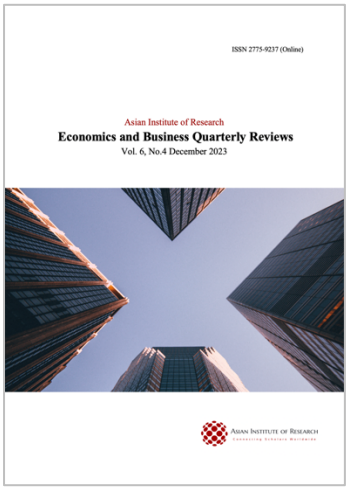

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Regulation of Medical Devices – A Poland and U.S. Study: Marketing and Legal Aspects

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Abstract
Consider this scenario: One of your former students working in the medical devices field for over twenty years has been approached by a medical device manufacturer in Poland who wishes to market its medical devices in the European Union and eventually expand into the United States. You learn that the Polish government is especially interested in pursuing this opportunity as part of its larger outward foreign direct investment strategy. Your student is being considered as the CEO of prospective U.S. operations. Part I is a study of the various issues that will confront the potential Polish exporter in meeting European Union standards which will guarantee compliance with EU Regulation (EU) 2017/745 on medical devices (MDR). Part II discusses U.S. regulations concerning the importation of medical devices into the United States and the advertising & labeling of such devices.

Keywords: Medical Devices, Foreign Direct Investment, Field Service Corrective Actions, Advertising, Conformity, Food and Drug Administration

1. Introduction: The Context of Foreign Direct Investment in Poland

Poland has remained one of the most attractive destinations for foreign direct investment in the European Union (adapted from Hunter & Lozada, 2022). According to the U.S. Department of State (2019), the Polish government has prioritized expanding the domestic economy by supporting high-tech investments, increasing productivity and foreign trade, and supporting entrepreneurship, scientific research, and innovation through domestic and EU funding. Rodl & Partner (2020) report that a study conducted by the Polish Investment and Trade Agency (PAIH) in 2019 found that the positive investment climate fostered in Poland has resulted in as many as 94 percent of foreign investors stating they would re-invest in Poland.

Gorynia, Nowak, and Wolniak (2011, p. 148) noted that "Foreign direct investment (FDI) has played a pivotal role in the transformation of post-communist economies of Central and Eastern Europe (CEE) for more than a decade now. This is especially true for Poland which experienced a phenomenal growth of inward FDI." Hunter and Ryan (2013, p. 14) commented that "From the start of the process of economic transformation in Poland in

the fall of 1989, attracting FDI has been considered as a main policy objective of nearly all political parties and parliamentary configurations that have governed Poland and of all the individuals who have held the critical position of Minister of Finance in the Polish government."

Lloyd's Bank (2023) reports that Poland has consistently ranked among the most attractive countries in Europe in terms of attracting FDI. According to UNCTAD's *2022 World Investment Report* (UNCTAD, 2022), FDI inflows to Poland reached a record-high level of USD 24.8 billion in 2021, compared to USD 13.8 billion one year earlier and 83% above the pre-COVID level (Lyttle, 2022). Lyttle (2022) also states that Poland was 14th globally and third in the EU in terms of the value of FDI inflows in 2021. In the same year, the *total inward stock* of foreign investments stood at USD 269.2 billion, a 7.8% increase yearly.

According to PAIH (2023), in the period 2019-2021, foreign investors in Poland contributed to the creation of 339,000 jobs. The largest investor in the country during 2021 in terms of capital investment was South Korea (USD 1.9 billion), followed by the U.S. (USD 364 million) and Germany (USD 155 million). The majority of FDI stocks are held by Germany (21.2%), France (10.8%), the Netherlands (10.4%), and the United States, with investments directed mainly towards manufacturing (31.3%), wholesale and retail (14.8%), financial and insurance activities (14.2%), and real estate sectors (10.4%). Poland's main assets are its strategic position, literally in the "heart of Europe" (Pogonowski, 1987), a large population of nearly 38 million people, its membership in the European Union, economic stability, skilled labor at a competitive cost, advancing infrastructure, and a fiscal system attractive to businesses (Davies, 2022; PAIH, 2023). Moreover, Poland has established and nurtured many dynamic Special Economic Zones (Dorozynski, Swierkocki, & Urbaniak, 2016; Ambroziak & Harwell, 2017), which hold out the promise that the current trend will continue well into the future, especially by non-EEA and non-OECD investors (Cieslik, 2020; Gubanski, Gac, & Malobecki, 2023).

The Polish Investment and Trade Agency, (PAIH), supports the foreign expansion of Polish businesses and the inflow of FDI into Poland (see Hunter, 2019; Przezdziecka, 2021). In addition, PAIH assists in boosting Polish exports and supporting the new generation of entrepreneurs who have grown up in post-1989 Poland. Specifically, PAIH assists in overcoming administrative and legal roadblocks related to implementing specific projects, finding a suitable location in Poland for either a *greenfield* or *brownfield* investment (Hayes, 2021), and identifying reliable partners and suppliers to ensure the sustained success of an investment (see www.PAIH.gov.pl).

According to Rutkowski (2021) and Baker McKenzie (2022), as of this writing, more than 300 companies are operating in the medical products and devices industries, offering approximately 500,000 medical products as part of the government's export strategy. These products and devices have been approved for sale under strict EU regulations. The medical products and devices segments are a strong component of the Polish economy, indicating the success of efforts to bolster FDI activities.

Rutkowski (2021) states that the medical devices and equipment industry has become one of the priority industries of the Polish economy.

> Between 2000 and 2018 expenditure per capita in public healthcare increased from USD 200 to USD 979 (EUR 166 to EUR 812)1. This is reflected in the rising value of the domestic market for medical devices, which in 2017 was estimated at EUR 2.5 billion by the 'Technomed' Medical Industry Organization, compared to EUR 1.5 billion only four years earlier. The value of domestic market for medical devices and equipment was estimated by the Polish Investment and Trade Agency (PAIH) at EUR 2.9 billion in 2018 (Rutkowski, 2021, p. 8).

2. What are the Obligations of Producers of Medical Devices in Poland?

Melvin and Torre (2019) assert that medical device manufacturers entering the EU must have systematic methods for examining their devices once they are available. This entails thoroughly gathering, recording, and analyzing

data on safety and performance. These regulations were critical in establishing a modernized and more robust EU legislative framework (Melvin and Torre, 2019).

The product safety regulatory regime that applies to medical devices in Poland is based on EU Regulation (EU) 2017/745 (European Union, 2017) on medical devices (MDR) (see MedTech Europe, 2020; Chodorek, Tracz, Lokaj, & Izydorczyk, 2022). Vasiljeva, van Duren, and Pandit (2020, p. 123) noted:

> Up until 2017, medical devices were placed on the European Union's (EU) single market in accordance with either Medical Device Directive 93/42/EEC for general medical devices or Medical Device Directive 90/385/EEC for active implantable devices. However, some devices that complied with these directives still failed catastrophically. In the orthopaedic device field, these failures were most pronounced in metal-on-metal hip devices causing severe patient morbidity with increased need for revision surgery which had unpredictable outcomes. Subsequently, the newly introduced Medical Device Regulations 2017/745 are aimed at addressing patient safety based on previous experience and thorough device assessment prior to and post-release on the EU single market; to accommodate for this they are substantially different (and more stringent). This poses a greater challenge for manufacturers and regulatory bodies in terms of time and resources.

CE Marking (2022) notes that the new Polish national legislation on medical devices became a reality when Polish President Andrzej Duda signed the regulations on April 20, 2022. This has led to better consistency between the national law and the European directives. Polish regulations now align with EU Regulation 2017/745 (on medical devices, the MDR) and EU Regulation 2017/746 (on in vitro diagnostic medical devices, the IVDR; see also Pitkanen, Raunio, Santavaara, & Stahlberg, 2021).

According to Polish law (KG Legal, 2023):

> Medical device means a tool, apparatus, device, software, implant, reagent, material, or other article intended by the manufacturer to be used, either singly or in combination, in humans for one or more of the following specific medical uses:
>
> – the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or mitigation of disease,
> – to diagnose, monitor, treat, mitigate, or compensate for an injury or disability,
> – the study, replacement, or modification of an anatomical structure or process or physiological or disease state,
> – for providing information through in vitro testing of samples collected from the human body, including those collected from organ, blood, and tissue donors, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means in or on the human body, but whose action may be assisted by such means."

The following products are also considered medical devices:

– devices for the purpose of controlling conception or assisting conception,
– products specifically intended for the cleaning, disinfection or sterilization of devices.

The *Act on Medical Devices of 7 April 2022* specifies some of the most important obligations for medical device manufacturers, importers, and distributors (Swidrak, 2022). The law repealed the Act on Medical Devices of 20 May 2010 (see Urzad Regestracji Produktow Leczniczych Wyrobow Medycznych i Produktow Biobojczych, 2022).

A manufacturer is defined as**:**

> a) the entity responsible for the design, manufacture, packaging and labeling of the product before placing it on the market under its own name, regardless of whether these activities are performed by the entity itself or on its behalf by another entity,

b) an entity that assembles, packages, processes, completely reproduces or labels a finished product or gives it an intended use, in order to place it on the market as a product under its own name, with the exception of an entity that assembles or adapts products already placed on the market, in the purpose of their intended use by an individual patient.

A manufacturer residing or having its registered office in Poland is required to notify the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) at least 14 days before placing the device on the market or submitting the first device for evaluation (Baker McKenzie, 2022). The product manufacturer is responsible for the product, for the conformity assessment of the product before its placing on the market, and for placing the product on the market.

If the manufacturer is not a resident or is established in Poland, this responsibility is assumed by the authorized representative for that device. If the manufacturer has not appointed an authorized representative or if the product is not placed on the market under the responsibility of the manufacturer or the authorized representative, liability will be assessed to the entity or party that placed the product on the market.

The manufacturer with the place of residence or registered office in Poland is obliged to keep a *list of all healthcare providers and distributors* to whom the manufacturer has supplied the devices for the period of use of the device, and to make the list available during any inspections. The list must be immediately available at the request of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, (see http:urpl.gov.pl) Koperny, Maciorowska, Lesniak, & Bala, 2017; Cromos Pharma, 2022).

The manufacturer or its authorized representative is required to perform a clinical evaluation of the medical device or of an active implantable medical device to confirm compliance with the requirements relating to the properties and operation of the evaluated device and to assess any adverse effects and the acceptability of the clinical benefit to risk ratio (see Kaul, Stockbridge, & Butler, 2020) under normal conditions of use of the evaluated device. Exceptions are allowed when demonstrating compliance with the requirements without clinical evaluation is based on a performance evaluation, performance tests, and pre-clinical evaluation or is otherwise justified in the documentary evidence relating to conformity assessment. The documentation should justify any exclusion based on risk management results, considering the device's specific interactions with the human body.
The manufacturer is required to ensure that the authorized representative and any other entity authorized by the manufacturer to act on its behalf in cases of medical incidents and in matters related to product safety will implement *Field Safety Corrective Action*, hereinafter referred to as "FSCA" under MDR, Article 87 (generally, Gatt & Halliday, 2017). FSCA is an activity undertaken to reduce the risk of incidents to enhance the safety and performance of a medical device. These actions are not unique to Poland and may include:

- Problem identification
- Risk assessment and decision to implement FSCA
- Preparation of FSCA strategy
- Notification to authorities and affected consignees/parties
- FSCA execution
- Collection of FSCA information and data
- Submission of FSCA Report to the competent authority (see generally, Ministry of Health Malaysia, 2020).

Specifically relating to an in vitro device (IVD), the World Health Organization (2023) notes that a field safety corrective action (FSCA) is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of an IVD that is already in the market. An FSCA is triggered by information about any problem with an already distributed IVD posing an unacceptable increased risk when that IVD is used. The WHO indicates that such problems include malfunction or deterioration affecting the performance or operational characteristics of an IVD, as well as any inadequacy in the instructions for use which might lead or might have led to the death of a patient, user, or other individual or to a serious deterioration in his/her state of health. Such information may be collected during pre-distribution or post-distribution lot testing,

from reports from the field, during the review of IVD design, or changes in production or component specifications.

The manufacturer must investigate a *medical incident* (Simunovic, Kranjcec, Pekas, & Tomic, 2023) that has been reported to the manufacturer. In so doing, the manufacturer can assess whether the reported medical incident is an event that meets the criteria for reporting the incident to the President of the Office.
According to the *Act of 20 May 2010 on Medical Devices*, found in the Journal of Laws of 20 May 2010 (Wyrob Medyczny, 2012), the definition of a medical incident is as follows:

- a malfunction, defect, or deterioration in the characteristics or performance of the device, as well as an abnormality in its marking or instructions for use which may or may have led to the death or serious deterioration of the health of the patient or user of the device or, in the case of an in vitro diagnostic medical device or in vitro diagnostic medical device, indirectly another person, or

- a technical or medical cause related to the characteristics or performance of the device which may or may have led to the death or serious deterioration of the health of the patient or user and, in the case of an in vitro diagnostic medical device or in vitro diagnostic medical device, indirectly to another person, and leading, therefore, to external safety corrective action taken by the manufacturer."

The manufacturer who places a medical product on the market for use in Poland that requires special spare parts, consumables (a piece of single-use medical equipment that healthcare providers use in hospital and surgical settings), or consumables specified by the manufacturer of the device for its proper and safe operation, is required to attach to the product a list of suppliers of such parts and materials.

A manufacturer who places a product on the market for use in Poland, requiring professional installation, periodic maintenance, periodic or ad hoc service, software updates, periodic or ad hoc inspections, adjustments, calibrations, calibrations, checks or safety checks which, according to the instructions for use of the device, *cannot be performed by the user*, is also required to attach to the device a list of entities authorized by the manufacturer or authorized representative to perform these activities.

Issues Relating to Marketing and Advertising

The 2022 Law on Medical Devices provides for the introduction of a new, broad regime of regulations relating to the advertising of medical devices. The law will require Polish manufacturers to adapt their promotional communications in the Polish market (Czerw & Marek, 2013). In particular, the regulations refer to advertising to the general public, as opposed to "professional users," bringing the rules for advertising medical devices in line with the regulations applicable to advertising medicinal products.
Interestingly, the provisions:

- prohibit the use of images of healthcare professionals;
- prohibit advertising concerning devices intended for use by professional users (e.g., in hospitals or by persons conducting surgical procedures);
- require that templates (visual records) of advertisements and information where they were disseminated be kept for two years.

The Act provides that the Minister of Health may issue regulations further specifying additional rules on advertising. The contemplated regulation is intended to strongly limit the possibility of advertising to the public by requiring "\the use of warning signs specific to medicines, information on contraindications, and the familiar *"consult ... before use"* messages."

The regulations exhibit significant differences from the general European Union rules on advertising, which generally provide only for the prohibition of misleading advertising, or to rules established in the area of product warnings in the United States which provide:

1. A warning must be displayed in such a way as to reasonably *catch the attention* of the person expected to use the product. (This requirement deals with such factual questions as size, position, and even the color of the warnings.)

2. A warning must fairly apprise a reasonable user of the nature and extent of the danger and *not minimize* any danger.

3. A warning must instruct the user as to how to use the product in such as to avoid danger—essentially how to *safely use* the product (see Hunter, Shannon, & Amoroso, 2018, p. 19, citing *Spruill v. Boyle-Midway, Inc.*, 1962).

Advertising a medical device in Poland in breach of the regulations is subject to a fine of up to PLN 2 million—nearly a quarter million in US currency. The new advertising regulations came into force on January 1, 2023. However, the regulations will not apply to advertising that has already been disseminated but which does not meet the new regulation's requirements in the first six months of the year or until June 30, 2023.

According to Matczak, Kaczynski, and Kruczyk-Gonciarz (2021), the legal requirements for advertising to professionals are listed in the Pharmaceutical Act and the Regulation of the Ministry of Health of 21 November 2008. These regulations mandate that the following are included:

- The name of the medicinal product and the name commonly used.
- The product's qualitative and quantitative composition in respect of active substances and the excipients essential for the product's proper use.
- The pharmaceutical form.
- An indication or therapeutic indications for use.
- The dosage and method of administration.
- Counterindications.
- Special warnings and precautions for use.
- Adverse reactions.
- Identification of the marketing authorization holder (MAH).
- The number of the marketing authorization and the name of the authority that issued it.
- Information on the reimbursement category, and in the case of medicinal products on the lists of reimbursed medicines information on the official retail price and the maximum price.
- Information as to when the particular marketing material was drafted or revised."

Regulations Concerning Language (see Safar, Colquhoun, & Hill, 2012; Christen, 2021)

Article 10 (11) of Regulation (EU) 2017/745 requires manufacturers to include information in one or more official language(s) determined by the Member State in which the product is made available. In addition to labeling requirements, this regulation also requires that this information be clearly understandable to the intended users or patients. Concerning specific linguistic regulations, Article 23.1 a) states:

> The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

Christen (2021) notes that manufacturers of medical devices cannot avoid dealing with the language requirements of each country in which they wish to market their products. This also means that the internal processes for the

respective countries are to be adapted accordingly so that the products are delivered to the respective countries with the correct information or that users receive instructions for use in the local language upon request. Christen (2021) states that the MDR unequivocally makes distributors and importers responsible for compliance with the language requirements.

According to the law, medical devices intended for use by lay or non-professional persons must contain labels, instructions for use, and user interfaces in Polish. Devices for professional users in Poland may be supplied with documentation in English, except for patient-specific private information.

According to the MDR, advertising of devices must not be misleading concerning the device's intended *purpose, safety, and performance* by:

- ascribing functions and properties to the device which the device does not have;
- creating a false impression regarding treatment or diagnosis, functions or properties that the device does not have;
- failing to inform the user or the patient of a likely risk related to the use of the device in line with its intended purpose; or
- suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was conducted."

3. An Overview of the Approval Process for Medicinal Products and Medical Devices

The European Commission is responsible for issuing a marketing authorization for medicinal products as part of the centralized procedure for approval of medical devices, veterinary medicinal products, and biocides which are chemical compounds or biological products used to kill, control the growth of, or repel a specific organism.

Poland has also established a specialized Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) (Kaczynski, Pachocki, & Radzikowska, 2021). This office is responsible for all matters relating to:

- Marketing authorization for medicinal products.
- Marketing and use of products.
- Marketing authorization, making available on the market and using biocidal products.
- Clinical trials, including veterinary clinical trials" (see also Manita et al., 2019).

Medicinal products can be placed on the market after the competent authority has issued the relevant decision relating to a marketing authorization of the medicinal product. Before issuing such a decision, the URPL will examine whether the medicinal product's quality is sufficient, and the product is *safe and effective*. The assessment is based on an application submitted by the "marketing authorization" holder and the documentation attached.

The URPL has published a detailed overview of the regulatory framework to assist medical device manufacturers and importers in complying with the applicable requirements (see Patryn, Zagaja, & Drozd, 2021).

URPL's Powers and Responsibilities

The URPL is responsible for the following matters for medical devices:

- approving medical devices to be marketed and used in Poland;
- Post-market surveillance and collection of the information regarding adverse event reports and notifications;
- Safety monitoring;
- Supervising clinical trials connected with medical devices;

- Making the final determination regarding the correct classification of medical devices and accessories thereto;
- Cooperation with the foreign national regulating authorities and international organizations operating in the sphere of medical devices; and
- Issuance of Free Sales Certificates for medical devices.

The "Free Sale Certificate" for Exporting Medical Devices

A manufacturer or authorized representative of medical devices, biomedical devices (Lam & Chen, 2019), in vitro diagnostic medical devices, or active implantable medical devices who wishes to export such devices outside the European Union must obtain a certificate of free sale (Government of Poland, 2018).

A free sale certificate (Noah, 2021) is a document intended to facilitate the exportation of medical devices, in vitro diagnostic medical devices, and active implantable medical devices outside of the European Union. The certificate is issued for a medical device bearing the CE marking and a custom-made medical device. To receive a certificate, a party must be either a manufacturer or the manufacturer's authorized representative and have a place of residence in Poland. The certificate is a statement or attestation confirming that the product is CE-marked, under the manufacturer's sole responsibility, and may be placed on the market and put into service in Poland and that it can be exported.

The CE Marking

Placed on commercial products, the letters **CE** (or the logo CE) means that the manufacturer or importer affirms the goods' *conformity* with European Economic Area (EEA) standards. It is not a quality indicator or a certification mark (see Lam & Chen, 2019). CE marking is required for goods sold in the EEA, but it is also found on products sold elsewhere manufactured to EEA standards (see Gronkvist, 2022).

Gronkvist (2022) notes that the following information is often included in a Certificate of Conformity:

- **Registration/Report Number:** The report or certificate number can be used to verify if the document is valid. All certificates have some registration or report number.
- **Issuing Company:** The company that issued the Certificate of Conformity, including their contact details and address.
- **Certificate Holder:** The company for which the certificate was issued. This is usually the importer or manufacturer which intends to sell the product.
- **Product Information:** Product name, SKU ("stock keeping unit" used for inventory control), or model number. One certificate can sometimes cover more than one product.
- **Regulations/Directives/Standards:** Summary of the regulations, directives, and standards to which the product is certified to conform.

The CE mark indicates that the product may be *traded freely* in any part of the European Economic Area, regardless of its country of origin. It consists of the CE logo and, if applicable, the four-digit identification number of the notified body involved in the conformity assessment procedure. "CE" is the abbreviation of *"conformité européenne* (French for "European conformity"). The CE mark on a product indicates that the manufacturer or importer of that product affirms its compliance with the relevant EU legislation and indicates that the product may be sold anywhere in the European Economic Area (EEA). It is a criminal offence to affix a CE mark to a product that is not compliant or offer it for sale.

Step-by-Step Procedures for Product Approval (Kaczynski, Wycichowski-Kuchta, & Zielinska, 2020)
The following are the steps required for product approval:

1. Submit an application, which includes the following documentation:

    - Application for issue of the certificate of free sale
    - Proof of payment of the fee
    - Power of attorney for administrative matters
    - Proof of payment of the fee for the power of attorney

2. The URPL will then evaluate the application and any supporting documentation: If the application does not contain proof of payment or any errors or deficiencies, or if the documentation found in the application contains errors or deficiencies, the office will ask the party to correct any errors or deficiencies. The party applying will have seven days to make any necessary corrections. If the party fails to make the required corrections, the application will not be considered further.
3. If all of the procedures are complied with, the submitting party will receive a certificate of free sale in both Polish and English. The applicant will normally receive the certificate within 15 days of application submission.

Poland employs what may be termed a *risk-based approach* to classifying medical devices (see Johner, 2019). Following Poland's medical device classification, all medical devices are divided into four classes (I, IIa, IIb, or III) depending on the risk associated with using the device. In particular, 18 rules are used for classification, depending on the device's intended purpose. Rules 1-4 are relevant for non-invasive medical devices; rules 5-8 are relevant for invasive medical devices; rules 9-12 are relevant for "active medical devices"; and rules 13-18 are special rules (Brkic, 2021). The medical device manufacturer makes the initial classification before applying for marketing approval. At the same time, the final classification of a medical device will be made by the regulating authority.

Any entity that is intended to place its medical device on the Polish market should contact and actively cooperate with the URPL during the whole lifecycle of the product, from initial approval for marketing and use to post-market surveillance, adverse event reporting, and corrective and preventive actions.

4. Marketing Medical Devices in the Polish Market

In addition to the requirements of the 2022 law, any medical device intended to be marketed and used in Poland is required to meet certain requirements. Depending on the type of the device, it should comply with the requirements set forth by the applicable regulation, namely:

- Regulation on the essential requirements and procedures for assessing the conformity of medical devices dated February 17, 2016, which established general *safety requirements for medical devices*;
- Regulation on the essential *requirements and conformity assessment procedures for in vitro diagnostic (IVD) medical devices* dated January 12, 2011;
- Regulation of the essential *requirements and conformity assessment procedures of active implantable medical devices* dated January 12, 2011.

In addition to the requirements outlined in the above-stated regulations for the marketing and use of medical devices in Poland, a medical device must comply with the requirements relating to safety and health protections for personal protective equipment if the device contains any hazardous substances or electronic or radio components, it must also meet the appropriate safety requirements relating to these substances or components as mandated in the Act on Conformity Assessment System, dated August 30, 2002 (Miareczko & Jedrzejewska, 2002).

Labeling Requirements and Instructions for Use

Requirements for a medical device intended to be marketed in Poland are related to the *labeling* placed on the device itself, its *packaging*, and the *instructions for use* to be supplied with the device. The manufacturer, its

authorized representative or agent, a supplier, or an importer is required to take into consideration the following general rules:

- Any device intended to be distributed in Poland is required to provide both labeling and instructions for use provided in Polish. However, the information contained in the labeling could be provided with the help of harmonized symbols generally recognized to provide the required information. [See Appendix I- Medical Device Symbols in the European Union]
- At the same time, if a foreign medical device is intended to be used in the particular healthcare facility that applies for its approval, it is suggested that the device be supplied with the labeling and instructions for use provided in English, while the information that is intended for patients should be provided in Polish.
- If the labeling of the device is provided in Polish, the instructions for use could be provided either also in Polish or described with the help of harmonized symbols.
- If the labeling placed on the package containing more than one medical device (a group or batch packaged) is provided in Polish, the labeling of each particular device could be provided either in Polish or with the help of harmonized symbols.

The URPL provides a detailed description of the obligations of the parties involved with medical devices including medical device manufacturers, authorized representatives of foreign medical device manufacturers, and importers and distributors. A foreign medical device manufacturer is required to appoint an authorized representative who is required to participate in all regulatory procedures related to medical devices. However, this rule can be waived if the medical device manufacturer is registered within the European Union (see Jarman, 2021). A domestic medical device manufacturer is required to keep its business records containing information about suppliers and distributors. All such records must be provided to the regulating authority upon request.

Before placing a new medical device on the market, the manufacturer is required to perform clinical trials in order to assess the effectiveness of the device and its compliance with applicable safety requirements. In the course of the clinical trials, the manufacturer of the device is required to evaluate the *balance between the benefit and risk* attended to the device (Kouroumalis, 2019) and document all identified side effects in connection with using the device. At the same time, the medical device may be exempted from the mandatory clinical trial procedure if it falls within the scope of an exemption due to the evaluation of the nature and risk associated with its use.

Another important consideration relates to a requirement of the Field Safety Corrective Actions (FSCA), described above. This requirement mandates "special actions" to be undertaken without undue delay if any *significant malfunctions of the device* or *new risks* associated with its use are identified after making the device available to healthcare facilities and patients (see Pane et al, 2019). In particular, such actions are intended to mitigate risks, reduce hazards, and prevent injuries that could be caused by the medical device based on this new information. In the course of such corrective actions, the medical device manufacturer is required to undertake one of the following measures:

- Issue the updated version of the instructions for use and provide users of the device with the necessary safety information;
- Make changes to the device to mitigate identified risks;
- Withdraw the devices from the market; or
- Revoke the devices already distributed among users.

PART II

Part II deals with the intention of Polish medical device manufacturers to export its products into the United States.

5. Importing Medical Products into the United States (adapted from USA Customs Clearance, 2020; see also Kramer, Xu, & Kesselheim, 2017).

In the United States, the Food and Drug Administration, (FDA), ensures that all imports under their jurisdiction comply with relevant statutes and administrative rules (Horvath, 2019; Alford, 2020). The FDA also ensures import compliance with the *Federal Food, Drug, and Cosmetic Act* of 1938, as amended by the *Medical Device Regulation Act* or *Medical Device Amendments of 1976.*

No individual or business entity can sell medical devices in the United States without the approval of the FDA. They must present proof that the device is *safe* and can be used for a *specific purpose* (see Termini & Hoxha, 2020).

In addition to registering with the FDA, there is a requirement to procure a customs bond before importing medical devices into the United States. Zbyszewski (2018) writes: "A Customs bond is a contract between three parties (Customs, a principal (i.e., an importer), and a surety) to ensure that all the duties and fees associated with the rules and regulations of importing or other Customs activities are paid to Customs by the principal." An import customs bond can be either a single-entry or a continuous bond. A continuous bond guarantees the U.S. Customs & Border Protection, (CBP), that the importer will make good on its payment. If the importer fails to make its payments, the CBP can file a claim against the bond from the surety company that guaranteed payment. A continuous customs bond covers all entries for the entire year, requiring one flat fee per transaction.

However, it is important to note that an "import license" is not required for the importation of medical devices into the United States. Instead, importers or other entities are required to *register* annually with the FDA (FDA, 2018b). In the United States, the following domestic entities (termed "establishments") are required to register with the FDA:

- Manufacturer
- Contract sterilizer, providing a service for another party's products
- Relabeler or repackager
- Specification developer
- Manufacturer of devices for export only

In contrast, businesses such as wholesale distributors, customs brokers, and component parts manufacturers are not required to register with the FDA.
In the United States, the FDA has established separate criteria to determine registration requirements for foreign entities. Some of the foreign entities that must *register* with the FDA include:

- Foreign exporter of devices
- Manufacturer
- Component manufacturer (subject to some exceptions)
- Remanufacturer

FDA Requirements

The FDA may require additional information and documentation when an entity intends to import medical devices into the United States. Many of these requirements exist in the documentation that must be provided at the time of entry.

- Premarket Notification (510k) or Premarket Approval

Depending on the device, either a premarket notification or premarket approval will be required, designed to ensure that devices meet specific FDA standards before entering the U.S. market. Proof of approval from the FDA will be required at the time of import.
Rish (2021) asserts that Premarket Approval, (PMA), is a thorough and exhaustive process of affirming the quality and safety of Class III medical devices. These high-risk, high-reward products are cutting-edge medical devices often designed to address the most dire health conditions.

These may include items such as pacemakers, cochlear implants, implanted prosthetics, or high-frequency ventilators. Regardless of the intended use, the FDA has identified some key characteristics of Class III products. According to FDA, Class III medical devices are:

- Devices that support or maintain a person's life
- Have substantial importance in preventing an impairment
- Ones permanently implanted in the body
- Products which otherwise present an unreasonable level of risk and/or fatalities."

In 2021, the FDA cleared or approved 27 medical devices for use in the United States (Food and Drug Administration, 2021).

- Labeling

All medical devices coming into the U.S. are required to meet certain FDA labeling standards (Yeng, Yang, & Wolthusen, 2020). Section 201(k) of the *Food, Drug, and Cosmetic Act* defines a 'label' as a:

- display of written, printed, or graphic matter upon the immediate container of any article
  The term *immediate container* does not include package liners. Any word, statement, or other information appearing on the immediate container must also appear 'on the outside container or wrapper, if any there be, or the retail package of such article, or is easily legible through the outside container of wrapper.'
  Section 201(m) defines *labeling* as:
- all labels and other written, printed, or graphic matter
  (1) upon any article or any of its containers or wrappers, or
  (2) accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.
  The term *accompanying* is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. *Accompanying* also includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

Labeling standards include:

- Intended use
- Language requirements
- Unique device identification
- Proper disposal directions
- Warning statements

Some devices such as condoms, hearing aids, eyeglasses and sunglasses must meet additional labeling requirements. The FDA (2020) notes that *labeling* is defined in the *Federal Food, Drug, and Cosmetic Act*, (FFDCA), as including all printed matter accompanying any article. The FDA does not exclude from the definition printed matter which constitutes advertising.

- Medical Device Reporting

The FDA must have access to past reports of complaints regarding any medical device. Devices deemed to be unsafe will be denied entry.

The FDA (2022) notes:

> Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries, and malfunctions. Medical Device Reporting, (MDR),

> is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.
>
> Mandatory reporters (that is, manufacturers, device user facilities, and importers) are required to submit to the FDA certain types of reports for adverse events and product problems about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

QualityMedDev (2021) notes that the requirements mentioned in Code of Federal Regulation 21 CFR 803 consider that an event is reportable when:

- a device may have caused or contributed to a patient death or serious injury
- a malfunction of the device did occur and would likely cause or contribute to a death or serious injury if the malfunction were to recur.

> **Caused or Contributed**: A death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) Use Error.
> **Serious Injury:** it is an injure that: 1) Is life-threatening; 2) Results in permanent impairment of a body function or permanent damage to a body structure; 3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
> **Malfunction** : The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed."

- Medical Device Tracking

Some devices are required to be physically tracked from manufacture through purchase and use by the consumer. This requirement applies to certain Class 2 and Class 3 medical devices.

The FDA (2018a) notes that's the purpose of device tracking is to ensure that manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution. Tracking information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices. Because of this, manufacturers must adopt a method of tracking devices whose failure would be reasonably likely to have serious, adverse health consequences; or which is intended to be implanted in the human body for more than one year; or are life-sustaining or life-supporting devices used outside of a device user facility.

How to Determine Medical Device Classification

There are three main classes of medical devices. The FDA, under the authority of the U.S. Food, Drug, and Cosmetic Act, requires that all medical devices must comply with FDA regulations before being allowed importation into the United States in order to ensure safety and effectiveness. Generally, the FDA does not recognize regulatory authorizations (endorsements) from foreign nations.

Device Class and Regulatory Control

The classification of a device is based on several factors, including its intended use and also indications for use (Guintoli, 2020). There are three general classifications of medical devices (Lamph, 2012):

Class I – General Control: Class I devices are subjected to what has been termed *general control*. Most medical devices in Class I may enter the United States by ensuring their naming conforms to FDA guidelines. Class I devices are not meant to help life or draw out life, or be fundamentally significant in preventing injury to human well-being. Examples of Class I devices are bandages, assessment gloves, and hand-held clinical instruments. DeviceLab (2021) states that about 50% of all FDA-regulated medical devices are class I devices. Class I medical devices have a low risk-to-benefit profile, i.e., these products are well established, and there are non-significant consequences or injuries associated with the misuse. Since these devices are non-life sustaining or life-supporting, diagnoses from a Class I device would not be life-altering.

Class II - General Control with Special Control: Class II devices represent a higher risk than those in Class I (Hetrick, 2021). A defect in a Class II device may cause injury to consumers if defective. BMP Medical (2023) notes that Class II medical devices have a moderate to high risk to the patient and/or user. About 43% of medical devices fall under this category.

The main difference between a Class I and Class II medical device is the level of risk and the degree to which the device comes into contact with the patient. While Class I devices present minimal harm to the patient and are generally simple in design, Class II devices, while typically non-invasive, pose a higher degree of risk and must offer a higher level of assurance that it will not cause injury or harm (BMP Medical, 2023). Although some Class II devices are excluded from premarket procedures, special controls may include adherence to performance guidelines, labeling requirements, and post-market surveillance.

Some examples of Class II medical devices include wheelchairs, pregnancy tests, syringes, blood transfusion kits, and contact lenses.

Class III - General Control and Premarket Approval: Devices fall under this classification when there is not adequate information to ensure the overall safety and effectiveness of these products to be categorized under either Class I or Class II (Rimsys, 2022). Such devices require premarket validation and possess the overall controls of Class I. Class III devices are generally meant to support or extend human life, are critical in forestalling injury of human wellbeing, or reduce the chances of avoidable risk of injury. Examples of Class III devices are breast implants, pacemakers, defibrillators, high-frequency ventilators, and HIV diagnostic tests, and may require premarket notification (see Martinez, 2021).

Rimsys (2022) asserts that almost all Class III medical devices in the United States require the FDA's premarket approval (PMA) before being marketed. Due to the high-risk profile of Class III devices, the PMA process requires significant data to demonstrate the safety and efficacy of the device. Unlike Class II devices which require a 510(k) premarket notification, the PMA process requires a thorough review by the FDA that results in their approval of the product for entry into the U.S. market.

According to Rimsys (2022), a PMA will almost always require:

- Substantial clinical trial data
- A fully documented quality system compliant with design controls as defined in 21CFR Part 820
- Documented conformance to recognized consensus standards
- Detailed descriptions of the device and all of its components
- Product samples and/or the ability for the FDA to examine the device on-site.

Post-Market Surveillance

According to USA Customs Clearance (2020), “post-market surveillance, (PMS), is a system that provides continuous feedback about a device on the market to maintain a high standard of product quality. PMS is an

administrative requirement in the European Union and the United States. The surveillance system can be used to deny or verify the safety of devices and drugs after being used by a large population of people with various health conditions."

Smith (2023) maintains that post-market surveillance is how medical device manufacturers monitor their devices while on the market. It systematically generates and collects information on the device and its real-world use. This information may be used by manufacturers to:

- Discover safety issues with the design or use of the device
- Accurately understand how the device is used once on the market
- Gather clinical evidence on device use in the market, to promote commercial use cases or improve product and services
- Gather data for the production of iterations or new devices
- Comply with regulatory requirements.

ArborMetrix (2021) reports that many different aspects of a device or product are assessed in post-market surveillance (FDA 2023b). Examples include:

- **Clinical effectiveness:** Use data from real-world clinical settings to examine the relative effectiveness of a device or drug in a large, diverse patient group to compare that product to the standard of care or competition.
- **Adverse events and side effects:** Leverage real-world evidence to identify risks or adverse reactions that might have been missed in the initial clinical trial for a device or drug.
- **Utilization:** Examine how a product is actually used in the real world, which can be different than what is approved or marketed."

By way of contrast, Gimbel (2022) reports on post-market surveillance under EU MDR regulations:

> MDR Article 2 Section 60: 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.
> Requirements: MDR Article 83: For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.
> PMCF shall be understood to be a continuous process that updates the clinical evaluation…and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking…with the aim of confirming the safety and performance throughout the expected lifetime of the device ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence (see also Hoxey, 2017).

*Hoxey (2017) notes that PMS i*s a manufacturer's systematic and proactive collection and review of experience gained from their devices. The objective of PMS is to identify any need for corrective action. As such, PMS must follow a PMS plan, in cooperation with authorized representatives, importers, and distributors.

Import Issues

Items regulated by the FDA can be denied admittance to the U.S. in the event that they do not comply with FDA guidelines relating to labels that contain false information, unapproved new drugs, items restricted for sale in the U.S., and products that are contaminated and are unsafe for use.
If an imported device appears to be in violation of any U.S. import requirements, the device will be temporarily detained by customs and border personnel in coordination with the FDA and cannot be offered for sale on the U.S. market. The FDA will provide a notice of action along with specific details of the suspected violation. The importer will then have a chance to offer evidence opposing the determination of the violation within a defined period. Import alerts are of the following categories: country or area-wide; manufacturing/product specific; shipper alerts; country/worldwide alerts.

An *import alert* may be issued when information is available to the FDA to allow for *Detention Without Physical Examination* (DWPE) (FDA, 2023a) of products found on an import alert. Items may be subject to DWPE depending on past violations. These violations can be identified with a specific product, a manufacturer, a transporter, or a carrier, or can be based on other data showing the device may violate FDA regulations.

While importers of medical devices are not required to engage a customs broker, it is highly recommended due to the risk involved with importing FDA-regulated products. USA Customs Clearance (2020) notes that at several points in the import process, things can go wrong, and mistakes can completely derail an import. Customs brokers work directly with importers to ensure these mistakes don't occur.

Import Duties on Medical Devices

The duties on imported medical devices vary based on a number of factors. First, there are many different types of medical devices and each has its own unique *HTS code* (Office of United States Trade Representative, 2023). Devices often have multiple codes depending on unique product features such as component materials or size. Second, the country of origin where the finished device was manufactured is an important aspect in determining the imposition of any import duty (Abely, 2019).

USA Customs Clearance (2020) reports that the U.S. sees the value in high-quality imported medical devices and in turn assesses a 0% import duty on many devices. However, some devices are still assessed an import duty, typically ranging from 2-6%. Specifically, some medical devices imported from China are currently being assessed with additional duties due to the Section 301of the *Trade Act of 1974* (see Houser, 2020). The question remains whether political considerations have supplanted legitimate safety issues, not because of public policy but rather because of political considerations (Fandi, 2021). Issues relating to trade with China and the imposition of duties on imports from China remain unresolved.

The Congressional Research Service (2023) explained that Section 301 of the *Trade Act of 1974* grants the Office of the United States Trade Representative, (USTR), a range of responsibilities and authorities to investigate and take action to enforce U.S. rights under trade agreements and respond to certain foreign trade practices. Prior to the Trump Administration and with the establishment of the World Trade Organization, (WTO), in 1995, the United States used Section 301 authorities primarily to build cases and pursue dispute settlement at the WTO. President Trump, however, was willing to act unilaterally under Section 301 authority (Crump, 2019; Liming, Haibo, & Yafeng, 2020).

The Trump Administration claimed that unilateral action was required to close a persistent gap between U.S. and foreign government practices that it said disadvantaged U.S. firms. In addition, President Trump justified many of its tariff actions—particularly those against China—by pointing to alleged weaknesses in WTO dispute settlement procedures and the inadequacy or nonexistence of WTO rules to address certain Chinese trade practices. The Trump administration also cited the failure of past trade negotiations and agreements to enhance reciprocal market access for U.S. firms and workers in the Chinese market (see Hunter, Lozada, & Shannon, 2023).

U.S. Medical Device Advertising

According to Adfirehealth.com (2022b), medical device advertising is a strategy used by small, medium, and large medical device companies to promote their products to doctors, hospitals, and other healthcare professionals (HCPs) via paid digital channels. For example, a medical device marketer may promote its medical device using programmatic ads on websites and apps to help build a brand, create brand awareness, increase sales leads, and drive repeat sales. Medical device advertising is monitored by both the FDA and FTC. But as long as one's advertising for medical device products is for the product's intended purpose, that is, basing your communication on the reasons why the device was approved to enter the market, regulations in the U.S. are not as "strict" compared to EU and other European promotional regulations.

Some social media platforms have stricter rules regarding medical device advertising than the FDA or FTC do. For example, Facebook does not allow promoting or selling medical devices (Facebook.com, 2023a), but they make a distinction for personal care products provided they follow a few rules (Facebook.com, 2023b):

- Ad content should not contribute to negative self-perception, such as highlighting a specific body type as desirable.
- Ads should never draw attention to health conditions, such as zoomed-in images of acne.
- Ads shouldn't contain false, deceptive, or misleading claims.
- Ads that include debunked claims related to medical treatments are prohibited.

Google has its own variety of policies related to medical device advertising. Adfirehealth.com (2022a) provides examples of some of the policies medical device manufacturers and advertisers should know:

- Marketers cannot promote non-government approved medical products that are advertised in a way that implies they're safe and effective in treating a particular disease or ailment.
- It is prohibited to market products that have been subject to any government or regulatory warning.
- Promotion of experimental medical treatments is prohibited.
- Clinical trial recruitment is prohibited in many countries. However, it is allowed in Canada, the United States, and some other countries.
- It is prohibited to promote at-home HIV tests except in the U.S., France, the Netherlands, and the U.K.
- Ads related to fertility and birth control are prohibited in some countries, such as Iran, China, and Saudi Arabia.

Regarding the promotion of medical devices in Poland, manufacturers must follow the multi-layered guidelines and regulations of several entities. Manufacturers must acquaint themselves with any specific Polish regulations and regulations from the European Union. Additionally, the social media platforms in Poland may have different restrictions.

Additionally, advertisers must also acquaint themselves with the EU's "Television Without Frontiers" Directive. This directive originates from 1989 to guide the creation, utilization, and regulation of television programming across many members' borders. This directive is very detailed. In our opinion, the main concern is how *surreptitious advertising* and *surreptitious teleshopping* are described in this directive. T*he Television Without Frontiers* Directive C 102 (Council of the European Communities, 1989; 2004), hereon the Directive, defines in Article 1 surreptitious advertising as "the representation in words or pictures of goods, services, the name, the trademark or the activities of a producer of goods or a provider of services in programs when the broadcaster intends such representation to serve advertising and might mislead the public as to its nature. Such representation is considered to be intentional in particular if it is done in return for payment or for similar consideration." (p. No L 298/26).

To be considered surreptitious advertising, there are three cumulative conditions: it must be intended by the broadcaster, it must be done to serve advertising, and it must be capable of misleading the public as to its nature. While the Directive does not contain an absolute ban on all references in words or pictures to goods, services, the name, the trademark or the activities of a producer of goods or a provider of services, the distinction between

surreptitious advertising and a lawful reference to goods, services, brands or names of economic operators can, in practice, be rather difficult for the national authorities to draw. To address this, the Commission considers it appropriate to apply the criterion of the *undue prominence* of the good, service, brand or company name. The undue nature may result from the recurring presence of the brand, good or service in question or from the manner in which it is presented and appears. In this regard, the content of the programs in which the brand, good or service appears should be considered (feature films, news programs). For example, the fact that a good is displayed prominently is, among others, a sign of surreptitious advertising when such a display is not warranted on the editorial grounds of the programs, is the result of an influence on the content thereof for commercial purposes or is likely to mislead the public on the nature of such a presentation."

We submit that the Directive's definition of surreptitious advertising may be problematic for foreign advertisers, given that it is subject to interpretation depending on its application in the various cultures that make up the EU and how advertising is currently practiced. If an EU medical device manufacturer were to market its product in the U.S., it would have more strategic freedom to advertise and promote than in Poland. A US medical device manufacturer might have to alter its advertising strategies when trying to market its product in an EU member country like Poland due to the more restrictive Television Without Frontiers Directive.

We also want to address two additional related subjects: product placement and comparative advertising. In the U.S., product placement is a common promotional practice. Products, services, and trademarks are often literally placed on television shows and in films to promote the brand. The placement may have absolutely nothing to do with the television show or film's storyline or the character's use of the product in a scene or multiple scenes as part of the plot. Since the products are placed there simply for promotion, that is, to be seen, this would likely fall under the criterion of "undue prominence," and per the Directive, it would not be allowed in any EU member state. Comparative advertising is the practice of directly or indirectly comparing one's brand to a competitor's brand on some attribute or benefit in an advertisement. "Directly" simply means that a brand's ad mentions or shows a direct competitor of the brand by name. "Indirectly" means that the competitor's brand name is not mentioned but is referenced in another way by comparing the ad's brand to "the leading brand" on some attribute or benefit. This practice is used to gain viewers' attention to the ad and to educate the viewer that the advertised brand has something or does something better than the named competitor or referenced competitor brand. The practice of comparative advertising in the US for medical devices or any other good or service might not be allowed in an EU member country's medical device advertising per the Directive on "surreptitious advertising." This advertising practice appears to meet the three criteria of surreptitious advertising: the representation in words or pictures of goods, services, the name, the trademark, or the activities of a producer of goods or a provider of services must meet three cumulative conditions mentioned above.

6. Concluding Comments

When a manufacturer of medical devices in Poland indicates its intention to export its products into the United States, it will be confronted by a duality of administrative regulations—one set emanating from legislation adopted in Poland in conformity with statutes established in the European Union. In addition, the putative exporter-manufacturer will be required to comply with a host of administrative rules and regulations adopted by the Food and Drug Administration relating to product safety and efficacy. With this in mind, the government of Poland, in pursuit of its policy of expanding the outward flow of foreign direct investment, has engaged in a partnership with domestic medical device manufacturers to assure the success of these endeavors.

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APPENDIX I: MEDICAL DEVICE SYMBOLS IN THE EUROPEAN UNION