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THE ISSUE OF UNIFORM APPLICATION OF PROVISIONS ON MEDICAL DEVICES IN THE EU ON - CASE POLAND

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Abstract

The import and introduction of medical devices to the common market of the European Union constitutes a significant part of the community's trade exchange with the world. In this context, the harmonization of regulations relating to medical devices has become one of the key elements of the trade, medical, and customs policy of the European Union. This article briefly outlines the evolution of the Community regulations on medical devices and indicates some problems that are important from the point of view of members of the economic market, which may arise at the stage of application of regulations on medical devices by state administration bodies, as well as the related legal and business consequences. The analysis focuses on the two legal acts which are of key importance from the point of view of qualifying devices as medical Directive 93/42/EEC on medical devices (MDD), applicable from 1 January 1995 until 25 May 2021, Regulation (EU) 2017/745 on medical devices (MDR), fully applicable from 26 May 2021. Similarly, the role of public administration bodies in applying EU law is analyzed, and the related dangers to the principles on which the EU legal system rests are indicated. The issues raised constitute the basis for de lege ferenda conclusions, which focus on the possibility of unifying the practice of applying the law in the individual Member States through specific institutional solutions and thus eliminating potential particularisms.

Keywords: *Medical devices, European Union, MDD, MDR, harmonization, administration.*

1 INTRODUCTION

The European Union is one of the biggest single (Hallak, 2020) markets in the world, which was aimed not only to create free trade but is the base of one of the principles of the EU. One of its aims was to create certain structural changes in the European Union. (Allen, Gasiorek, & Smith, 1998) That is why the Union works for open world trade.

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The European Union is the second importer of goods in the world. The level of imports to the European Union in 2020 alone amounted to 5,125,673 USD (ITC, 2022A). In 2019, total imports of medical products amounted to 128 billion EUR (6.6% of EU merchandise imports). In 2020 Europe had a positive medical devices trade balance of 8.7 billion EUR: this represented a 27.5% decrease compared to 2019 (12 billion EUR). Europe's main trading partners for medical devices are the United States, China, Japan, and Mexico. (ITC, 2022B) The establishment of a

common or single market has been crucial for European integration since its inception in 1957. This was enshrined in the Treaty of Rome (Art. 2) as the main policy goal of the European Economic Community (EEC) but the process to achieve it has proved very complex and ineffective. The common EU market for medical devices embraces 28 member states of the EU but also Norway, Iceland, Liechtenstein, Switzerland, and Turkey. (Kumar, 2017) It is estimated that in 2021 there were over 500,000 medical and in vitro diagnostic devices on the market.

The European Union's approach to the harmonization of medical products which can be traded in a single market has evolved. Initially, the general approach was to lay down very detailed rules setting out many technical requirements in meticulous detail. However, rules laid down in such detail involve significant disadvantages: they are difficult to put into effect and are likely to prove incapable of keeping pace with technological developments. Consequently, from the mid-1980s, the legislature decided to take a different approach to technical harmonization. The advent of the "new approach", as the new strategy was described, took the form of a resolution adopted by the Council on 7 May 1985. (EC, Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, 1985) That document sets out the two essential elements of the new approach:

a) legislative harmonization covering only the essential requirements and
b) the harmonized (technical) standards playing a central role.

Under the ‘new approach’, the harmonization of legislation is confined to the 'essential requirements' of products, which are set out in detail in a series of sectoral directives. The fact that a particular product bears the CE marking is a sign that it satisfies those essential requirements. In general, responsibility for attesting compliance with the essential requirements lies with the manufacturer. Products that meet the "harmonized standards" are presumed to conform to the essential requirements. The harmonized standards are technical standards that are drawn up, at the national and European Union level, by the bodies responsible for industrial standardization. Compliance with the harmonized standards is not mandatory but strongly encouraged by the legislature, specifically using the presumption of conformity. A manufacturer can demonstrate that the essential requirements have been met without adhering to the harmonized standards; in most cases, however, this is an unnecessary complication. In practice, products are usually manufactured following the harmonized standards.

2 EVOLUTION OF MEDICAL DEVICES REGULATIONS

The EU legislative framework on medical devices consists of three current Directives (EC, Directives, 1990, 1993, 1998) and two new Regulations (EC, Overview, 2021):

- Directive 90/385/EEC on active implantable medical devices (EU Directive, Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC), 1990) (AIMDD), applicable from 1 January 1993 until 25 May 2021.
- Directive 93/42/EEC on medical devices (MDD) (EU Directive, 1993), applicable from 1 January 1995 until 25 May 2021. Directive 98/79/EC on in vitro diagnostic medical devices (IVDMDD) (Directive 98/79/EC, 1998), applicable from 7 June 2000 until 25 May 2022.
- Regulation (EU) 2017/745 on medical devices (MDR) (Regulation 2017/745, 2017), fully applicable from 26 May 2021.
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) (Regulation 2017/746, 2017), fully applicable from 26 May 2022.

Directive 93/42/EEC on medical devices (MDD) (Directive 93/42/EEC, 1993), applicable from 1 January 1995 was first to provide exhaustive definition of the medical device, The following definition of ‘medical device’ is set out in Article 1(2)(a) of Directive 93/42: ‘any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its

proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means ...'[1] It is worth noting that the above definition made the intention of the producer to use a certain device for the medical purpose a fundamental element of classification. Article 2 of Directive 93/42, entitled 'Placing on the market and putting into service', makes it clear that products covered by the definition under Article 1(2)(a) may be placed on the market only if they comply with the requirements laid down in that directive. According to Article 3 of Directive 93/42, this means, in essence, that the products must meet the "essential requirements" set out in Annex I. Article 5 of Directive 93/42, entitled "Reference to standards", lays down in the following terms the principle of the presumption of compliance in respect of products which meet the harmonized standards: 'The Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which conform with the relevant national standards adopted according to the harmonized standards the references of which have been published in the Official Journal of the European Communities; ...' Lastly, Article 17 of Directive 93/42 provides that all products which meet the essential requirements must bear the CE marking of conformity.

Beginning with its very title, Directive 93/42 refers to 'medical' devices. This is a clear indication of the background against which the legislature drafted the rules: the idea was to define a reference framework capable of adequately protecting persons who, whether actively or passively, come into contact with the products in a medical setting. Accordingly, it does not appear to be consistent with that basic idea, which informs the directive throughout, to bring within the scope of the directive products which are intended never to be used in a medical context. That is the position with a device like 'ActiveTwo': it is not used by the medical profession (or, at least, not by doctors in connection with the diagnosis and treatment of illness), and it is never used on patients but volunteers (participants in clinical trials). Directive 93/42 accorded a crucial role to the manufacturer's intended use of the product and that element must be always taken into account in interpreting the provisions of this Directive.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amended Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Given regulation is intended to lay down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union, it applies also to clinical investigations concerning such medical devices and accessories conducted in the Union. The New Regulations has a hard deadline for certifications and manufacturers cannot launch their product without certification, hence manufacturers must meet the new regulations within the given time frame. The change in regulation brings a disturbance to the medical device industry. The manufacturers must make strategic decisions to streamline their innovation pipeline and R&D processes in response to the increased cost of compliance and longer product certification time, so it is essential to conduct the SWOT analysis to evaluate the effect of new regulations. (Padmasri, Majety, Katru, Prakash Veluchuri, & Kumar Reddy Juturi, 2021, p. 1) An element of clarification is needed here, however. Even if the information provided by the manufacturer is the key factor in determining whether a product is intended to be used for a medical purpose, any product that, by its very nature, is intended to be used solely for a purpose of a medical nature will have to be regarded as a medical device, even if the manufacturer does not describe it as such. In any event, that proviso,

[1] Article 1(2)(a) of Directive 93/42.

which is designed to prevent abuse, ought not to be needed in most cases, since – including for obvious reasons of professional liability – the consistent practice of medical structures is to purchase only products which have been certified under the directive.

Where market surveillance authorities conclude that a product may not be placed on the market since it does not comply with the Union law applicable to it, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 25(1) not to release it for free circulation. Market surveillance authorities shall immediately enter that information into the information and communication system referred to in Article 34. (Regulation 2019/1020, 2019, p. Article 28 [2]) The MDR regulation has put the responsibility for Union harmonization legislation on the Member States, making their market surveillance authorities responsible for ensuring that the legislation fully complies with the regulation itself. The Member States were therefore obliged to establish systematic approaches to ensure the effectiveness of market surveillance and other enforcement activities. (Regulation 2019/1020, 2019, p. 9) According to the above-mentioned provisions the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products came into force. According to the art.2 ust.1 pkt.5 of the given Act the President of Registration of Products of the Office, Medical Devices and Biocidal Products, hereinafter referred to as the 'Office of the Office', is an organ of governmental administration in matters related to i.a. medical devices within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223 / 2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Official Journal EU L 117 of 05.05.2017, p. 1), hereinafter referred to as 'Regulation 2017/745'. (Act, 2011) Manufacturers' declaration of conformity of their devices with European rules and regulations and affixing of the CE mark (Communauté europeénne) (art. 10 and 20 MDR). CE marked products can then be placed on the EU / EEA market (MDR Articles 2 and 10). The affixing of the CE marking to a product is only legal after a conformity assessment has been carried out (Art. 20 MDR). Depending on the class of the equipment, a Notified Body must be involved in this process (Introduction [60] and MDR Art. 52-53). For some highly critical or novel products, additional testing by so-called 'expert teams' (Introduction [56] and Article 106 of the MDR) is mandatory.

3 THE ROLE OF MEMBER STATES ADMINISTRATION BODIES IN THE CLASSIFICATION OF EQUIPMENT INTRODUCED INTO THE EUROPEAN UNION MARKET

Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code The completion of the internal market, the reduction of barriers to international trade and investment, and the reinforced need to ensure security and safety at the external borders of the Union have transformed the role of customs authorities giving them a leading role within the supply chain and, in their monitoring and management of international trade, making them a catalyst to the competitiveness of countries and companies. The customs legislation should therefore reflect the new economic reality and the new role and mission of customs authorities. The importance of public administration bodies in ensuring the effectiveness of EU law in a Member State is usually marginalized in the science of law. (Poltorak, 2014) (Luczak, 2012) (Krawiec, 2009) Their role in the application of Community law, especially in the context of customs trading and the qualification of devices introduced into the territory of the European Union is primary and fundamental from the point of view of members of the economic trade. The EU model for the application of EU law, under which the public administration of the Member States performs the function of administration in a double role, i.e., also as the local EU administration. (Koszowski, 2014)

By assigning the above-mentioned powers to the administrative authorities of the Member States, the EU legislator assumed that thanks to the harmonization of customs and medical legislation, it will be possible to uniformly apply Community law, inter alia, in the area under consideration relating to medical devices. A consequence of the functioning of public administration bodies of an

EU Member State in such a system is a change in the pattern of conduct, conditioned by the principle of effectiveness, which, in the light of the CJEU jurisprudence, is the basic mechanism for ensuring the effectiveness of EU law. It is indicated that at present this principle is included in the primary EU law – in the first place in Art. 197 paragraph 1 TFEU (EU, 2004), according to which 'the effective implementation of Union law by the Member States, which is essential for the proper functioning of the Union, is regarded as a matter of common interest.'' (Sadl, 2015)

The principle of effectiveness, which, in the opinion of the CJEU, expresses the basic model of the relationship between EU law and the law of the Member States, and is combined with the principle of sincere cooperation (Article 4 (3) TEU.) (EU, 2004, p. item 864), it is not a mechanism specific to the EU. Its presence is also indicated in international public law. (Mayr, 2012) (Szpak, 2008) It is difficult to assess the nature of the principle of effectiveness. Among other things, it is indicated that this is an 'idea' above the general principles of EU law (Adamczak-Retecka, 2007) or the 'meta-principle' of the interpretation of EU law: '[...] a guideline that is not in itself a method of interpretation'. (Mayr, 2012, p. 16) The principle of effectiveness as a 'meta-principle' is implemented by 'means', and 'mechanisms', which are sometimes called 'principles for the application of EU law'. This concept is sometimes understood differently. For example, M. Niedzwiedz proposes a broad approach to it, pointing out that the principles of applying EU law in the national legal order define the limits of the interference of EU law in the process of applying this law in the national legal order (the principle of institutional autonomy, the principle of procedural autonomy, general principles of EU law, fundamental rights as guaranteed in the EU Charter of Fundamental Rights) (Niedzwiedz, 2014).

On the other hand, a narrower understanding of the concept of 'principles for applying EU law' relates directly to the problem of the conflict of norms and includes the following principles: the principle of primacy of EU law over the national law of a Member State and the principle of direct application of EU law, the principle of direct effect, an effective interpretation (compatible, pro-EU) principle of the liability of a Member State for breach of EU law. (Majkowska-Szulc, 2007, pp. 25–28)

Effective interpretation and the principle of the direct effect of EU law pay attention to the pragmatic dimension of the principle of effectiveness, as they aim to maximize the chances of an individual to obtain real legal protection under EU law against the authorities of a Member State at the earliest possible stage of the process of applying EU law in that country.[2] Due to the legal nature of the directive as a source of EU law, this need was particularly intense in the context of the issue of its transposition into the national order. The obligation to make an effective interpretation rest with all authorities of the Member State applying the law, irrespective of the initiative of the individual concerned. For this reason, from the point of view of an entity wishing to obtain benefits resulting from EU law, the mechanism reflected in the principle of direct effect is more attractive mainly because it entrusts the interested party with an independent initiative to seek legal protection of its interests. In this situation, meeting the requirements of the so-called 'Test of direct effect' by this entity is bound by the authority applying the law, obliging it to determine the legal situation of this individual entity based on the indicated norm of EU law.

[2] See judgment of the Court of 5 February 1963 in case 26/62 NV Algemene Transporten Expeditie Onderneming van Gend & Loos against Nederlandse administratie der belastingen, ECLI: ECLI:EU:C:1963:1; judgment of the Court of 4 December 1974 in case 41/74 Yvonne van Duyn against Home Office, ECLI: ECLI:EU:C:1974:133; judgment of the Court of 5 April 1979 in case 148/78 Criminal proceedings against Tullio Ratti, ECLI: ECLI:EU:C:1979:110; judgment of the Court of 19 January 1982 in case 8/81 Ursula Becker against Finanzamt Münster-Innenstadt, ECLI: ECLI:EU:C:1982:7; the judgment of the Tribunal of 10 April 1984 in case 14/83 Sabine von Colson and Elisabeth Kamann against Land Nordrhein-Westfalen, ECLI: ECLI:EU:C:1984:153; judgment of the Court of 22 June 1989 in case 103/88 Fratelli Costanzo SpA against Comune di Milano, ECLI: ECLI:EU:C:1989:256.

4 PRACTICAL PROBLEMS OF THE APPLICATION OF COMMUNITY LAW IN THE FIELD OF EQUIPMENT QUALIFICATION

Article 1 (2) 2 of Regulation 765/2008[3] states that the EU market surveillance framework will ensure "[...] high requirements for the protection of public interests such as general health and safety, health and safety at work, consumer protection, environmental protection, and public safety". This target must be met for all products available on the EU market, irrespective of whether they are produced in the EU or a third country. This regulation therefore also creates a framework for the control of products from third countries. The most effective way to prevent dangerous placing on the market[4]or non-conforming imported products are subject to appropriate checks before release for free circulation. This requires the involvement of the customs authorities, which are the only services with a complete picture of trade flows across the EU's external border. In addition, there is a need for uniform enforcement of EU rules on safety and compliance checks. This goal can be achieved through systematic cooperation between market surveillance authorities[5] and customs authorities. This cooperation will provide equal protection for EU citizens as goods, once released for free circulation, can move freely within the single market. To facilitate the implementation of Regulation (EC) No 765/2008, the Commission, together with the Member States, has drawn up guidelines for the use of customs and to develop cooperation between customs and market surveillance authorities. It should be emphasized, however, that these guidelines are not legally binding but serve to provide general recommendations and best practices.

The guidelines mainly deal with the situation where customs are "authorities responsible for external border controls" and must cooperate with national market surveillance authorities. This requires the development of a common approach to customs controls about product safety requirements and the achievement of good and close administrative cooperation and effective communication between customs and market surveillance authorities.

Attempts at non-normative shaping of the practice of customs authorities undertaken by the European Commission and the Member States may objectively have only a partial effect and may not result in the unification of the activities of authorities in different countries and even offices within the same Member State. At this point, one should focus on one of the basic customs procedures, which is the release of goods for free circulation. Under this procedure, the customs authority is entitled to ask one of the national control authorities for an opinion on the matter, also on the medical device. Referring to the above to the import of medical devices, it should be emphasized that when a manufacturer declares a medical product in a specific class, the cooperation of organs, due to the need to seek specialist knowledge, is even necessary. It is so surprising and worrying the phenomenon of increasingly wider questioning by customs authorities of the non-medical nature of devices [sic!], Which is most often the result of the safeguarding approach of the authorities, but also the treatment of some devices based on analogy. This phenomenon is best illustrated by the example of hyperbaric chambers increasingly imported to the customs territory of the European Union, which, depending on the intended use (intended by the manufacturer of the device), may be of a medical as well as non-medical (commercial) nature. Unfortunately, however, these are not isolated cases when the authorities, contrary to the manufacturer's declaration of conformity stating the non-medical purpose of the device and supporting documentation, try to assign this type of device a medical value and condition the approval of the device on the market by supplementing the deficiencies in formal declarations in terms of medical care and presenting relevant documentation. Such an action has no basis on the basis. of

[3] See Journal of Laws 2008, p. 30.
[4] See art. 2 lit. b) Directive 95/2001.
[5] List of national market surveillance authorities communicated to the Commission by the Member States under Art. 17 of Regulation (EC) No 765/2008 is available at the following link: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for- products / index_en.htm

Community law and has found its bright expression, among others, in the Opinion of the Department of Supervision and Clinical Research of Medical Devices of the Office for Registration of Medical Devices and Biocidal Products of November 3, 2021, No. DNB.070.683.2021.1.KP, on the compliance of the product with the essential requirements. This opinion, referring to the device (non-medical hyperbaric chamber) imported from Turkey to Poland, qualified the device as a medical device, contrary to the declarations of the manufacturer and importer, and therefore indicated that it did not meet the essential requirements for such devices. Such qualification of the device poses a serious procedural and financial problem for the importer, because due to the formally non-binding nature of the opinion (although cases of the customs authority acting against such an opinion are extremely rare), the only remedy in the hands of the importer is to request the authority to correct its opinion. based on the submitted evidence and explanations by the importer, it should be emphasized that in this case there are no deadlines binding the supervisory authority to respond to such a request or any regulations obliging it to respond to such a request. In the case of the above-mentioned opinion, following two requests from the importer, the supervisory authority issued a new opinion on December 13, 2021, in which it stated that the device is not a medical device, and therefore the authority itself is not competent to meet the essential requirements for the device. the soil of non-medical directives indicated by the manufacturer in the declaration of conformity namely: 2006/42/EC of 17 May 2006 Machinery Safety Directive.

Due to the protracted nature of the described state of suspension, i.e., two months, the agreement for exclusive distribution in the European Union did not come into effect, and the contract fell to a Spanish company, which did not experience similar problems with similar documentation and qualifications of the manufacturer.

5 CONCLUSIONS

The development of European law over the last decades can be described as the constant approximation of national law toward the European model. (Kowalik-Banczyk, 2013, pp. 283–307) The principle of organizational and procedural autonomy gives the Member States freedom to define the rules and procedures for implementing European law. In addition, European legislation does not provide for regulations the subject of which would be to define the principles of the functioning of the national administration. Consequently, the Member States have wide independence in determining the mechanisms and rules for the application of European law, which may pose a risk of inconsistency and weakened effectiveness. (Wrobel, 2005) Despite the definition by the European Commission and the OECD of the general principles of the functioning of the national administration and the definition of the EPA as an area of constant convergence between the administrative law systems of the Member States, which indicated the need to approximate national solutions not only in the area of law-making but also at the level of its application, it has become clear that the goal of ensuring the uniformity and full effectiveness of EU law will not be achieved solely by harmonizing or unifying the provisions of substantive law. The implementation of solutions allowing for the elimination of national particularisms at the level of implementation and application of EU law is a necessity. (Torma, 2011)

When assessing the current MDR regulation in the context of the above-mentioned practical problems related to the uneven application of EU law in the field of qualifying devices as medical, it seems reasonable to formulate de lege ferenda conclusions relating to securing members of the economic trade (both the importer and the exporter) of the sensitive goods at the time of customs clearance, i.e., the correct classification of the goods in terms of its medical condition. The responsibility of the authorities accountable for admitting imported equipment to the market in the European Union in many cases generates an overly cautious attitude in terms of the interpretation and application of the law. Consequently, not only is the principle of uniform application of the law eroded in practice, but also the right to good administration. In the author's opinion, the solution to the described problems may be entrusting classification competencies to a central regulatory body similar in nature to EMA. Leaving the rules for the organization of national administrations and the procedures for applying

European law to the exclusive competence of the Member States may lead to the escalation of dangerous precedents. Creating closer networks and systems of links between national administrative authorities and European institutions, one element of which would be the proposed central regulatory authority, could very likely positively affect the uniform application of law within the single market and thus strengthen the principle of legal certainty, which is fundamental to trade business with third countries.

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