedostatek odborníků (2018).
11. Král, J.: Farmaceutické právo (1. vydání). Praha: Erudikum (2014).
12. Král, J.: Zákon o zdravotnických prostředcích: komentář (2017).
13. Král, R.: Směrnice EU z pohledu jejich transpozice a vnitrostátních účinků. V Praze: C.H. Beck (2014).
14. Ministry of Health of the Czech Republic, http://www.mzcr.cz/, last accessed 2018/12/10.
15. Parlament České republiky. O zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů., Pub. L. No. 268/2014 (2014). https://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=268/2014&typeLaw=zakon&what=Cislo_zakona_smlouvy, last accessed 2018/12/10.
16. Sovová, O.: Zdravotnická praxe a právo: praktická příručka. Praha: Leges (2011).
17. Směrnice Rady 90/385/EHS ze dne 20. června 1990, o sbližování právních předpisů členských států týkajících se aktivních implantabilních zdravotnických prostředků.
18. Směrnice Rady 93/42/EHS ze dne 14. června 1993, o zdravotnických prostředcích.
19. Směrnice Evropského Parlamentu a Rady 98/79/ES ze dne 27. října 1998, o diagnostických zdravotnických prostředcích in vitro.
20. Státní ústav pro kontrolu léčiv, http://www.sukl.cz/sukl, last accessed 2018/12/10.
21. Zákon 268/2014 Sb., o zdravotnických prostředcích.