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# The Legal 500 Country Comparative Guides

## Eu

# LIFE SCIENCES

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in EU.

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# EU
# LIFE SCIENCES

## 1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

**Medicinal products** for humans are primarily governed by Directive 2001/83/EC and Regulation (EU) 726/2004. These rules encompass, *int. al.*, the requirements and procedures for marketing authorizations (**'MA'**), the monitoring of authorized products as well as provisions for the manufacturing and advertising of medicinal products. Due to its legal nature, Directive 2001/83/EC had to be transposed into national law in order to be applicable in each Member State. National legislators had some leeway doing so, which led to some divergences in the national laws. The relevant legislation is therefore not yet fully harmonized across Europe. In addition, the European legislator has still adopted further rules on specific types of medicinal products, such as Regulation (EU) 141/2000 in relation to rare diseases, Regulation (EU) 1901/2006 on medicinal products for children or Regulation (EU) 1394/2007 on advanced therapy medicinal products.

**Biologicals** are governed by the abovementioned provisions for medicinal products. With a view to **biosimilar medicines**, the EU pioneered by establishing a dedicated framework for their authorisation (*cf.* article 10 (4) of Directive 2001/83/EC). Further requirements for biosimilars are set out in various scientific guidelines of the European Medicines Agency ('**EMA**') which provide an important source for developers of biosimilars for the MA application process.

The legal requirements for **medical devices** are widely harmonized throughout the European Union under Regulation (EU) 2017/745 ('**MDR**') which applies, with immediate effect, in all Member States. This regulation has replaced the previous Directive 93/42/EEC and has introduced more stringent and partly even stricter requirements for the placing of medical devices on the European market. Coinciding with the MDR, Regulation (EU) 2017/746 has been adopted which lays down specific requirements for *in vitro* diagnostic medical devices. Due to some stricter requirements under the new regulatory framework, the re-certification of Notified Bodies (as requested by the MDR) had been delayed, which has led to a temporary (and still enduring) backlog in conformity assessment procedures for medical devices. For this reason, the transition periods for compliance with Regulation (EU) 2023/607 and Regulation (EU) 2022/112 have repeatedly been extended. In addition to both aforementioned regulations, there are numerous non-binding guidelines governing the placing of medical devices on the European market such as, for example, those of the Medical Device Coordination Group (**'MDCG'**). While non-binding, some of these guidelines have become *de facto* standards.

**European food law** lays down strict prerequisites for foodstuffs and food supplements and has been largely harmonized within the European Union through European regulations which apply with immediate effect in all Member States. These harmonized requirements encompass, amongst others, product presentation and labelling, packaging, hygiene, advertising and marketing, ingredients, additives, flavourings and enzymes, authorization proceedings, good manufacturing practice, safety assessments, borderline products, functional food, dual use, health and nutrition claims, product risk management, consumer information as well as market surveillance. With regards to foodstuffs, the regulations are designed to ensure a comprehensive approach throughout the entire supply chain ("from farm to fork"). Some key examples of European food legislation are:

- Regulation (EU) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (**'EFSA'**) and laying down procedures in matters of food safety (known as the **'Basic Regulation'**),
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules as well as,

 

- Regulation (EU) 852/2004 on the hygiene of foodstuffs,
- Regulation (EU) 853/2004 laying down specific hygiene rules for food of animal origin,
- Regulation (EU) 609/2013 stipulating provisions for foods for infants and young children, foods for special medical purposes and daily rations for weight control nutrition, and
- Regulation (EU) 2015/2283 on novel foods (known **'Novel Food Regulation'**).

Food supplements are foodstuffs and therefore subject to and governed by the legal provisions on foodstuffs. In addition, there are a few additional rules for food supplements, including those relating to their composition and labelling. At European level, these requirements are primarily laid down in Directive 2002/46/EC on food supplements, which has been transposed into national law by all Member States and sets out *int. al.* which vitamins and minerals may be used in food supplements. In addition, Regulation (EU) 1925/2006 lays down which "other substances" are prohibited in food supplements.

## 2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

For **medicinal products**, the EU law stipulates an authorization requirement, whereby medicinal products can be authorised through one of the following four procedures: a national procedure; a mutual recognition procedure, if the medicinal product already has a **MA** in another Member State; a decentralized procedure which allows for the simultaneous authorization of a medicinal product in multiple Member States; and a centralized procedure. The authorization procedure is preceded by an extensive research and development process on the efficacy, safety, and quality of the medicinal product in pre-clinical and clinical trials. Under the EU centralized application procedure, a medicinal product can be authorised for all Member States of the European Economic Area (**'EEA'**) with one single application. This centralized procedure is governed by Regulation (EU) 726/2004. For all medicinal products listed in Annex I to this Regulation, the centralized authorization procedure is mandatory. The EMA is the competent authority for this procedure. As part of this procedure, the EMA's Committee for Medicinal Products for Human Use ('**CHMP'**) conducts a scientific assessment based on the application documents that pertain to quality, efficacy, safety, and environmental safety. Through the CHMP, scientists from all European regulatory authorities are involved in the processing and assessment of applications. Two Member States take the lead as rapporteur and co-rapporteur for each application and prepare an assessment report, which is commented on by the other Member States and then discussed and approved in the CHMP. At the end of the assessment procedure, the CHMP prepares a scientific opinion and issues a positive or negative recommendation for or against authorization. This recommendation serves as the basis for the European Commission's decision to grant or not to grant authorization. If granted, it has a term of five years which can be extended after another review. Following the authorization of a medicinal product, the marketing authorization holder (**'MAH'**) is required to continuously carry out post-marketing surveillance (s. Question 4).

The MDR has resulted in a widely harmonized regulatory process for **medical devices**. Unlike medicinal products, there is no official MA requirement. Rather, medical devices must undergo a conformity assessment procedure before being marketed or placed in service in Europe and must carry a CE mark. Medical devices labelled in this manner are generally freely marketable throughout the EEA. Through a successful conformity assessment procedure, medical devices demonstrate their compliance with all applicable legal prerequisites (*e.g.*, regarding their general safety and performance requirements). This compliance is then documented by a CE mark. Manufacturers must demonstrate not only technical safety but also the clinical performance and risk-benefit ratio acceptability of their devices, all based on clinical data. Furthermore, they must establish a quality management system that includes a risk management procedure and a clinical evaluation for each device. Within the conformity assessment procedure, the involvement of an independent certification body (**Notified Body**) may be necessary, depending on the product's risk class. Even though operating under private law, Notified Bodies are subject to a state designation procedure following European rules, as set out in the MDR. Only for the lowest risk class (class I), the manufacturer is allowed to perform the conformity assessment on its own, *i.e.* without the involvement of a Notified Body. According to the MDR, all medical devices must be assigned a unique device identification ('**UDI'**) and registered in the European database for medical devices ('**EUDAMED'**). Once placed on the market, medical devices are subject to vigilance and surveillance obligations (see Question 4).

 

### 3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

The placing of **food supplements** on the European market is not dependent on a formal MA. Rather, it is the responsibility of the manufacturer, importer, supplier, or distributor to ensure that a food supplement placed on the market is safe and that all legal requirements applicable to the food supplement are met. The relevant legal prerequisites originate primarily from European and national food law as well as further specific regulations on food supplements (s. Question 1). In accordance with Directive 2002/46/EC which has been transposed into national law, Member States may, for the purpose of efficient monitoring, require a notification to be made to the relevant national competent authority prior to placing a food supplement on the market.

Before placing a food supplement on the European market, particular attention should be paid to maximum levels of vitamins and minerals. Even though the European Commission has not yet adopted an implementing measure under Directive 2002/46/EC to set standardised maximum and minimum levels for vitamins and minerals in food supplements, several Member States have their own national maximum levels, which can have a direct impact on the marketability of food supplements on the relevant local markets. In addition, manufacturers of food supplements are well advised to ensure that their product cannot be classified as a medicinal product (*e.g.*, due to its mode of action or presentation). Once placed on the market, product compliance is monitored by the competent national food regulatory authorities in the Member States.

**Novel foods** constitute an exception from the general principle that food does actually not require a marketing authorization in Europe. Novel food is food that was not consumed in the EU to a significant degree as a food before 15 May 1997. It is governed by Regulation (EU) 2015/2283. According to its article 10, anyone wishing to place on the market a novel food or a food/food supplement containing a novel food not yet included in the EU list of authorized novel foods must submit an application for authorization of the novel food to the European Commission. The authorization procedure is carried out by the European Commission in consultation with the EFSA.

### 4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

Following the authorization of a **medicinal product**, the MAH is required to inform the competent authority of the Member State of the date of actual marketing of the medicinal product in that Member State. The same applies if the MAH temporarily or permanently ceases the medicinal product to be placed on the market. This provision also serves the purpose of being able to react to any resulting potential shortages. The MAH is ultimately responsible for the medicinal product placed on the market and must fulfil certain obligations. According to article 104 of Directive 2001/83/EC, this encompasses the establishment and maintenance of a pharmacovigilance system. At the pharmaceutical company, this system must be under permanent oversight of a qualified person for pharmacovigilance within the EEA. With regards to the pharmacovigilance system, the MAH must comply with the EMA Guideline on Good Pharmacovigilance Practice. Part of the pharmacovigilance obligations are the submission of periodic safety and update reports (**'PSURs'**) at specific intervals as well as the reporting of suspected adverse reactions.

Once placed on the market, **medical devices** are subject to post-market surveillance (**'PMS'**) by the national authorities responsible for the vigilance and surveillance of medical devices to identify and address any risks that may arise. Within their responsibilities, they can check medical devices based on random samples. Ultimately, the authorities may decide to withdraw a medical device from the market. It is therefore the duty of the manufacturer to continuously determine whether corrective or preventive action is necessary and inform the competent national authorities and/or the Notified Body if necessary. The PMS obligations are laid down in chapter VII of the MDR and national laws, and include the establishment, maintenance, and application of a formal PMS system according to a PMS plan. The PMS system, which is to be integrated into the manufactures' quality management system (**'QMS'**), shall be suited to gathering, recording, and analyzing relevant data on the quality, performance, and safety of a medical device throughout its entire lifetime. Moreover, the manufacturer is subject to several reporting and vigilance obligations, like the submission of PSURs for class IIa, IIb and III medical devices and the reporting of serious incidents.

 

## 5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

At European level, the EMA is responsible for the authorization and supervision of **medicinal products** in the EU. Its main tasks include the evaluation of MA applications as part of the EU centralized authorization procedure, monitoring of product safety, facilitating the development and accessibility of medicinal products and providing information to healthcare professionals and patients. **Medical devices** are monitored by the competent national authorities of the Member States. At European level, market surveillance is supported by EUDAMED, which shall give the competent national authorities rapid access to information on manufacturers and their authorised representatives, products, certificates, and vigilance data. Eventually, **food and food supplements** are monitored by the competent national authorities of the Member States. The EFSA does not act as a general European supervisory authority. Its role is more of a scientific advisory and risk assessment body.

## 6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

Regulation (EU) 726/2004 sets out the procedure for amending, suspending, or revoking a MA for **medicinal products** authorised via the EU centralized procedure. This is the responsibility of the relevant bodies of the EMA and the Commission. The procedure of challenging regulatory decisions with regards to **medical devices** is laid down in the MDR as well as the remaining national laws on medical devices and therefore slightly differs in the Member States. Responsible for the procedure are the respective national competent authorities. Prohibition orders against the distribution of **foodstuffs or food supplements** are also issued by the competent national authorities.

## 7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

At European level, regulations governing the authorization and conduct of clinical trials with **medicinal products** are set out in the Clinical Trial Regulation (EU) 536/2014 (**'CTR'**) and the Commission Delegated Regulation (EU) 2017/1569 which specifies the principles and guidelines for good manufacturing practice (**'GMP'**) for investigational medicinal products for human use and regulations for inspections. Clinical trials with medicinal products require authorization. The 'Clinical Trials Information System' (**'CTIS'**) streamlines the submission process for trials by requiring only one central application, which the sponsor submits through an online portal, together with information on the clinical sites in the EU countries participating in the trial. The procedure is coordinated by a medicinal product authority in one of the designated Member States, known as the rapporteur Member State. The new standardised procedure aims to simplify clinical trials in all Member States by eliminating the need for separate applications in each Member State concerned. The application procedure is divided into two parts: Part I covers general aspects, including protocol, risks, manufacturing or importing of investigational medicinal products, labelling, and the investigator's brochure. This section of the application is jointly approved by all participating Member States. Part II covers national aspects, such as information, consent, remuneration for investigators, and compensation for trial participants. These aspects are reviewed by the competent national authorities in the Member States concerned. At the end of the procedure, the authorization is granted or refused. The processing time has been significantly reduced to a maximum of about 100 days for multinational clinical trials. Failure to respond to queries within the statutory period will result in the application being deemed withdrawn and requiring resubmission. Furthermore, clinical trials that were approved under the previous Directive 2001/20/EC and are expected to continue beyond 30 January 2025 must be approved in accordance with the CTR. According to the CTR, the appeal procedure against the rejection of an application is subject to national law.

The MDR lays down the legal basis for the authorization of clinical investigation with **medical devices**. It distinguishes between three scenarios: Clinical investigation with non-CE marked medical devices, clinical investigation after placing on the market and other clinical investigation. Clinical investigations with medical devices that are not yet CE-marked require authorization. The relevant application must be submitted to the national competent authority of the

 

Member State via EUDAMED. As long as EUDAMED is not yet fully functional, the application is submitted via the respective national portal of the Member State. The application procedure is divided into a validation phase and a review phase. In the validation phase, it is checked whether the MDR is applicable at all and whether all required documents have been submitted. The subsequent review phase then examines the content of the documents submitted and sets different requirements depending on the risk class of the medical device. Article 70 (7) MDR gives the Member States the option to define different rules for those requirements. For clinical investigations with a CE-labelled medical device that has already been placed on the market, a notification to the competent national authority of the Member State is mandatory under the conditions of article 74 MDR. Once EUDAMED is fully operational, this notification should also be made through this central database. However, according to the revised plan of the European Commission, the full operation of EUDAMED may not be achieved before 2027. For other clinical investigations involving medical devices as defined in article 82 MDR, the Member States are responsible for their regulation. In all three scenarios, and regardless of the outcome of the clinical investigation, the sponsor must submit the report and an investigation summary to the Member States where the trial was conducted via EUDAMED.

## 8. Is there a public database for clinical trials in your country, and what are the rules for publication?

For **medicinal products**, it is required to make certain information relating to clinical trials accessible to the public. The CTR tightens this requirement and mandates the publication of results from clinical studies involving healthcare institutions/practices in the EU. All information on clinical trials submitted under the CTR is available under Clinical Trails, and clinical trials information submitted under the former Directive is available under the EU Clinical Trails Register. Additionally, the EU Commission's Guideline 2012/302/03/EC outlines requirements for publishing. Furthermore, EMA's Policy 0070 provides for the publication of clinical data submitted by pharmaceutical companies in support of their MA applications under the EU centralized procedure. However, the EU regulation on clinical trials does not specify any requirements for disclosing raw trial data. Therefore, the European Federation of Pharmaceutical Industries and Associations ('**EFPIA**') has adopted Principles for Responsible Clinical Trial Data Sharing' as self-committing guidelines for its member companies and associations. These guidelines concern the responsible sharing of clinical data, including raw trial data. The requesting party must comply, *int.al.*, with data protection regulations, including anonymisation, non-re-identification, and agree to be bound to research purposes. Disclosure to third parties is prohibited.

Like CTIS, EUDAMED shall also provide information on clinical investigations and performance studies with **medical devices** to the public via a publicly accessible website to increase transparency. It follows the rules laid down in the MDR. For the time being, information on clinical investigations with medical devices is not available, since EUDAMED has not yet achieved its full functionality. According to the MDR, the publication obligation only comes into effect six month after the European Commission has rendered its notice that the clinical investigation and performance module has achieved full functionality, which may not be achieved before 2027.

## 9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

The data produced during a clinical trial is classified as 'special categories of personal data' under the EU General Data Protection Regulation (EU) 2016/679 ('**GDPR**'). This applies to both the 'raw' data held at the clinical trial site and the pseudonymised data transferred from the clinical trial site to the sponsor. Processing of this data is only permitted within the narrow limits of Art. 9 para. 2 GDPR. The sponsor must also comply with strict data protection requirements before conducting clinical trials, including obtaining the consent of trial participants. If data is anonymised, GDPR does not apply; however, the requirements for anonymisation are strict. Next to the GDPR, the CTR also sets out data protection rules, so that the interplay of both regulations must be taken into account. The transfer of clinical data typically requires the consent of trial participants, which can be a time-consuming process. To facilitate the exchange and use of health data, the EU is currently discussing a draft regulation to create a European Health Data Space ('**EHDS**') (see Question 24).

## 10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

In addition to the digitalisation of the clinical trial application procedure, as set out in the CTR and MDR, decentralization of certain trial elements is currently

 

under discussion, *e.g.* with trials been relocated from trial centres to the participants' home, allowing for home health visits, home delivery of trial medication and electronic consent. To promote decentralization, the Clinical Trials Coordination Group ('**CTCG**') oversees the EU Decentralized Clinical Trials ('**EU DCT**') project, which has produced the Recommendation Paper on Decentralized Elements in Clinical Trials. The guiding principle in choosing a particular element of decentralization is that it must not compromise the safety of trial participants, the protection of their rights and dignity, or the reliability of the data. The Regulation COM(2021) 206 laying down harmonized rules on Artificial Intelligence (**AI Act**), will also have an impact on the digitalisation of clinical trials, *e.g.* when it comes to the use of AI for R&D purposes (see Question 24).

## 11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

According to Article 40 of Directive 2001/83/EC, Member States shall take all appropriate measures to ensure that the manufacture of **medicinal products** within their territory is subject to the holding of an authorization. The holder of a manufacturing authorization must ensure that any imported product has undergone an appropriate quality control testing prior to the batch release onto the market within the EEA. Article 41 further specifies the minimum requirements for authorization, including suitable and sufficient premises and technical equipment. According to Directive 2001/83/EC, an entity exporting medicinal products out of the EEA must have a wholesale distribution authorization or a manufacturing authorization.

The production of **medical devices** does not require an official authorization under the MDR. However, since the manufacturing process is also part of the conformity assessment and the QMS, it is subject to at least indirect testing and assessment. There is also no uniform European legal requirement for authorization of manufacturing plants producing **food and food supplements**, but the EU hygiene legislation (Article 6 of Regulation (EU) 852/2004) requires food business operators involved in the manufacture or distribution of food or food supplements to register with the competent national authority.

## 12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

For **medical devices**, the principle of harmonized marketability across Europe applies, due to the full harmonization through the MDR. In general, this principle also applies to **food supplements**, given the Basic Regulation. However, in the absence of a harmonized rule, the maximum and minimum levels of vitamins and minerals allowed in a food supplement may differ from one Member State to another, which may lead to differences in the marketability. For **medicinal products**, the (as yet) not fully harmonized regulation process may lead to borderline decisions, with the result that a product may be classified differently in various Member States. The EU centralized authorization procedure avoids this situation, at least for those medicinal products listed in Annex I of Regulation (EU) 726/2004, with the result that centrally authorized medicinal products can be marketed throughout the entire European market. Specific types of distribution (*e.g.*, through pharmacies or drugstores) is determined separately by national laws in the Member States.

## 13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Reimbursement and pricing of medicinal products and medical devices are not regulated at European level, but rather separately by each Member State.

## 14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The legal framework for advertising is generally governed by national rules, with the EU setting the general framework. As a guiding principle, advertising may not be misleading. The relevant EU laws are:

- Directive 2006/114/EC concerning misleading and comparative advertising, and
- Directive 2005/29/EC concerning unfair business-to-consumer commercial practices.

Furthermore, the EU laws relevant to medicinal products, medical devices and food supplements set out further specific requirements. For example,

- Title VIII of Directive 2001/83/EC imposes

 

restrictions on the advertising of medicinal products, *g.* the prohibition of advertising for prescription-only medicinal products to the general public;
- Article 7 MDR contains a special prohibition of misleading advertising for medical devices;
- Article 6 and article 7 of Directive 2002/46/EC stipulate that no healing or soothing properties may be attributed to food supplements, and that advertising must not state or suggest that the intake of adequate amounts of nutrients is generally not possible with a balanced, varied nutrition;
- Article 7 of Regulation (EU) 1169/2011 specifies the general protection against misleading advertising for foodstuffs.

With regards to nutrition and health claims made on food supplements, Regulation (EU) 1924/2006 applies, together with Commission Regulation (EU) 432/2012 which established a list of authorized health claims. The European Register of Health Claims contains a comprehensive list of all authorized and non-authorized claims, together with their respective conditions of use. For nutrition claims, the Annex to Regulation (EC) No 1924/2006 provides for a limited list of approved claims.

## 15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

A **trademark** can be registered at international, EU or national level. At EU level, a European Union trademark ('**EUTM**') may be registered at the European Union Intellectual Property Office ('**EUIPO**'). All three registration forms (*i.e.*, international, EU and national) coexist, and therefore the same trademark can be registered at international, EU and/or national level for EU Member States. The EUTM allows the owner an exclusive right in all EU Member States within one single registration procedure. The legal basis is provided by Regulation (EU) 2017/1001 and Directive (EC) 2015/2436.

**Patents** can also be registered at international, EU or national level. European patents may be registered with the European Patent Office ('**EPO**'), following a standardised application and grant procedure, as laid down in the European Patent Convention ('**EPC**'). A European patent has the same effect in each of the EPC contracting states for which it has been granted and is subject to the same rules as a national patent granted in that state. The EPC contracting states are the 27 EU Member States and 12 further states (including Switzerland, Norway and Turkey). Since 2023, inventions in the EU can also be protected through a European patent with unitary effect ('**Unitary Patent**'). The Unitary Patent provides protection in those EU Member States that have ratified the Unified Patent Court Agreement, and it is administered centrally by the EPO. It is supplemented by a Unified Patent Court ('**UPC**'). The legal framework for the Unitary Patent is provided by Regulation (EU) 1257/2012 and Regulation (EU) 1260/2012.

Life science products are generally patentable in Europe, with the exception of diagnostic, surgical and therapeutic procedures performed on the human or animal body (which are explicitly excluded from patentability). As to active pharmaceutical ingredients, it is recommendable to apply for patent protection already during the early R&D process for medicinal products in order to benefit from legal protection as soon as possible. Under current law, patent protection lasts for 20 years from the date of patenting. As research on active pharmaceutical ingredients may take a long time, manufacturers of medicinal products in the EU have the option of applying for a supplementary protection certificate (**'SPC'**), extending the protection period by a further maximum of five years (plus six months in case of completed studies that comply with an agreed paediatric investigation plan). To set up an uniform authorization procedure at the EUIPO for SPCs, the EU Commission has rendered two regulation proposals for medicinal products (COM(2023) 222) and plant protection products (COM(2023) 221 ).

Based on Directive 2001/83/EC, a document protection for medicinal products is granted to the MAH as original manufacturer against third-party use of its own study data in MA applications from generic manufacturers. For all medicinal products, this is eight years from the date of MA plus a further two years of market exclusivity, during which manufacturers of generics can apply for and receive MA but are not yet permitted to market the generic product.

With regards to food, microbiology and biotechnology, inventions relating to biological material or genetic resources are generally patentable. However, plant varieties and animal breeds, as well as essentially biological processes for breeding plants and animals, are excluded from patentability under the EU Biotechnology Directive 98/44/EC.

## 16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are

 

### addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

The UPC is responsible for disputes concerning European Patents and Unitary Patents, with the exception of European Patents for which the patent proprietor has submitted a so-called “opt-out” application to the UPC. The court procedure involves the exchange of written pleadings and an oral hearing and should ideally result in a decision within one year. The decision of the UPC is binding for all countries that have decided to join the Unitary Patent System and has direct legal effect on the patent there.

### 17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Restrictions on the use of trademarks are primarily based on the prohibition of misleading designations. This is explicitly stated, for example, in article 7 of the MDR which *int. al.* prohibits the use of names and trademarks that may mislead the user or the patient with regard to **medical devices**‘ intended purposes, safety and performance by a certain manner. In terms of **medicinal products**, the EMA has published a Guideline on the acceptability of names for human medicinal products processed through the EU centralized procedure. This guideline is a reliable aid for medicinal products authorised under the single EU procedure and also contains rules on umbrella brands. For **food supplements**, article 6 (2) of Directive 2002/46/EC provides that the labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

### 18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

Product liability for medicinal products, medical devices and food supplements is governed by national rules, with the EU setting up the general framework in Directive 85/374/EEC, (**‘Product Liability Directive’**) regulating the liability of manufacturers for damage caused by the defectiveness of their products. The specific EU legal acts for medicinal products, medical devices and food supplements do not contain more specific regulations on product liability but refer to the Product Liability Directive (c.f. article 5 (4) of Directive 2001/83/EC, article 10 (16) MDR and article 21 Basic Regulation). In order to better protect consumers and keep up with the development of new technologies (particularly artificial intelligence), the provisions of the Product Liability Directive are to be updated (which has already been initiated by the European Commission with the draft directive COM/2022/495, currently being negotiated by the European Parliament).

### 19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

National rules and regulations determine the risks of liability, including criminal, serious administrative and civil liability, while the EU sometimes provide a general framework.

- For **medicinal products**, articles 99 and 118a of Directive 2001/83/EC stipulate that Member States shall lay down rules on penalties in the event of infringements of the directive and its national equivalent. This concerns in particular the manufacturing, distribution, brokering, import and export of falsified medicinal products and active substances, the sale of falsified medicinal products at a distance to the public by means of information society services and the provisions on the use of excipients. The Member States shall take all necessary measures to ensure that those penalties are implemented. In addition, the penalties must be effective, proportionate, and dissuasive.
- A similar approach for **medical devices** can be found in article 113 MDR, according to which the Member States shall lay down penalties for infringements of the MDR.
- According to article 17 (2) Basic Regulation, the Member States shall enforce and monitor **food** law and the fulfilment of its requirements and shall lay down rules on effective, proportionate and dissuasive measures and penalties applicable to infringements of food law.

### 20. Does your jurisdiction provide for a

 

### specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Unlike various Member States (such as Germany, France and Belgium), the EU does not provide for specific laws for digital health applications. However, European legislation directly affects digital health applications since they are typically to be classified as medical devices, and thus subject to the MDR.

### 21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

In response to the exacerbation of shortages in the healthcare sector, not least triggered by the Covid-19 pandemic, the European Commission has adopted Regulation (EU) 2022/123, establishing a harmonized system for the monitoring and management of shortages of medicinal products and medical devices by the EMA. The relevant platform for reporting will be the 'European Shortages Monitoring Platform' (**'ESMP'**) to be developed by the EMA. Additionally, the 'Medicine Shortages Steering Group' (**'MSSG'**) will be established within the EMA to develop lists of critical medicines to ensure their monitoring and to make recommendations on the necessary actions. Furthermore, the European Commission recently published a proposal for a new Directive COM(2023) 192 and a new Regulation COM(2023) 193 containing provisions to improve the security of supply of medicinal products throughout the EU. If enacted, these Regulations would amend and further harmonize existing European pharmaceutical legislation. In addition, the Commission's proposed Regulation COM (2023) 224 on compulsory licensing for crisis management also plays an important role in the EU's initiatives to address supply shortages. The purpose of compulsory licensing is to provide access to patented medicines in the event of an EU-wide crisis or emergency.

### 22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

At European level, the political interests of the pharmaceutical industry are represented by the EFPIA, and those of the medical technology industry by MedTech Europe. Additionally, EFPIA and MedTech Europe have adopted codes of conduct through which their members submit to voluntary self-regulation. For pharmaceutical companies and associations belonging to EFPIA, these are set out in the EFPIA Code of Practice, constituting a collection of ethical rules for the promotion of medicinal products to healthcare professionals (**'HCPs'**) and the interaction with HCPs as well as healthcare organisations (**'HCOs'**) and patients' organisations (**'POs'**). In addition, the EFPIA Code stipulates disclosure provisions committing all EFPIA members to disclose transfer of value to HCPs and HCOs and to disclose the support and services provided to POs. MedTech Europe has set out its ethical rules in the European Code of Ethical Practices regulating various aspects of the relationships between the medical device technology industry with HCPs, HCOs and POs.

### 23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

- Decision of the CJEU of 13th July 2023 in case C-606/21: The case concerned the online distribution of non-prescription medicinal products in France via a web portal (www.doctipharma.fr), which enabled internet users to purchase over-the-counter medicinal products from pharmacists operating their websites for trade with the help of doctipharma's technical solution. In this regard, the CJEU confirmed that (i) a service provided on a website consisting in connecting pharmacists and customers for the sale, via the websites of pharmacies which have subscribed to that service, of medicinal products not subject to medical prescription falls within the concept of an "information society service" within the meaning of article 1(2) of Directive 98/34/EC, and (ii) Member States may, on the basis of the applicable rules, prohibit the provision of such a service, if it transpires, having regard to the characteristics of that service, that the provider of that service is itself selling such medicinal products without being authorised or entitled to do so under the law of the Member State in whose territory it is

 

established.

- Decision of the CJEU of 19th January 2023 in joined cases C-495/21 and C-496/21: The cases concerned the clarification of criteria for distinguishing pharmacological from non-pharmacological products and whether a product can be considered a medical device if its main intended effect cannot be conclusively determined. Moreover, the court had to decide whether the "doubt rule" in article 2 (2) of Directive 2001/83 also applies to medicinal products by presentation.
- Decision of the CJEU of 22th December 2022 in case C-530/20: In this case, the CJEU clarified *al.* the scope of the term "advertising of medicinal products" within the meaning of Directive 2001/83/EC with regard to content that does not refer to one specific, but rather to unspecified medicinal products.
- Decisions of the CJEU in case C-418/21 of 27th October 2022 and in case C-760/21 of 2nd March 2023: In these cases, the CJEU dealt with various demarcation issues with regard to food supplements, medicinal products and foods for special medical purposes as well as with the legal requirements for foods for special medical purposes.

## 24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

The proposed EU AI Act will have a significant impact on the life sciences industry where artificial intelligence (**'AI'**) is increasingly used in various ways. This concerns for instance medical devices falling with the category of an AI system, digital companion diagnostics using AI systems or software that is used in clinical trials and that relies on AI. With regards to medicinal products, the EMA and the HMA have published a Reflection Paper providing considerations on the use of AI and machine learning in the lifecycle of medicinal products, including R&D, authorization and post-authorization. The AI Act is expected to come into force in April 2024. The date of first application of the new provisions from the AI Act reaches from six month to two years after its entry into force.

Moreover, the EU aims at creating a harmonized EU internal market for health data. In 2022, the European Commission published its proposal for a Regulation COM(2022) 197 on the European Health Data Space ('**EHDS'**) which is – in addition to further EU "digital and data" legislation like the Digital Services Act, the Digital Markets Act, the Data Act and the Governance Data Act – part of the European Strategy for Data. According to the European Commission, the EHDS is a health-specific ecosystem setting out rules, common standards and practices as well as infrastructures and a governance framework to empower individuals through increased digital access to and control of their electronic personal health data at national and EU level, supporting the free movement of this data and fostering a genuine single market for electronic health record systems (referred to as primary use of data). In addition, the EHDS aims at enabling the EU to make full use of the potential of using health data for the purpose of research, innovation, policy-making and regulatory activities (referred to as secondary use of data).

Regarding national health systems, the EU has initiated the EU4Health program through Regulation (EU) 2021/522. The program aims at enhancing the strength, resilience, and accessibility of national health systems to counter long-term health threats. The four objectives are to improve and promote health in the EU, protect people, provide access to medicinal products, medical devices, and crisis-relevant products, and strengthen health systems.

## 25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

In addition to the legal developments and initiatives outlined in questions 21 and 24 of this Guide, the Pharmaceutical Strategy for Europe lays down further significant strategic topics. Key objectives are to improve patient access to innovative and affordable medicines, support competitiveness and innovative capacity of the EU's pharmaceutical industry, and contribute to the green and digital transition and the consequences of demographic change.

 

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