
Bartłomiej ŻYŁKA
Silesia University, Katowice, Poland
zykabartek@gmail.com

Abstract: The entry into force of the free trade agreement between the European Union and the Republic of Korea on July 1, 2011 (EFTA) eliminated customs duties on 98.7% of products and removed non-tariff barriers to the export of key goods between them. The agreement in question is in many respects a pioneering solution both due to the broad subject of regulation and the degree of liberalization of trade, but also due to the fact that it is the first free trade agreement concluded by the European Union with an Asian country and the first so-called “next generation”. Thanks to the implementation of the provisions of the agreement, the parties managed not only to reverse the negative balance of bilateral trade, but also to change the material structure of imports and exports of goods, among which medical devices play an increasingly important role, together with pharmaceutical products generate an annual trade surplus of EUR 60 billion. This article analyzes the functioning of the medical device market in the context of EFTA EU-Republic of Korea pointing to the need for the parties to take steps to harmonize medical device certification standards with particular emphasis on the potential of MDSAP.

Keywords: EU; Republic of Korea; EFTA; Medical; MDSAP

JEL classification: K39, L15, L50, L59, L69, N40, N60

1. INTRODUCTION

The trade agreement between the European Union and the Republic of Korea (FTA) dates back to August 2011, and its formal ratification took place in December 2015. This agreement was the first far-reaching agreement to remove existing trade and customs barriers, as well as the first trade agreement concluded between the European Union and an Asian country. Currently South Korea is in 9th place for the European Union when it comes to exports. Since July 1, 2011, the volume of trade has increased by over 70.8% and in 2021 alone it reached the value of EUR 107.3 billion. The European Union is at the moment the third direct investor in the South Korean market, after Japan and the United States[13] at the same time according to data for April 2022, the European Union became third, after China and the United States, in the ranking of sources of Korean imports.[3] This free trade agreement was the first of the so-called new generation agreements between the European Union and external trading partners.[3]
Despite the abolition of the vast majority of tariffs and such a significant increase in the trade volume between the parties to the agreement, over 11 years of practice also revealed more significant differences, among others in the field of certification of medical devices placed on the market of the EU and South Korea.

2. COMPARASION OF THE LEGAL FRAMEWORK

It’s obvious that EU as an organization faces different legal and structural issues than South Korea does, nevertheless serious steps have been already made in order to harmonize and unify standards of introducing medical devices into the common market throughout member states imports. The establishment of a common or single European 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 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- legislative harmonization covering only the essential requirements and 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.

Currently the EU legislative framework on medical devices consists of two new Regulations:


Global medical device industry is characterized by rapid pace of technological innovation.[2] However, in this industry, it takes a long time to launch new products, and there are always regulatory issues due to safety and validity.[7] More patents are issued every year in the medical device field in Europe than in computer, IT communications, and pharmaceutical fields.[11]

In all those fields Korean medical device industry is doing just great with the recent growth rate which is faster than the global
average. From 2014 to 2018, the average annual growth rate of the global medical device market was 4.0% while the Korean market grew by 8.0%[12]

At the moment the framework of Korean legislation regarding medical devices is created by:

- Medical Devices Act (MDA) [9]
- Enforcement Decree of MDA [17]
- Enforcement Regulations of MDA – framework of major regulatory programs and basis for GMP requirements in Annexes [10]
- MFDS notifications of MDA – which is the most detailed regulations for technical requirements, review standards, and processes.
- MFDS standards and guidelines – guidelines for industry and MFDS assessors.

Most detailed regulations for technical requirements, review standards, and processes are regulated as MFDS notifications. Some important notifications for device registration process are Regulation on approval, notification and assessment of medical devices, Standards for manufacture and quality management of medical devices (GMP), Regulations for product classification of medical devices, Re – evaluation (re-examination) of medical devices

Under the Medical Devices Act (MDA), a medical device is defined as an instrument, equipment, device, material, software or other similar product that falls under any of the following categories, excluding any product that is a pharmaceutical, quasi-pharmaceutical or assistive device regulated under the Disabled Persons Welfare Act Product used to diagnose, cure, alleviate, treat or prevent a disease. Product used to diagnose, cure, alleviate, or correct an injury or impairment. Product used to test, replace, or transform a structure or function. Product used for birth control.[9]

Supervision over Korean medical devices market is held by the Ministry of Food and Drug Safety (MFDS) formerly known as the KFDA. This government agency was created in 1996 with the creation of Medical Devices Management Division and Bioproduct Technical Support Division[16], restructured in 2013, when it was renamed and upgraded to a ministry.[18] The MFDS is in charge of the approval of medical devices, GMP standards, and pre- and post-market management of the medical device classification process. MFDS issues decisions on whether a product is a medical device and regulates the manufacture, advertising and sale of medical devices.[14]

A medical device manufacturer must obtain a business licence, a product registration for each product and a GMP certification for each category of product that the company manufactures (there are 26 product categories). GMP is a medical device manufacturing and quality management standard, that is, GMP (Good Manufacturing Practices). One of the most important aspects of GMP is to ensure consistent quality, and validation is performed for this purpose. Validation is the process of verifying through a series of plans and performance results that equipment, processes, and test methods are operating as intended and the results are consistent. Validation is one of the key points of GMP for medical devices along with risk management in that it can prove that the manufacturing and quality control process of medical devices is properly planned, executed and managed.

Medical devices are classified into four classes, depending on the possible health risks they pose, Class I medical devices are subject to a reporting requirement only. This means that the medical device can be manufactured or imported after it has been registered using the online registration system of the MFDS. Information that must be provided includes the product’s name, specifications, intended use, operation methods, warnings and origin of manufacture. Classes II to IV consist of medical devices that must be approved by the MFDS. Technical documentation is the most important part of the application for approval. Whether the product is equivalent to existing products is determined by the MFDS-approved third party institution that considers factors such as equivalence in the medical devices’ intended use, principles of operation,
material composition, performance, specifications and operation methods. If there is no equivalence, a clinical data report is required. For new medical devices, new technologies, new intended uses for class II medical devices and all class III/IV medical devices, the MFDS requires submission of technical documentation (including clinical trial data) to conduct a review of the medical device’s safety and efficacy. The technical documentation for certain class II medical devices designated by the MFDS is reviewed by the MFDS-authorised third-party institution. All other technical documentation is reviewed directly by the MFDS.

In addition, a company must obtain GMP certification from an MFDS-authorised evaluation body before submitting an application for product approval. The certification process includes an audit of the manufacturing site. Class II, III and IV medical devices are subject to this audit. A GMP certification is valid for three years while business and product approvals are valid for an unlimited period of time provided that the product is not modified.

To be an official holder of a manufacture or import product registration, an entity must be located in South Korea. Therefore, a foreign entity must establish a branch or subsidiary in South Korea or designate a third-party domestic entity to obtain the product registration.

Currently, the Korean medical device industry is mostly composed of small- and medium-sized enterprises (SMEs), while the market is occupied by global medical device firms. The medical device market in Korea is largely composed of three groups. Multinational corporations with accumulated R&D capabilities and infrastructure are monopolizing high-tech, high-priced medical devices such as CT and MRI, mainly in large hospitals in Korea. Next, medium and large domestic corporations are increasing their market share by equipping core technologies in such fields as ultrasound imaging devices, dental CT, and in vitro diagnostic reagents. The remaining 90% of SMEs produce low- and mid-priced medical devices.[11].

3. PRACTICAL PROBLEMS AND THE MDSAP

In 2021, Germany was second in the export structure of medical devices from South Korea with a volume of $1,498.02. [15] It should be emphasized that such a high position of Germany in the ranking results from the benefits for European importers of bringing medical devices through the port in Hamburg.

For many entrepreneurs, customs clearance in import to Hamburg is a tax advantageous solution, exemption from payment of VAT when importing to Germany and the possibility of cross-border transfer of imported goods will ultimately entail the obligation to pay the VAT due when the equipment is actually sold.

The global development of the medical device market, a part of which is the trade exchange between the European Union and South Korea, illustrates the complexity of problems related to the process of production, certification and implementation of medical devices on the market.

The fundamental problem for all participants of trade between the European Union and South Korea is the issue of recognizing the device as medical or non-medical. Both in the case of the EU and Korea, we are dealing with markets that impose strict requirements in all matters related to the production, marketing and marketing of medical devices. Nevertheless, which device is considered to be a class of medical device in South Korea as the country of origin does not translate into the actual status of that device in the European Union. There is no automatism at work here. The need for a Korean manufacturer to demonstrate European standards and directives that qualify the device as a medical device of a specific class.

Entry into force of the Regulation (EU) 2017/745 of the European Parliament and of the European Council of April 2017 on medical devices (MDR) which sets out new rules for the classification of medical devices. Depending on the duration of use, the degree of invasiveness or the possibility of reuse, medical devices of classes I, IIa, IIb and III are distinguished.
The product classification is established by the manufacturer on the basis of 22 rules of Annex VIII of the MDR Regulation (extension to 18 rules of Directive 93/42 / EEC). Importantly, according to the new guidelines, some products require reclassification to higher classes.

For each medical device, before placing the device on the market, a so-called “Conformity assessment”. It is important that all products of class higher than I require the participation of a notified body in the conformity assessment. In the case of class I devices, the conformity assessment procedure is carried out by the manufacturer himself. Class I devices that are placed on the market in a sterile condition, have a measuring function or are surgical instruments are an exception, in which case the participation of the unit in the conformity assessment is limited to these particular aspects. After conducting the appropriate conformity assessment according to the class of conformity, medical devices should be marked with the CE mark.

Both in the current legal situation, as it was during the period in which European Council Directive 93/42 / EEC (the so-called “MDD directive”) was in force, a significant source of problems is the customs clearance of a Korean medical product in the European Customs Area. Even the correct formal marking of the device in accordance with EU regulations may result in its detention by the customs authorities and the importer’s obligation to present documentation confirming its declared medical class, which, taking into account the classification differences between the European Union and Korea, causes numerous misunderstandings, which are consequently related to storage costs for the importer; and uncertainty.

Another important problem is the need for the entity introducing Korean medical devices to the market to carry out its conformity assessment, which in the case of devices from class II upwards will mean the participation of a notified body. As a consequence, the importer is doomed to a costly and time-consuming process which, at the same time, creates a state of limbo due to the inability to bring the device to the market smoothly.

The dynamics of development and the specificity of the medical market require action at the international level, which will lead to the gradual elimination of the problems described above. Already in 2001 ‘A model regulatory programme for medical devices: An international guide’ was published by the World Health Organization (WHO).[5] It has provided a certain framework to assist member states in establishing regulatory programmes for medical devices. It was based on experiences from areas that had already established comprehensive regulatory programmes. The aim was to provide information to nations without medical device regulatory systems that would enable the production of internationally compatible regulations.[6] Another important step was made in 2003 when the World Health Organization published ‘Medical device regulations. Global overview and guiding principles’ guidance to member states wishing to create or modify their regulatory systems for medical devices.[1]

Regulatory Bodies have limited resources and are hard pressed for enough time. They need to keep pace with the rapid developments in the industry while having to ensure that the safety and performance of the devices is not compromised. Patient safety remains the ultimate aim. Therefore, the regulators looked for a single harmonized strategy for regulatory audits.

In this dynamic and vibrant scenario, the Medical Device Single Audit Program (MDSAP) was launched as a solution that allows a single audit of manufacturers against multiple regulatory requirements.

This program promotes an international approach to auditing and monitoring the production of medical devices. Currently, the official members of the program is Therapeutic Goods Administration of Australia, Brazil’s Agência Nacional de Vigilância Sanitária, Health Canada, Japan’s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency oraz U.S. Food and Drug Administration. Obecnie oficjalnymi obserwatorami pozostają European Union, United...
Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA), The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme, while associate members is Argentina’s National Administration of Drugs, Foods and Medical Devices (ANMAT), Ministry of Health of Israel (NEW), Republic of Korea’s Ministry of Food and Drug Safety and Singapore’s Health Sciences Authority (HSA).

The foundational work done by the Global Harmonization Task Force (GHTF) was taken up by the International Medical Device Regulators Forum (IMDRF) in 2014, which set up a working group to create a harmonized single audit program. The pilot program, launched from 2014-2016, was found effective and therefore in Jan 2017, the MDSAP was officially implemented with five countries participating in it.

The MDSAP audit is based on ISO 13485:2016 with the applicable regulatory requirements of the participating jurisdictions – Australia, Canada, Japan, Brazil, USA – included as areas of focus. Audits conducted to MDSAP follow a closely prescribed process of defined tasks that the auditors have to perform. An MDSAP audit uses a process approach, based on a foundation of risk management, to select samples of procedures and records to examine. The audit is focused on how risks are identified and addressed. The audit process is described in the MDSAP Audit Model.

The MDSAP Companion Document originally identified the audit tasks that have to be covered and the links to the applicable regulatory requirements for participating jurisdictions. In September 2020, the Companion Document was combined with the description of the MDSAP Audit Approach in a single document. This updated, combined MDSAP Audit approach document did not make fundamental changes to the audit process but there are some minor changes to a few of the audit tasks. Changes in the updated document provide clarification on some of the audit tasks, particularly in relation to some of the regulatory requirements from MDSAP participating jurisdictions. The updated document also includes a new Annex containing a quick reference guide to the reporting timeframes for adverse events and advisory notices for the MDSAP jurisdictions.[4] Despite of the fact that the MDSAP remains mostly voluntarily program (mandatory for a medical device license only in Canada) and manufacturers still have to follow pathways of approving and registering medical devices in each country, nevertheless it’s already clear how beneficial and perspective this program is.

Thanks to a single audit program, manufacturers can approach ISO 13485:2016 requirements along with the regulatory compliance of the five participating jurisdictions which are built into the QMS requirements. The need for multiple audits is eliminated. Secondly, it optimizes resources, effort, and producer’s time. One of the most significant advantages of the MDSAP program is its standardization and therefore a serious improvement of audit’s predictability which helps to reduce subjectivity.

4. CONCLUSIONS

The global covid pandemic and the progressive aging of the populations of many highly developed countries make modern solutions in the field of medical technologies extremely desirable. The increased demand for medical devices obviously affects the value of the market, which is expected to reach $ 491.4 billion in 2023, with an annual growth rate of 4.8%. [8] Another factor stimulating the market of medical devices is the unprecedented development of new technologies, especially in the field of electronics and IT, and their easier than ever transfer.

The examples of South Korea and the European Union perfectly illustrate the above-mentioned trends. They are also examples of how restrictive the medical device market can be. Numerous, nationally and regionally differentiated, legal requirements imposed on manufacturers and the devices themselves are primarily aimed at protecting the most important value, which is human health and life. The same restrictions, however, contribute to
the aggravation of unfavorable phenomena in the sphere of trade consisting in discrepancies in the sphere of requirements and certification standards, which in turn result in the generation of a frequent state of uncertainty among exporters and importers. Undoubtedly, the scale of globalization of the modern world and the multifaceted nature of its integration should also translate into the plane discussed in this article.

Many years of successful operation of EFTA between the European Union and South Korea, despite the lifting of numerous barriers, did not in any way affect the certification procedures of the parties. Harmonization of production and certification practices should be considered a necessity if the aim is to maintain and disseminate uniform high production standards, user safety and optimize the liquidity of economic transactions. The interest shown by both the European Union and South Korea in the MSDAP program should be considered a positive sign that may herald the extrapolation of common certification practices and standards in the legislation of the FTA parties.

REFERENCES