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Regulating medical devices in the European Union

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The overall goals of the European regulatory framework for medical devices are the same as the goals of the framework for medicines. The framework aims to protect public health by ensuring that medical devices are of good quality and safe for their intended use. The framework also seeks to promote the good functioning of the internal European Union (EU) market by treating medical devices as goods governed by the principle of free movement within the EU market. Although as for medicines, this is accomplished through extensive regulation of medical devices throughout their lifecycle, the regulation of medical devices in Europe is very different from the regulation of medicines, especially in two regards. First, unlike medicines, there is no pre-market authorisation by a regulatory authority for medical devices to lawfully enter the EU market. Similar to the requirements for certain devices in the United States, the manufacturer has to ensure the conformity of its medical devices to essential requirements[1] for all medical devices, including upon approval of a notified body (a formally designated conformity assessment body) for certain medical devices. Such procedure, commonly called "certification procedure", leads to the affixing of a 'CE' mark to the product concerned. It is less burdensome than the marketing authorisation applicable to medicines. That is why companies will prefer their products to be categorised as medical devices, rather than medicines, so as to reach the European market more quickly. Second, unlike in the United States where the Food and Drug Administration is primary regulator of devices throughout the nation, the European Union does not have a single regulator, such as the European Medicines Agency, of medical devices. Instead several organisations may be involved, and mainly a notified body in specific cases.

Moreover, medical devices represent a huge legal category of health products that ranges from certain toothpaste to cardiovascular catheters. Artificial joints, heart defibrillators and pacemakers, IUDs, and ophthalmoscopes are other commonly used devices. This category of medical devices is far wider than medicines, and has always been considered different to medicines in European regulatory contexts. Unlike in the United States, where the modern statutory scheme for devices was enacted in 1976, European Union-level medical devices legislation was first enacted in the 1990's, with a set of three Directives distinguishing implantable and diagnostic medical devices from other types of medical devices ("the 90's Directives").[2] The adoption of these directives

[1] Essential requirements are a set of criteria for the safety and performance of the devices, including the establishment of a risk management system, the justification for the presence of specific substances as substances which are carcinogenic, mutagenic or toxic to reproduction… They are specified in the European legislation, mainly Annex I of regulation 2017/745.
[2] Council Directive 90/385/EEC; Directive 98/79/EC; Council Directive 93/42/EEC

has been included within the "New", and then, "Global approach" aiming to limit restrictions on the free movements of goods, here medical devices, through technical harmonization at the European Union level. These directives have established safety objectives for medical devices without making it necessary for manufacturers to follow specific manufacturing processes. The directives also save manufacturers from specific approval procedures for Member States. More particularly a harmonization of "essential requirements" (that have replaced national requirements because they are "essential") has been provided. Harmonization has been completed by the standardization of technical specifications established by standardization organizations, such as the European Committee for Standardization for medical devices.

However, substantial divergences have emerged between the Member States of the European Union and the European Free Trade Association countries regarding the interpretation and application of the rules (such as national differences in product classification). Moreover, certain products have raised uncertainties or fallen under regulatory gaps (e.g. manufactured products based on non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes).

The Poly Implant Prothese scandal definitively highlighted the limits of the directives. The French health authorities found that Poly Implant Prothese (PIP), a French manufacturer, had used industrial silicone instead of medical grade silicone for the manufacture of breast implants, contrary to the approval issued by the notified body, causing harm to thousands of women around the world. After that, the European regulatory framework for medical devices was revamped, the main objective being to further strengthen patient safety. Consequently, two new European Regulations on medical devices ("the 2017 Regulations") were adopted: one on medical devices including implantable devices and one on in vitro diagnostic medical devices.[3] These Regulations entered into force on 26 May 2017 and will be applicable from 26 May 2020 although there are many transitional periods.

Thus, the 90's Directives currently apply, and two legislative frameworks (the 90's Directives and the 2017 Regulations) will be running in parallel from May 2020 until May 2024. After May 2024, only the 2017 Regulations will apply. This chapter will therefore focus on the 2017 Regulations.

Overall, these new medical devices regulations revise the definition of medical devices, clarify the obligations of economic operators (manufacturer, authorised representative, importer, and distributor) in medical device markets, and strengthen the role of private "notified bodies" (see further below) and their surveillance by national authorities. The regulations also generalise obligations associated with clinical assessment and clinical investigation, and improve medical devices vigilance and traceability.

First, this chapter explains what constitutes a medical device and how devices are classified according to their level of risk in the EU. It then discusses how medical devices reach the market, how their risks are managed all along their life cycle, and what kinds of incentives are provided for innovation and competition. The chapter also analyses the balance between public and private actors in the regulation of medical devices. It then concludes with case studies of innovative medical technologies that have challenged the traditional European regulatory scheme and that have led to many revisions in the 2017 device regulations.

I. Legal definitions of medical devices in the EU

[3] Regulation (EU) 2017/745, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Regulation (EU) 2017/746.

The EU Regulations apply to products that are considered to be medical devices and that are to be marketed or used in the EU. European law generally defines medical devices similarly to the way U.S. law defines devices. As in the U.S., these include diagnostic instruments such as stethoscopes, blood sugar monitoring kits, or chemicals used by pathologists to facilitate their examination of biopsy tissue. There are many devices used in the treatment of disease as well, including implantable therapies such as cardiac stents, insulin pumps, and metal screws and plates for bone fractures.[4]

While medicines have a pharmacological, immunological or metabolic mode of action, medical devices generally have a mechanical mode of action. In addition, they must be intended for use in some aspect of health care, such as prevention, diagnosis, monitoring, or treatment. Since the 2017 Regulations, the EU's definition of medical devices now also includes software, of which the aim is the production of physiological or pathological information on the body, such as that used in monitoring of intensive care patients.

Where a product, taking into account all its characteristics, may fall within the definition of either a medicine or a medical device and there is doubt as to which definition applies, the legal regime for medicines applies.[5] In this context, the European Commission has adopted guidance on medical devices (known as the MEDDEVs guidance). It includes a manual that specifically includes guidance on the borderlines among medical devices, medicines, biocides, and cosmetics.

Despite these general rules, it may be difficult to know whether a product will be regulated as a medical device or a medicine, especially where both types of products are combined. In that context, similar to the United States, the principal intended mode of action is the main criterion for determining how the product is categorized. For instance, the European Commission concluded that for the group of products depending on proanthocyanidins present in cranberry (Vaccinium Macrocarpon) to prevent or treat cystitis, the principal mode of action was pharmacological as the constituents of cranberry "exhibit most probably a pharmacological activity" and "a mechanical mode of action (…) is highly unlikely". Consequently, these products are not medical devices.[6]

The medical devices sector is far more heterogeneous than the medicines sector and includes many innocuous products, such as tongue depressors. That is why, unlike medicines, medical devices are explicitly classified according to their intended use (to be used alone or in combination with another device, to be used only or principally in a specific body part, to be used temporarily, on short or long term use) as well as to the potential risks with which they are associated (class I for low risk medical devices, class IIa for middle risk, class IIb for high risk, and class III for medical devices raising most

[4] More specifically, medical device "means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means." Article 2.1 of regulation 2017/745.

[5] Article 2.1 of directive 2001/83/EC.

[6] European Commission, Decision on the qualification of cranberry products published on 03/10/2017.

risks and being regulated more strictly).[7] The rules to be applied vary according to such classification.

II. Access to the market

In the European Union, medical devices' access to the market depends on a certification process that varies according to the type of devices. To this end, the devices shall comply with a set of legislative criteria and the conformity with these criteria shall relay on clinical evidence, a requirement that has been particularly strengthened with the 2017 regulations. Beyond the general rules applicable to most medical devices, two kind of medical devices have been considered distinctly: in vitro diagnostic medical devices have been regulated specifically given their specific features, and specific rules apply to custom-made devices in comparison with other devices to find the right balance between the need of evidence and access to medical devices.

A. Certification: CE marking

In order to be commercialized, medical devices must follow a certification procedure which aims to ensure compliance of medical devices with minimum and essential quality and safety criteria, and ends with the affixing of the "CE marking" for all devices, except custom-made devices and investigational medical devices.[8] It is delivered for five years either by the manufacturer (auto-certification for low risk class I medical devices[9]) or by a "notified body" chosen by the manufacturer (for higher risk classes IIa, IIb, III and implantable medical devices). As discussed below, notified bodies are private regulatory entities.

Such CE mark shows a medical device complies with a set of minimum requirements called the "general safety and performance requirements." These include demonstrating the attainment of a number of objectives. For example, companies must ensure the safety of patients, users and third parties; show an acceptable benefit/risk balance; and reduce risks related to ergonomic features (usability or human factors) and consideration of the use environment. The safety requirements take into account the technical knowledge, experience, education, training and use environment, the medical and physical conditions of intended users, the generally acknowledged state of the art for safety principles, and the creation of a risk management system.

Companies must also ensure the quality of the medical devices, i.e., the conformity of each produced unit to its claimed nature and intended use. To this end, a quality management system has to be established by the manufacturer, and will be controlled via the notified organisms' audits. Companies also have responsibilities regarding maintenance of the characteristics and intended level of performance of devices during their intended use, transport and storage. For instance, potential temperature and humidity fluctuations should be considered by manufacturers in transportation and storage restrictions on device labelling. Requirements regarding the information supplied with the device are related to the label and instructions for use for all medical devices.

The conformity to essential requirements regarding health and safety of patients, users, and third parties is provided for each category of medical devices. The amount

[7] Article 51.1 of regulation 2017/745. The US, similarly, has a system for classifying devices by risk level. [Insert cross reference to U.S. devices chapter] [Zettler and Lietzan]
[8] See below.
[9] Except for sterile devices, devices with a measuring function or reusable surgical instruments.

and type of evidence to be given by the manufacturer is higher mainly in accordance with the level of risk (and *a fortiori* the classification) raised by the medical devices.

Unlike class I medical devices (e.g. simple bandages) which have the lowest perceived risks and as such are self-certified by manufacturers, notified bodies are involved for every other class of medical devices, with a growing role according to the level of risk raised by the devices. The notified body assessing class IIa medical devices (e.g. syringes for pump infusion) must have regard to the quality assurance system and the clinical evaluation of the product. The notified body must go even further for class III medical devices (e.g. stents), as it must also verify their design. The notified body may also consult an expert panel for the clinical evaluation of certain class IIb medical devices (e.g. anaesthesia machines) and implantable class III medical devices.

B. Clinical evaluation and investigation

One of the biggest changes from the previous regimes of the 90's Directives is the strengthened requirements for clinical evaluation that include both prior and post-commercialization studies.

Clinical data for all classes of medical devices must provide sufficient evidence to confirm conformity with the relevant general safety and performance requirements under normal conditions for the intended use of the device. Data also must confirm the evaluation of any undesirable side effects and the acceptability of the benefit-risk ratio. To that end, manufacturers are required to plan, conduct and document an assessment using several possible options for clinical data: to evaluate relevant scientific literature currently available; to conduct clinical investigations; to use data available from a similar medical device.

The demonstration of equivalence with another medical device already on the market, which is not a new concept, is similar to the "510(k)" notification in the U.S. However, the new EU medical device regulation has provided a narrowed and refined definition of 'equivalence', as regards as the U.S. concept of "substantial equivalence". Indeed, according to EU law, the device to which equivalency is claimed must share the same technical, biological, and clinical characteristics to show there is no clinically significant difference in the safety and clinical performance of the device. Moreover, sufficient levels of access to the data (technical documentation) of the equivalent devices has to be justified. As a practical matter, this will require explicit agreement between the two manufacturers.

The conduct of clinical investigations is the most complicated as being long, risky and expensive, but it is generally required for implantable devices and class III medical devices.[10] They shall be conducted under specific conditions, including authorization of the Member State(s) in which the clinical investigation is conducted following an application on the EUDAMED database (see below), positive opinion of an ethics committee, sponsor or its legal representative being established in the EU, and protection of vulnerable populations. The company also has to show that the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences, obtain informed consent of the participants or their legal representative,[11] ensure protection of fundamental rights of the participants, and

[10] Clinical investigations are not required for minor modifications of existing devices.

[11] In case of emergency situations, such as "the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition", information can be given and informed consent can be obtained after the decision to include the subject in the clinical investigation. Article 68 of regulation 2017/745.

conform the investigational device to the applicable general safety and performance requirements.

The regulation of clinical investigations for medical devices thus converges with the regulation of clinical trials for medicines. In both cases, the scientific elements of the applications are common to every EU Member State, as provided by the European regulation, and the ethical elements are specific to national laws.

Finally, for all class III and certain class IIb medical devices, the manufacturer also may consult an expert panel prior to its clinical evaluation and/or investigation with the aim of reviewing its intended clinical development strategy and proposals for clinical investigation.

As far as implantable devices and class III devices (other than custom-made or investigational devices) are concerned, a summary of safety and clinical performance is required. It will be validated by the notified body as part of the technical documentation.

C. In vitro diagnostic medical devices

Like the earlier directives, the 2017 Regulations include specific rules for *in vitro* diagnostic medical devices (IVD medical devices), such as pregnancy tests or tests for determining the level of cholesterol or glucose in blood. The new definition of IVD devices now clearly includes genetic tests and companion diagnostics.[12] Generally, the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance have been significantly reinforced, and provisions ensuring transparency and traceability have been introduced to improve health and safety.[13]

The directive on IVD medical devices has provided for two limitative lists (respectively high risk and moderate risk) of IVD medical devices for which the involvement of a notified body is required. By default, all other IVD devices are "low risk", except self-testing ones. The use of these limitative lists implies that newly developed tests not mentioned in these lists, such as a test for Creutzfeldt-Jakob disease, do not require scrutiny of a notified body, irrespectively of their risks. That is why Regulation 2017/746 renews the classification of IVD medical devices according to their risks and their final use, from class A for low risk IVD medical devices (such as specimen receptacles) to class D for higher risk IVD medical devices (such as HIV test): a rule-based classification system as for other medical devices. Indeed, the conformity assessment procedure for lowest risk medical devices (here class A) is under the sole responsibility of the manufacturer, while notified bodies are involved for class B, C and D medical devices.

Examples of factors determining the risk of IVD medical devices are the possible consequences of an incorrect test result or severity of the disease or disorder tested. Based on the work of the Global Harmonization Task Force and its follow-up initiative, the International Medical Devices Regulators Forum, classification criteria that have been used, such as the impact of the diagnostic test result on the individual and on public health, have contributed to the reclassification of certain IVD medical devices, like genetic tests from a lower class to class C. In this context, a Dutch study carried out by the National Institute for Public Health and the Environment on the impact of the new Regulation 2017/746 on the classification of IVD medical devices

[12] Companion diagnostics are in vitro diagnostic tests supporting the safe and effective use of specific medicines through the identification of suitable patients to be treated by these medicines.
[13] Recital 4 of regulation 2017/746.

has shown that many more IVDs will end up in a higher risk category (84 instead of 7 percent). It implies that the involvement of notified bodies in the commercialization procedure will considerably increase as well as the efforts needed from the manufacturers to comply with the conformity assessment procedures.

D. Navigating the tradeoff between wanting evidence and wanting access: custom-made devices

As with medicines, the standard process for securing commercialization is time consuming and expensive, which can significantly delay patient access to new medical devices. As a result, two mechanisms allow patients access to medical devices under specific conditions, less strict than the ones provided by the standard process.

1. Custom-made devices

A custom-made medical device is specifically designed solely to meet the individual needs of a particular patient. This category does not include mass-produced devices (such as contact lenses) that are adapted to meet the specific needs of patients, even though the devices are supplied for the sole use of a particular patient.

As long as custom-made devices are made for the specific needs of an individual patient, the regulatory requirements for manufacturers are lower than those applicable to other medical devices developed to by widely commercialized in the EU. For instance, the authorization of a notified body is not required for custom-made devices. Nevertheless, the manufacturers must ensure their devices are safe and perform as intended.

To place a custom-made medical device on the market, manufacturers must comply with the essential, i.e. general safety and performance, requirements and draw up a statement that the device conforms to these requirements. They must also establish, document, implement, maintain, keep up to date, and continually improve a quality management system. They must draw up technical documentation, which is a lighter regulatory burden than that required for classical medical devices in that it does not include a clinical evaluation report, a post market surveillance plan, or the updates of the periodic safety update report. Manufacturers shall also perform a post market clinical follow-up and report any problem coming to light through post market vigilance.

Finally, it should be noted that Member States may not create obstacles to custom-made medical devices being made available on the market in accordance with the European medical devices Regulations.

2. Use of devices in the interest of public health or patient safety or health

Unlike in the U.S., there is no concept of “humanitarian use devices”. Nevertheless, EU law provides derogation from the assessment procedures with the possible authorization from any national competent authority, to place on the market or put into service a device in the interest of public health or patient safety or health. For instance, this procedure has been used in France to allow delivery of non-class III partial replacements of already implanted medical devices for joints and teeth. Indeed, it has notably been considered that in the interest of the patient, a surgical procedure of partial change is more limited and less traumatic than the one necessary for a total replacement.

Such derogative authorization has to be communicated to the European Commission and other Member States when granted for use other than for a single patient. Moreover, in exceptional cases relating to public health or patient safety or health, the European Commission can extend this authorization to the entire EU for a limited period of time.

III. The balance between public and private actors

Both public and private actors are involved in the regulatory process applicable to medical devices in the EU. The 2017 Regulations have established a "pyramidal system" with a base constituted of private bodies including economic actors (e.g. manufacturers, importers and distributors) with wide and strengthened obligations especially for manufacturers (A), on top of which sits the position of notified bodies as the main private regulators (B), and above that a public oversight, mainly from national authorities in Member States, with the European Commission responsible for coordination (C). Consequently, most regulation is done and implemented by private actors that form the large base of the pyramid (economic actors and notified bodies, both being private companies) and public actors only do a small portion of regulation, in accordance with the obligations imposed by laws.

A. The obligations of economic operators: the base of the pyramidal system

The 2017 Regulations reinforce the basic legal framework of medical devices, notably through imposing stricter requirements on the private companies in the device market. The 2017 Regulations clearly set out who holds those obligations, which range from the manufacturers as the actors having most obligations to the authorized representatives they have designated, and the importers and distributors. Such private actors are at the base of the pyramidal system.

1. Manufacturers' responsibilities

Manufacturers are the main operators in the supply chain for medical devices. They are responsible for bringing into the market medical devices that are fully compliant with legal requirements. It includes ensuring enforcement of the Regulations regarding the design, manufacture, and technical documentation. For instance, the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices shall be adequately described in the documentation of the quality management system. Manufacturers are in charge of the analysis of risks linked to their medical devices and of providing the relevant dossier in compliance with the essential requirements set out in the Regulations. In accordance with these responsibilities, they will decide on the commercialisation of their devices, upon authorisation of a notified body for other devices than Class I medical devices. Manufacturers also append the CE mark after obtaining the conformity certificate (including auto-certification for class I medical devices) and informing their national competent authority.

Manufacturers must conclude agreements with other private actors where relevant. In that context, it should be underlined that the definition of 'manufacturer' in the 2017 Regulations clarifies the situation regarding the so-called "Own Brand Labeller" (OBL). The OBL is a company that buys a finished medical device with CE marking from an original manufacturer to sell it under its own brand name, while not necessarily being the person who actually designs, manufactures, packages or labels the device. This practice consequently raises the question: who is the entity who is legally

responsible for enforcing the manufacturer's obligations? Indeed, it appears that some Member States found, when inspecting OBL sites, that the OBL did not have the required technical file, as it had been kept secret by the original manufacturer. While the 90's Directives were not very clear about the responsibility of an OBL, the European Commission recommended twice, in 2008 and 2013, that an OBL should have the same responsibilities and obligations as the original manufacturer. This clarification is clearly confirmed by the 2017 Regulations in their definition of the "manufacturer".

Under the 2017 Regulations, manufacturers are obliged to conduct a clinical evaluation for every medical device in accordance with strengthened requirements, whatever its classification. Previously, medical device manufacturers had frequently used the "equivalence procedure", which in effect established clinical safety through references to the existing scientific literature. When the Regulations enter into force, this procedure will become exceptional, especially for implantable devices and class III medical devices which will generally require clinical investigations. As is the case for medicines, manufacturers of all classes of medical devices must have a designated person in their organization (or to have such person permanently and continuously at their disposal for micro and small enterprises) who is responsible for regulatory compliance. That person's qualifications must be demonstrated by diploma or professional experience. The designated person must also ensure compliance with the "Unique Device Identifier" assignments (see further below). Manufacturers are the main operators liable for defective medical devices which cause damage.[14]

Where a manufacturer is not established in the EU, they must designate an authorized representative within the EU. Regulation 2017/745 provides a list of mandatory obligations for the authorized representative (such as the verification of the drawing up of the EU declaration of conformity and technical documentation) which shall, at least, be included in the mandate of designation by the extra-EU manufacturer. Two elements of the new obligations of the authorized representative can been highlighted. First, the authorized representative must terminate the representation if the manufacturer does not comply with his obligations. Such obligation goes beyond the classical mandate rules where the mandator controls the authorized representative. Second, "the authorized representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer." Such a rule, although justifiable on safety grounds, appears to be contrary to the classical regime applicable for the liability of defective products where the authorized representative is only obliged to complete operative and administrative tasks on behalf of the manufacturer, inasmuch as the manufacturer is the only economic operator able to modify a device to ensure its conformity with essential requirements under the Regulations. These two obligations that go beyond the classical mandate rules show the specificity of the situation which is international (extra- EU manufacturer and EU authorized representative) and the primary position that is given to safety considerations in the EU legislation on medical devices.

Finally, unlike the 90s Directives, the 2017 Regulations explicitly provide obligations for importers and distributors. Generally, before placing medical devices on the market, importers must ensure that the manufacturer and the medical devices comply with the requirements of the medical devices Regulations. Moreover, they must display their details on the medical device or on its packaging, and must register in the EUDAMED database (see further below). The new EU regulation defines

[14] Council Directive 85/374/EEC.

distributors,[15] mentions the activities of distributors,[16] and includes them among the economic operators in the medical devices supply chain. Distributors consequently also have specific obligations notably regarding the verification of manufacturers' and importers' compliance with legal requirements, the supply of medical devices to end-users or third parties, their involvement pre-marketing (compliance with essential requirements) and post-marketing (vigilance), even though there is no Good Distribution Practice for medical devices. Although distributors are not covered by the obligation of registration on EUDAMED, Member States are permitted to maintain or introduce obligations on registration of distributors of medical devices made available on their territory.

B. The main role of private regulators: European "notified bodies"

It is a peculiarity of the European system that it relies on private regulators to decide whether medical devices may enter the European market. Manufacturers decide on entry for low risk- class I medical devices. "Notified bodies" decide for class IIa, class IIb and class III devices.

"Notified bodies" are private conformity assessment bodies established where the safety of various products is regulated through European technical harmonisation, such as the safety of toys, radio or pressure equipment. The approach has its roots in what is still called the 'New Approach' to standardisation of product safety, adopted to facilitate the free movement of products across national borders within the EU in order to create the EU's "internal market". The approach operates as follows. Minimum regulatory standards, agreed by EU legislation, apply across the whole EU. Manufacturers must apply these standards to products, including medical devices. Notified bodies are responsible for assessing and certifying the conformity of the products (including medical devices) to those standards, as a matter of public interest. Each Member State of the EU must mutually recognise the conformity assessment of notified bodies in other Member States, and must permit the certified products to be marketed as safe within its territory. Notified bodies are designated and monitored by national competent authorities, such as the French National Agency for Medicines and Health Products (ANSM) for medical devices.

Notified bodies have been used by the EU's medical devices legislation from its inception. Under the 90's Directives, they were around 80 notified bodies across Europe. The manufacturer can choose the notified body of the country in which it is established, or any other notified body recognised anywhere in the European Union. This arrangement led to a kind of regulatory competition between notified bodies, like with respect to States regulation in the U.S. It was alleged that the resultant varying quality would potentially lead to an uneven level of patient protection and a possible distortion of competition between manufacturers of similar products. For this reason, Member States' control over notified bodies has been strengthened in the 2017 medical devices Regulations.

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[15] "'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service." Article 2.34 of regulation 2017/745.

[16] For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices. Recital (28) of regulation 2017/745.

C. The oversight role of public regulators: the balance between European and national

Contrary to the EU's regulation of medicines where the European Medicines Agency (EMA) coordinates regulation across the European Union, the oversight role of public regulators of medical devices comes mainly from Member States and their national competent authorities. Indeed, as there is no equivalent to the European Medicines Agency, there is only a limited coordination role for the European Commission.

As mentioned above, the national competent authorities have control over the designation and monitoring of notified bodies, and must only inform the European Commission. National competent authorities also authorise clinical trials of devices, especially regarding the newly-required clinical investigations for implantable devices and class III medical devices, for which a positive opinion from an ethics committee is needed. However, national competent authorities do not intervene in the awarding of the CE mark.

National competent authorities also collect data forwarded by the manufacturers, especially regarding their vigilance notifications, and are in charge of market surveillance. Member States may also authorise derogation from the conformity assessment procedure, on a duly justified request, where the classical procedures have not been carried out but the use of the medical device is in the interest of public health or patient safety or health, as noted above.

Member States are in charge of implementing and controlling the proper implementation of EU rules. Moreover, key aspects of medical devices regulation, such as the prescription of medical devices, and the management of national health care systems including prices and reimbursement of medical devices, remain at national discretion.

There is much less involvement of EU-level regulators than in the case of medicines regulation. The European Commission plays a coordination role, in the classification of medical devices and the management of the European database for medical devices: EUDAMED.

Regarding classification, two groups are in charge of advising the European Commission. First, a medical devices expert group including representatives of the Member States competent authorities, European trade federations and professional organisations, and notified bodies, is in charge of advising the European Commission on borderlines and classification of medical devices. Second, a medical devices coordination group, composed of persons designated by the Member States based on their role and expertise in the field of medical devices and IVD medical devices, has been established by the 2017 Regulations to provide advice to the European Commission and to assist it (as well as the Member States) in ensuring a harmonised implementation of the medical devices regulations. This group notably ensures coordination and cooperation between notified bodies. As this group is also competent on borderline and classification of medical devices, its links with the older medical devices expert group are not clear, and the future of the latter may be questioned.

Furthermore, although medical devices are generally not covered by the EMA, the EMA or national competent authorities shall be consulted regarding combination products. First, the European Commission can consult the EMA regarding borderline products involving medicines, as is also the case for the European Chemicals Agency

and the European Food Safety Authority regarding biocidal products or food products. Second, the EMA or national competent authorities shall be consulted by a notified body on medical devices composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body. Third, they shall also be consulted by a notified body on companion diagnostics which are newly defined and explicitly considered by the 2017 Regulation on IVD medical devices. Fourth, they shall also be consulted by a notified body on medical devices incorporating an ancillary medicine (e.g. substances derived from human blood or human plasma, or biotechnology products). Fifth, the EMA or national competent authorities are in charge of delivering marketing authorisation dossiers for medicines with integral device component, such as prefilled syringes. In that case, the dossier must contain the EU manufacturer's declaration of conformity or the CE certificate issued by a notified body.

IV. Risk Management

Medical devices are health products. As such they raise risks for patients' safety, but also for other persons such as third parties or health professionals who manipulate medical devices. That is why safety and the management of risks is a priority in the EU's medical devices Regulations, with the broad objective of protecting public health. Although all medical devices are associated with some risk, it is necessary to reduce the risks linked to the use of medical devices and to accept the residual risks only after a benefit/risk assessment. That is why the EU legislation on medical devices requires the management of risks all along the therapeutic chain. The "pyramidal system" of responsibility established by the 2017 Regulations deals with risk management by setting wide and strengthened obligations for manufacturers, who must ensure traceability all along the life cycle of a medical device; some freedom to the national competent authorities regarding the management of vigilance on their territories; and a new coordination role for the European Commission. Indeed, the latter has both an arbitral role where there is disagreement between Member States and a control role over the national competent authorities regarding preventive measures adopted in case of potential risk for health.

With a new system that is more complete, especially regarding traceability and vigilance, and clearly strengthened requirements on risk management, the 2017 Regulations should as such better protect public health. Nevertheless, the new system has proven difficult to set up, and already there have been delays in the implementation of some parts of the new regulations, especially the full operationality of the EUDAMED database.

A. Managing Risk from the Time of Market Entry

The management of risk is required for medical devices to enter the European market. Much of this has been covered previously in the discussion of access to the market.

Once a device is cleared for access, risk can be managed on a case-by-case basis, as with medicines, by requiring a health care professional's prescription. There are no specific EU-level rules on the prescription of medical devices. But national rules can exist on this matter and European Union law does not affect them.[17]

[17] Article 1.15 of regulation 2017/745.

Beyond the prescription of medical devices, there will inevitably be manufacturing defects or other problems with some devices, so it is important to be able to trace a patient's device back to its manufacturer, distributor, or other participants in the distribution chain. It also is important to be able to identify other devices that may have the same problem. Accordingly, the 2017 Regulations on medical devices enhance transparency to provide a better management of risks and strengthen the confidence of medical devices' users. To this end, two main tools have been developed: the traceability processes and the European database on medical devices "EUDAMED". They both contribute to the management of risks all along the development chain of medical devices.

For a long time, traceability has been required, from the description of the raw material as part of the quality management system to detail about the manufacturing process. But the new regulation goes further in expanding traceability to the identification of, and cooperation among, all different economic operators. Moreover, users are also targeted by traceability requirements. For instance, implantable class III medical devices, as well as devices to be listed by the European Commission, have to be registered and traced by health establishments supplying them. This is also recommended for other types of devices. Other examples for implantable medical devices are the implant cards delivered with the devices to patients.

Moreover, the 2017 device Regulations established a Unique Device Identification system ('UDI system') to contribute to the efficiency of traceability in allowing a better identification of medical devices and reducing the risks linked to errors of devices' choices and selection. This system includes two parts: a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, and a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable, the packaged devices, and that relies on an internationally recognised nomenclature. The UDI-DI is given by the manufacturer, before commercialisation, and communicated to the European Commission with other information such as name and address of the manufacturer, the medical device nomenclature code, and risk class of the device.

Thus, the UDI system contributes to the traceability and control over medical devices all along the supply chain. As such, it also participates in the fight against falsified devices that has been targeted within the new EU Regulation 2017/745. The Regulation defines "'falsified device' as any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures". This definition is similar to that for falsified medicines. But, unlike in the case of medicines, the obligations regarding falsified devices are not primarily on manufacturers. Rather, importers and distributors must inform the competent authority of their Member State when they consider or have reason to believe that a device presents a serious risk or is a falsified device. It is then part of the market surveillance activities of the competent authorities to confiscate, destroy or otherwise render inoperable falsified devices.

Finally, the European database on medical devices "EUDAMED" where all medical devices have to be registered by their manufacturer before commercialization also participates in the efficiency of traceability and in the better management of risks. In addition to the name, label and instructions for use, EUDAMED will provide data about devices placed on the market, potential clinical investigations, certificates issued by notified bodies where relevant, and information about the relevant economic operators. More specifically, EUDAMED includes an electronic system related to clinical investigations permitting Member States, the European Commission and notified bodies to exchange information. Indeed, the sponsor can submit a single

application for several Member States and report serious events, device deficiencies and related updates via EUDAMED. Consequently, this system reduces the delay for information exchange and accelerates the decision on investigation and on corrective measures where necessary.

EUDAMED also includes an electronic system related to vigilance and surveillance after commercialization.

B. Monitoring and Managing the Risks of Marketed Devices

As is also the case for medicines, EU law requires post-market monitoring of the risks associated with medical devices.

First, vigilance implies the reporting of serious incidents[18] and of corrective actions taken by the manufacturer. Manufacturers must report serious incidents and corrective actions to the national competent authorities of the Member States for all medical devices on the EU market. The competent authorities of the Member States assess these notifications in collaboration with the manufacturer and the notified body where relevant.

Vigilance also applies broadly beyond the reporting of serious incidents. It is part of a larger process of post-market surveillance and market surveillance that aims to prevent risks of incidents. Vigilance involves every actor: the manufacturers but also Member States and their national competent authorities, the notified bodies and the European Commission.

Manufacturers and Member States both have surveillance responsibilities. For manufacturers, the 2017 Regulations require a post-market surveillance plan to be established for class I medical devices as well as a post-market surveillance report to be updated when necessary. For the other classes of medical devices (class IIa, class IIb and class III devices) which raise more risks, a Periodic Safety Update Report (PSUR) must be prepared and updated annually in addition to the surveillance plan. The PSUR analyzes data gathered through post-market surveillance plans and discusses any preventive or corrective actions taken. These post-market surveillance data are gathered all along the medical device life cycle and used to update the benefit/risk balance and the materials on the medical device, such as those relating to technical documentation, risk assessment, and clinical evaluation. As long as the data gathered are used to update the relevant part of technical documentation, it contributes to transparency.

The national competent authorities of the Member States are in charge of market surveillance. To this end, they can organise expected or unexpected inspections of manufacturers, distributors, hospitals, and health professionals marketing or using the medical devices. If a device presents "an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health" (these notions being freely interpreted by the Member States in the absence of a European definition) or does not comply with the legislative requirements, the national competent authorities of the Member States can recall a device, restrict its use, or

[18] It should be highlighted that Regulation 2017/745 distinguishes serious incidents and serious events. The former is linked to the medical devices without a necessary impact on health (article 2.64 of regulation 2017/745) while the latter occurs during a clinical investigation (see above) and is not necessarily linked to the studied medical devices (article 2.57 of regulation 2017/745). Both can be « serious » in specific situations.

require other corrective action to bring the device into compliance with the 2017 Regulation.

The national competent authorities are also obliged to report the situation to the European Commission and the other Member States where a certificate has been issued for the device concerned.

Furthermore, Regulation 2017/745 on medical devices distinguishes between 'recall' ("any measure aimed at achieving the return of a device that has already been made available to the end user") and 'withdrawal' ("any measure aimed at preventing a device in the supply chain from being further made available on the market"). All market participants – manufacturers, importers and distributors- have the obligation to withdraw or recall a device when they consider or have reason to believe that a device they have made available on the market is not in conformity with Regulation 2017/745. For instance, in December 2018, Zavation Medical Products Pan Medical US has recalled of all its medical devices marketed in Europe from August 2016 because of falsified ends of date certificates by the society it has acquired, Pan Medical US.[19] Member States and their competent authorities must also withdraw or recall a device for the same reasons as the companies, fulfilling their duty to protect health.

C. Unique challenges presented by Cybersecurity

Cybersecurity raises unique challenges, including for networked medical devices. Challenges relate to intrinsic safety problems, such as with pacemakers or implantable cardiac defibrillators or insulin pumps, which, in the event of a data compromise, could result in harm to a patient. But cybersecurity also poses challenges regarding the confidentiality of personal data stored or transmitted by medical devices. There is a need for trust in the use of electronic and connected medical devices.

Somewhat unlike in the United States where the FDA has begun to collaborate with other government agencies and to provide recommendations to manufacturers to address cybersecurity risks, EU regulation, thus far, has not focused specifically on cybersecurity. Nevertheless, the EU view seems to be changing, as illustrated by three complementary domains.

First, within EU Regulation 2017/745 on medical devices, cybersecurity of devices is intrinsically considered through the new inclusion of software within the definition of medical devices: for instance, insulin dosage planning stand-alone software (Class IIb), software for the presentation of the heart rate or other physiological parameters for intensive care monitoring (Class IIb), and software that uses an algorithm to characterize viral resistances to various drugs. More specifically, some safety and performance requirements of this Regulation relate to cybersecurity, notably as devices that incorporate electronic programmable systems or software that are devices are specifically targeted. For instance, their design or manufacture shall remove or reduce the risks associated with the IT environment, or take into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen). These new rules within the EU Regulation on medical devices show that EU law is taking into account in specific and detailed disposals the challenges raised by electronic and networked medical devices regarding the information stored or transmitted by the devices, i.e. by cybersecurity of medical devices.

[19] French ANSM, Recall of medical devices from Pan Medical US corporation, 28/12/2018, here.

Second, EU Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the 'General Data Processing Regulation') completes this legal frame regarding the personal data stored or transmitted by the medical devices.[20]

Third, the challenges raised by cybersecurity of medical devices could be considered in the EU's general cybersecurity policy currently under development. As part of the EU cybersecurity strategy adopted in 2013, a second mandate has been given to the European Union Agency for Network and Information Security (ENISA). A Directive on security of network and information systems, promoting a culture of risk management, was adopted in 2016. The latter introduces security requirements as legal obligations for key economic actors, especially operators providing essential services and suppliers of key digital services. Nevertheless, neither of these two texts mentions medical devices. In contrast, the European Commission's proposal for a Cybersecurity Act explicitly mentions medical devices. The proposal is to provide uniform requirements for cybersecurity via a certification scheme for specific IT processes, products, and services and to transform ENISA into a permanent agency for cybersecurity within the European Union. It remains to be seen how this proposal will complement the medical devices Regulation 2017/745 and General Data Protection Regulation (EU) regarding cybersecurity in the field of medical devices. In general, the EU approach appears more segmented than the U.S. approach to this topic.

V. Innovation and competition

The EU Directives on medical devices, and the 2017 EU Regulations on medical devices constitute in themselves the main incentives for competition of medical devices in order to create a single European market for medical devices. More targeted incentives are missing. For instance, like in the U.S., there is no "generic" device concept, as it exists for medicines. And, unlike in the U.S., there is no period of exclusive marketing regarding data exclusivity for medical devices.

Consequently, in the EU, incentives for innovation in the medical devices field are limited to patent protection. As for competition, the absence of generics makes it essentially brand to brand, and advertising is only partially regulated at the European level, leaving discretion to EU Member States to regulate at the national level.

A. Incentives for innovation: patent protection

Patents for medical devices rely on the same legal landscape as the one applicable for medicines.[21] Device manufacturers generally enjoy a twenty-year period of patent protection. Also, as with medicines, while the devices themselves can be patented, patents are not available for the methods by which the devices are used. Thus, for example, a company could patent a new scalpel for making surgical incisions but not the method of making a horizontal rather than vertical incision.[22]

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[20] Cross refer data protection chapter [Hoffman and Herveg]

[21] [Insert cross reference to EU medicines chapter] [other Mahalatchimy chapter]

[22] Article 53(c) of the European Patent Convention and Recital 35 of Directive 98/44/EC. Moreover, inventions the commercial exploitation of which would be contrary to "*ordre public*" or morality are also excluded. Id. Art. 53(a). European patent law provides a non-exhaustive list of these inventions: processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; and uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical

Moreover, there is no Supplementary Protection Certificate for medical devices. The Court of Justice of the EU even stated a supplementary protection certificate could not be granted for a substance which was an integral and active part of a patented medical device.[23]

B. Competition

As mentioned, all competition is brand to brand for medical devices, as there is no "generic" device concept. Due to the decentralized system based on several competent authorities (notably the notified bodies), the European legal framework has been considered as an incentive by itself. Indeed, as said before, the choice of a notified body by the manufacturer anywhere in the EU has led to a kind of regulatory competition between notified bodies. The EU also had the lowest approval times among leading markets for high-risk devices in the world.[24]

Nevertheless, the strengthened requirements for notified bodies as well as for the medical devices as such regarding pre-market and post-market requirements will probably have an impact on European competitiveness. Beyond the first times of uncertainty due to the implementation of the new legal frameworks which could lead to more burdens for companies (lack of notified bodies, additional cost for new regulatory compliance), the new frameworks aim to ensure the smooth functioning of the internal market as well as a high level of protection of public health.

Although only time will tell us whether the competitiveness of the medical devices sector in Europe has been maintained and how much this is the result of the new legal frameworks, two main comments can be made regarding a positive impact of the European regulation on competition. First, the strengthened requirements which shall lead to safer medical devices as well as enhanced transparency should give more trust in this sector in Europe. Second, the electronic systems of EUDAMED will make exchanges of information easier and quicker. Consequently, the European Union may be more competitive compared to other countries, regarding clinical investigations and post-market vigilance and surveillance.

C. Advertising

The new EU Regulation 2017/745 covers claims in labeling, instructions for use, making available, putting into service and advertising of devices. Only CE marked devices can be placed on the EU market and promoted.

Moreover, it is prohibited to make explicitly false statements or misleading statements. It is also forbidden to fail to inform of the risks associated with the use of the device, and to make off-label promotion. Indeed, the user or patient would be misled with regard to the device's intended purpose, safety and performance. However, the Regulation does permit manufacturers to exchange scientific information (without advertising the device as safe and effective) before CE marked. Additionally to these medical devices-specific EU provisions, other EU provisions on advertising and promotion may be applicable to medical devices, especially Directive 2006/114/EC on misleading and comparative advertising, and Directive 2005/29/EC on unfair business-to-consumer commercial practices in the internal market.

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benefit to man or animal, and also animals resulting from such processes. Rule 28 of the implementing regulations to the European Patent Convention and Article 6(2) of Directive 98/44/EC.

[23] CJEU, 25 October 2018, Boston Scientific Ltd, C-527/17, ECLI:EU:C:2018:867.

[24] Emergo Group, "Compare the Time, Cost, and Complexity of Getting Regulatory Approval," December 2017, here.

Apart from these EU provisions, the advertisement of medical devices is regulated at the national level. For instance, in Italy, the advertising of non-prescription medical devices requires the prior authorization of the Ministry of Health.[25] As another example, in France, the prior authorization of the French Medicines Agency (ANSM) is required for medical devices and IVD medical devices that are listed in specific regulations;[26] and French law distinguishes between advertising to the general public and healthcare professionals.[27]

Moreover, two databases, mentioned above, aim to spread information to the public: the Unique Device Identification Database including core elements for the identification of the marketing devices and the EUDAMED database, the latter being under construction. Note, however, that the EUDAMED database already existed under the medical devices Directives' central repository for exchanges of information on market surveillance between national competent authorities and the European Commission only. The 2017 medical devices Regulations provide for a much larger EUDAMED database including different modules on actors, Unique Device Identification and devices, notified bodies and certificates, vigilance, clinical investigations and performance studies and market surveillance. The implementation of the new EUDAMED database was initially scheduled to go live in March 2020, but the European Commission has recently delayed it to May 2022 in order to achieve full functionality of the different modules and to submit them to independent audit for EUDAMED to be operational. Such delay may be seen as an opportunity for the industry that will have more time to get adapted. Indeed, the EUDAMED database is challenging in terms of necessary adaptation for companies regarding time and resources, especially IT resources.

VI. Examples of challenging products (covered by the new EU Regulations)

Emerging technologies, in particular genetic testing, 3D printing and e-health which are discussed below, may challenge the EU's regulatory scheme, especially as the issues they raise are not entirely known. However, the 2017 EU Regulations on medical devices and IVD medical devices have taken into account all these technologies as far as they are medical devices. It is difficult to know whether the new disposals are fully operational and adapted to these emerging technologies as long as their implementation is ongoing. Nevertheless, one common particularity of the EU scheme applicable to these emerging technologies is that it is fragmented. Beyond the sharing of requirements between national legal frameworks and the European legal framework (which is an intrinsic difficulty of EU law), several European legal texts may apply to these technologies. Indeed, most of the time their legal frame is not limited to the EU legislation on medical devices, as it also includes EU rules on unfair commercial practices, protection of personal data, patients' rights in cross-border

[25] Article 21 of the Legislative Decree No. 46 of 24 February 1997 (the Italian law on medical devices). To go further on this Italian rule, see: Italian Supreme Court Decision No. 10892, 7 May 2018.

[26] Arrêté du 24 septembre 2012 fixant la liste des dispositifs médicaux présentant un risque important pour la santé humaine et dont la publicité est soumise à autorisation préalable en application de l'article L. 5213-4 du code de la santé publique, JORF n°0230 du 3 octobre 2012 page 15475 texte n° 6 ; Arrêté du 24 septembre 2012 fixant la liste des dispositifs médicaux de diagnostic in vitro dont la publicité est soumise à autorisation préalable en application de l'article L. 5223-3 du code de la santé publique JORF n°0230 du 3 octobre 2012 page 15474 texte n° 5.

[27] Décret n° 2012-743 du 9 mai 2012 relatif à la publicité pour les dispositifs médicaux, JORF n°0109 du 10 mai 2012 page 8767 texte n° 99.

healthcare, and general product safety. Although the application of each of these sets of rules may raise concern, their combination, complementarity and sometimes overlapping will also raise issues which will need to be measured once the necessary delay in the full implementation of the 2017 Regulations on medical devices and IVD medical devices is over.

A. Direct-To-Consumer (DTC) Genetic testing

DTC genetic tests with medical purpose are considered to be in vitro diagnostic medical devices, and as such the EU Regulation 2017/746 regulates them. Interestingly, during the process of adoption of this text, the European Parliament called for a ban on DTC advertising of genetic testing, as the previous IVD medical devices Directive did not regulate this aspect of genetic testing. The final text, however, did not include such a prohibition, and instead only prohibits misleading claims for medical devices including in DTC advertising of genetic testing. Therefore, it does not deviate much from the existing generally applicable Directive 2005/29/EC on unfair commercial practices against misleading advertising.

Moreover, EU Regulation 2017/746 provides rules on genetic tests in general, i. e. for physician-ordered tests, without focusing on DTC genetic tests. It requires that the individual being tested is provided with relevant information on the nature, the significance and the implications of the genetic test, and in particular an "appropriate access to counselling" is required.[28] Nevertheless, Member States can adopt or maintain measures that are more protective of patients, as is the case in France where a genetics counselor must provide the counseling and consequently DTC genetic tests are prohibited.[29]

Consequently, apart from advertising and general rules on genetic tests, DTC genetic testing remains regulated at the national level only, involving a fragmented regulatory landscape in Europe, with some countries essentially banning it (France, Germany) while others only restricting it on the basis of general laws regarding patients' rights and healthcare services for instance (Luxembourg, Poland).

B. 3D printing

3D printing, or "additional manufacturing," is transforming how products are designed, developed, manufactured and distributed, including in the medical technology sectors. It refers to "the various processes used in the manufacture of products, by depositing or fusing materials layer by layer"[30] to obtain 3 dimensional objects. Within the health field, 3D printing has been used or is being developed for the rapid and cost-effective production of implants and prosthetics such as dental implants and prosthetic limbs, but also for surgical planning and tools, and 3D bio-printing such as the printing of cells, tissues and organs, although this latter is in its infancy.

3D printing raises important legal challenges such as those linked to the standardization process, the legal definitions, and intellectual property (patents,

[28] However, it does not "apply in cases where a diagnosis of a medical condition and/or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used". Article 4.2 and 4.3 of regulation 2017/746.
[29] Article 1132-1 of the French Public Health Code.
[30] European Commission, The disruptive nature of 3D printing, January 2017 : https://ec.europa.eu/growth/tools-databases/dem/monitor/sites/default/files/DTM_The%20disruptive%20nature%20of%203D%20printing%20v1.pdf (last access February 15, 2019).

copyrights and trademarks). At the moment, the EU legal regime regarding 3D printing is unclear overall in all of those domains. Indeed, there is no sui generis regulatory regime governing the whole printing process. Where 3D printing processes or printed objects correspond to the legal definition of medical devices, the legal regime of medical devices will apply. However, some will be considered as standard medical device (such as mass-produced pillar for dental implants), while other may be custom-made medical device (such as the implant designed for a particular patient, and to be adapted on the pillar).

For 3D bioprinting, piecemeal legislation is relevant in relation to tissue engineering and regenerative medicine, all being applicable at different stages of production.[31]

C. E-health (Novel diagnostic and monitoring technologies)

Many information and communication technology-based tools are being developed at an exponential rate to assist with prevention, diagnosis, treatment, health monitoring, and lifestyle management. These innovative tools include electronic health records, telemedicine services, personal wearable devices, and portable communicable systems.

The European Commission defines e-health as "the application of information and communications technologies across the whole range of functions that affect the health sector". [32] Using its public health competency, the European Union has established a European strategy in the field of e-health with the aim of favoring the development of a European e-health area. But the Commission has also adopted more concrete measures, using its internal market competency, for the setting up of e-networks to improve the interoperability of health systems in the European Union.[33] These are very much in their infancy, as each EU Member State retains responsibility for its own health system.

Besides e-health services, many e-health products should be qualified as medical devices and as such are regulated by EU Regulation 2017/745 which includes software. When they are not, they are regulated by the EU Directive on general product safety.[34]

The particularity of e-medical devices is that the personal data they include or transmit are health data governed by the General Data Protection Regulation. These health data are considered sensitive data and as such their processing is in principle prohibited, although exceptions exist.

However, the definition of data concerning health as provided in the GDPR does not include well-being data which are difficult to define. Consequently, many e-objects used for well-being data, such as a connected watch/bracelet counting the number of daily steps, will not be governed by the prohibition on processing health data, although the e-objects may be covered by other generic provisions of the GDPR.[35] The line

[31] Li, Phoebe and Faulkner, Alex (2017) 3D bioprinting regulations: a UK/EU perspective. European Journal of Risk Regulation, 8 (2). pp. 441-447. ISSN 1867-299X.

[32] Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 30 April 2004, COM(2004)356.

[33] Directive 2011/24/EU.

[34] Directive 2001/95/EC.

[35] E. Rial-Sebbag, Les produits de santé connectés : quelle sécurité ?, in N. de Grove-Valdeyron, Les nouveaux enjeux de la politique pharmaceutique européenne: pour des produits de santé sûrs, innovants et accessibles, Journées Louis Dubouis, 23- 24 mai 2018 Toulouse, Les Actes de la Revue de droit de l'Union Européenne, Editions Clément Juglar, Janvier 2019, pp. 23-32, p. 30.

between health data and well-being data appears very unclear. Consequently, the data provided by the same watch/bracelet could be considered as well-being data if they are used by the source person only while they will be considered as health data if they are required or transmitted to a healthcare professional. The same is true for the watch/bracelet's legal qualification as medical device.[36]

Overall, the EU regulation of e-medical devices includes specific provisions both in the EU Regulation on medical devices and in the EU's GDPR. The legal qualification of e-objects and their associated data depends not only on the legal definitions but also on the objects' intended use. The EU regulatory landscape thus relies on a case-by-case analysis and companies may use the grey zones for choosing the legal regime that is the most adapted to their economic strategies. For instance, they could claim to produce well-being data, to process them and sell them.

Conclusion

The European framework on medical devices has historical specificities which have led to less burden for the commercialization of medical devices than medicines: mainly harmonization of essential requirements only, access to the market without direct intervention of European or national authorities, with control performed by the notified bodies. This has facilitated access of medical devices to the market, although the real access of European patients to medical devices is limited by heterogeneous national regulations on pricing and reimbursement evolving continuously towards a rationalization and decrease of expenses due to the imperative of controlling national health budgets.

Beyond this pricing and reimbursement challenge that is the same for medicines, the 2017 Regulations on medical devices have established strengthened requirements to better achieve the objective of ensuring a high level of protection of public health as well as trust in the medical devices sector. In addition to the reinforced role and control over notified bodies or the clarification of the economic operators' obligations, one main innovation of the medical devices' Regulations is to make necessary the concept of clinical evaluation based on a continuous analysis of clinical data from research to commercialization. One consequence may be that the criteria of efficacy of medical devices, which has never been officially recognized as fundamental as it is for medicines except in the national contexts of reimbursement regarding effectiveness (cost-efficacy), may be more necessary with the implementation of the new Regulations.

Moreover, in addition to the provisions in the Regulations discussed above, a range of other guidelines and benchmarks that apply to medical devices have been developed by national health authorities[37] but also Professional bodies[38]. In this regard as well as regarding the strengthening of safety requirements of these health products, especially for Class III medical devices, the 2017 medical devices Regulations bring the legal regime for medical devices in the EU closer to that for medicines.

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[36] For instance, the European Court of Justice of the European Union has considered a drug prescription assistance software, since it has a medical purpose, is a medical device. Judgment of the Court (Fourth Chamber) of 7 December 2017, Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé, C-329/16, ECLI:EU:C:2017:947.

[37] For instance, the French "Haute Autorité de Santé" provides numerous recommendations on patients care.

[38] For instance, MedTech Europe has adopted a Code of Ethical Business Practice.

The slider between the evidence to be generated for a safe access to good quality medical devices and the promotion of innovation and economics objectives has been moved in favor of public health and patients' protection. The appropriate level of regulation and evidence to be generated will clearly be higher than under the previous medical devices' Directives. Although such an approach can be recognized from the public health objective, one can wonder whether the consequences for the medical devices market which will become more regulatorily burdensome have been adequately considered. Indeed, apart from the EUDAMED database and patent protection, the European incentives for innovation and competition which rely more on the legal framework itself under the European Directives, has not been particularly strengthened as this chapter has shown.

While only time will tell whether the new legal framework does not impose more burdens or barriers on innovation and access to the market than necessary, we can expect that specific incentives, such as a period of exclusive marketing regarding data exclusivity for medical devices as in the U.S., will be needed.

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