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European Union overview
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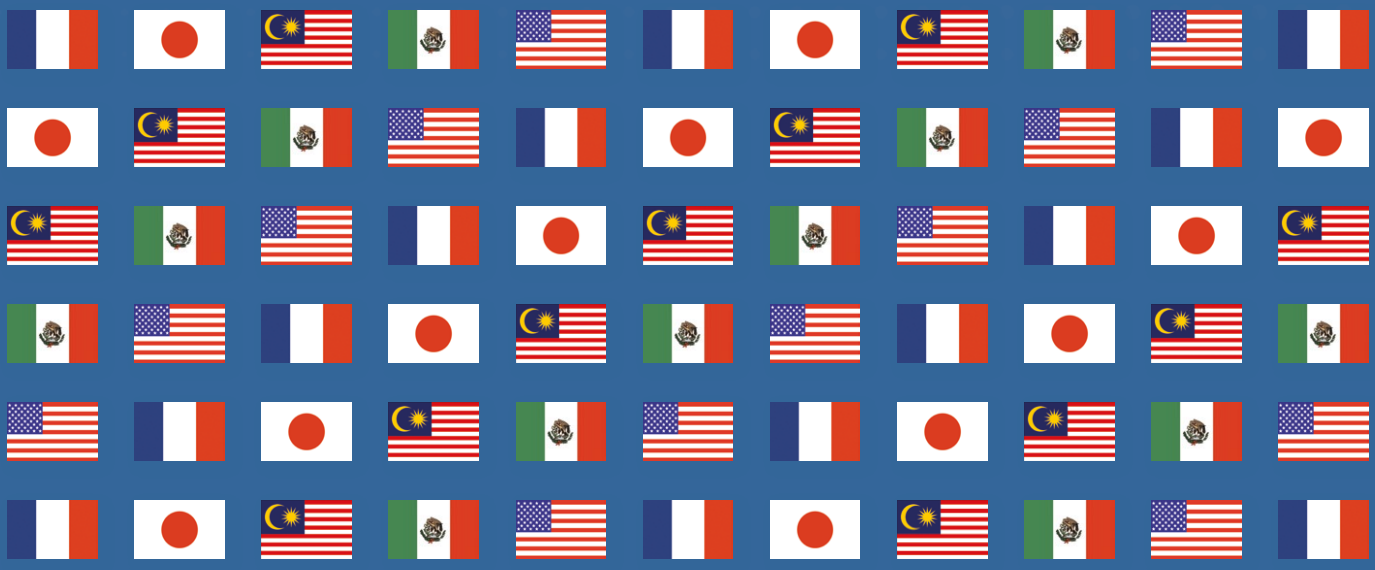

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European Union overview

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Overview

The legal framework of healthcare enforcement responsibilities in the European Union is separated between the statutes for pharmaceutical products and the ones for medical devices. Given the different regulatory approaches to both categories, the regulation of pharmaceutical products is deeper than the one for medical devices. However, in both fields, the competencies and responsibilities are primarily at the member state level, with European authorities having mainly a more coordinative role.

Regulation of pharmaceutical products and medical devices

The main EU-harmonised enforcement regulations for pharmaceutical products relate to the pharmacovigilance of pharmaceutical products. These regulations go back to the Contergan tragedy, which led to stronger harmonisation of the European regulation of pharmaceutical products. In addition, there are certain measures relating to clinical trials provided at EU level.

The legal framework for pharmacovigilance of pharmaceutical products in the European Union is governed by Regulation (EC) No. 726/2004 and Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended in 2010 by Regulation (EU) No. 1235/2010 and Directives 2010/84/EU and 2012/26/EU respectively, as well as by Commission Implementing Regulation (EU) No. 520/2012 on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No. 726/2004 and Directive 2001/83/EC (the new pharmacovigilance legislation in the European Union).

Chapter 3 of Regulation (EC) No. 726/2004 as amended, Title IX (articles 101 to 108b) of Directive 2001/83/EC as amended and the Implementing Regulation contain the majority of pharmacovigilance provisions in the legislation. Basically, the European Union requires member states to operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in EU pharmacovigilance activities. The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards patients' or public health. That information shall in particular refer to adverse reactions in human beings, arising from the use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure. The same applies to marketing authorisation holders, who are also obliged to install a risk management system (see article 104, paragraph 3 of Directive 2001/83/EC as amended).

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The new pharmacovigilance legislation has the primary goal of strengthening and rationalising pharmacovigilance and increasing patient safety. According to article 108a(a) of Directive 2001/83/EC as amended, a set of guidelines for the conduct of pharmacovigilance in the European Union was developed by the European Medicines Agency (the Agency) in cooperation with competent authorities in member states and interested parties: the new guidance on good pharmacovigilance practices (GVP). The GVP aims to facilitate the performance of pharmacovigilance activities within the European Union and applies to marketing authorisation holders in the European Union, the Agency and competent authorities in member states. A table of contents of the GVP is accessible at the Agency's website. The pharmacovigilance legal requirements and the GVP apply to all pharmaceutical products authorised in the European Union, whether centrally or nationally authorised.

According to article 22 of Regulation (EC) No. 726/2004, the Agency, acting in close cooperation with the national pharmacovigilance systems, shall receive all relevant information concerning suspected adverse reactions to pharmaceutical products that have been authorised by the European Community and shall, where appropriate, draw up publicly accessible opinions on the measures necessary. Member states must implement such requirements. For instance, section 68 of the German Act on Medicinal Products (AMG) stipulates that all national competent authorities shall provide the Agency or the European Commission (the Commission) with all the information that is necessary to monitor compliance with the pharmaceutical product-related regulations.

Besides, there are several EU-wide enforcement provisions relating to the conduction of clinical trials. The long-awaited Clinical Trials Regulation (EU) No 536/2014 (CTR) has come into application (subject to a three-year transition period) with the Clinical Trials Information System (CTIS) having gone live on 31 January 2022. The CTR aims to harmonise the submission, assessment and supervision processes for clinical trials for medicines in the European Union. CTIS is a single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. Instead of submitting clinical trials applications separately to national competent authorities (NCAs) and ethics committees in each country to gain regulatory approval to run clinical trials in the past, sponsors can now apply for authorisations in up to 30 EU/EEA countries at the same time and with the same documentation. The CTR has an immediate effect on every member state and provides in its article 78 respective requirements for member state inspections. Among others, article 78, paragraph 5 of the CTR clarifies that the Agency shall coordinate the cooperation between member states concerned on inspections conducted in member states, in third countries, and inspections conducted in the framework of an application for a marketing authorisation under Regulation (EC) No. 726/2004. Pursuant to article 78, paragraph 7 of the CTR, the Commission shall specify, by means of implementing acts, the detailed arrangements for inspection procedures, including qualification and training requirements for inspectors.

The respective Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council provides under article 9, paragraph 1 in general that member states shall collaborate with each other, with the Commission and with the European Medicines Agency, to develop and improve commonly recognised standards of good clinical practice inspections, for example, in the form of joint inspections. Further, article 11 of Implementing Regulation (EU) 2017/556 sets forth an EU-wide mutual recognition of inspection conclusions.

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The field of medical devices (with the exemption of in vitro diagnostics) is, from 26 May 2021, widely harmonised within the European Union through Regulation 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR). With regard to enforcement, the MDR provides market surveillance rules in particular between the member states, but at EU level in a more cooperative way.

According to article 93, paragraph 9 of the MDR, the competent authorities of the member states shall coordinate their market surveillance activities, cooperate, and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all member states. Furthermore, Chapter VIII of the MDR relates to, among other things, European cooperation in a Europe-wide medical device coordinating group. According to article 102, paragraph 1 of the MDR, the competent authorities of the member states shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable the provisions of the MDR to be applied uniformly. The same provisions as in article 93, paragraph 9 and article 102, paragraph 1 of the MDR will apply, from 26 May 2022, on in vitro diagnostics according to article 88, paragraph 9, and article 97 of Regulation 2017/746 of 5 April 2017 on in vitro diagnostic medical devices, and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Relationships between healthcare professionals and suppliers

The collaboration of the pharmaceutical industry with healthcare professionals is in a field of tension between the EU member states' fight against corruption and the necessary cooperation of the industry with healthcare professionals in financing research activities in product development, clinical trials or monitoring of applications. The regulation of legal relationships falls under the competence of the EU member states and is governed by them in various ways. For instance, with the German Act to Combat Corruption in Healthcare, Germany introduced a regulation that makes it possible to punish a healthcare professional under criminal law if he or she accepts, demands or permits himself or herself to be promised an advantage in the exercise of his or her profession, for example, for prescribing pharmaceutical products and medical devices.

At EU level, there are only a few regulations that provide a legal framework. One such regulation concerns restriction of promotions of pharmaceutical products according to Directive 2001/83/EC. Directive 2001/83/EC provides in article 94, paragraph 1 that in the promotion of medicinal products it is prohibited to supply, offer or promise a gift or pecuniary benefit to persons authorised to prescribe or supply them. According to article 94, paragraph 3 of Directive 2001/83/EC, healthcare professionals may not demand or accept such inducements. The only exceptions are benefits that are of little value and are relevant to medical or pharmaceutical practice. According to the case law of the European Court of Justice (ECJ), the purpose of the statute is to prevent promotional practices by the pharmaceutical industry that are likely to arouse an economic interest in healthcare professionals in prescribing or supplying medicinal products (see ECJ, judgment of 22 April 2010, C-62/09, marg. No. 29). In contrast, direct or indirect hospitality is permissible at purely professional and scientific events. However, in this case, hospitality is strictly limited to the main purpose of the event and may only apply to healthcare professionals (articles 94, paragraph 2, and 95 of Directive 2001/83/EC). However, these regulations are not directly applicable in the

respective EU member states but require an act of implementation by the member states. For implementation, article 94, paragraph 4 of Directive 2001/83/EC provides an opening clause for the member states, whereas the restrictions on sales promotion measures do not affect national discount and price regulations for medicinal products.

For the enforcement of violations of the advertising restrictions, Directive 2001/83/EC provides that member states must establish adequate and effective methods to monitor the advertising of medicinal products. These methods must provide that a court can order the prohibition of advertising without the requirement of damage, intent or negligence, and can also order the temporary cessation of advertising (article 97 of Directive 2001/83/EC). Court proceedings at the national level are usually civil proceedings conducted by persons or nationally designated bodies.

In addition, the demand for more transparency in interactions between the pharmaceutical industry and healthcare professionals and organisations has been raised within the pharmaceutical and healthcare industry in the past decade and has led to a system of voluntary compliance by the pharmaceutical industry. To this end, in 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA), as the European umbrella organisation, adopted the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations. According to this code, pharmaceutical companies are required to disclose, among other things, all types of financial and other pecuniary benefits to healthcare professionals and healthcare organisations. On 22 March 2019, this code was merged with the EFPIA Code on The Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals and the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations to form a uniform code of conduct – the EFPIA Code of Practice. This is to apply as a uniform European minimum standard.

However, the EFPIA Code of Practice only links the 36 national associations and 39 pharmaceutical companies that are members of EFPIA. Via the 36 national associations, further pharmaceutical companies are also indirectly bound by the regulations of the EFPIA Code of Practice. For this purpose, the respective member associations must implement the regulations in their own code. Should stricter or more far-reaching requirements than those of EFPIA be imposed at the national level, these will not be affected by the regulations of the EFPIA Code of Practice. However, not all companies are covered by the EFPIA Code of Practice.

The EFPIA Code of Practice requires disclosing transfers of value to healthcare professionals and healthcare organisations. Under these regulations, EFPIA member companies must disclose the names of healthcare professionals or organisations that have received payments or other transfers of value from them. They will also have to disclose the total amounts of value transferred by type of activity. Payments to healthcare professionals include consultancy fees, speaker fees and sponsorship to attend meetings. Moreover, donations and grants to healthcare organisations must be disclosed. Payments made for research and development activities are disclosed in aggregate.

The disclosure of payments is published differently in the respective EU member states. In most countries, payments are disclosed annually on company websites. In some European countries (France, Belgium, etc), disclosure on a central government platform is also

required due to national legal regulations. In addition, disclosure is also performed through EFPIA's member associations in some countries.

Regulation of healthcare delivery

Within the scope of harmonising the European legal framework, article 168, paragraph 7 of the Treaty on the Functioning of the European Union provides for limitation of the EU's activities. Thus, the responsibility of the member states for the establishment of health policy and the organisation of healthcare services and medical care must be preserved. The administration of healthcare also falls within the responsibility of the member states. Therefore, the monitoring of healthcare delivery is also mainly the responsibility of member states and the authorities they entrust with these tasks.

Private enforcement

Whereas in cases of clinical negligence the legal framework for claims is established in national law, the grounds on which purchasers or users of pharmaceuticals or medical devices can seek recourse for regulatory and legal infringements are strongly influenced by European law.

In the European Union, producers are liable for damages caused by the defectiveness of their products. This liability is based on the Product Liability Directive (Directive 85/374/EEC), which was implemented into the law of the member states.

In accordance with the Product Liability Directive, producers must provide compensation to injured persons regardless of fault. A compensation claim requires that the injured person proves the damage, the defect and the causal relationship between the defect and the damage (article 4 of the Product Liability Directive).

The liability of the producer under this Directive cannot be limited or excluded towards the injured party by a clause limiting or excluding liability (article 12 of the Product Liability Directive).

However, the claim for compensation under the Product Liability Directive is time-barred after the expiry of a period of three years from the date on which the plaintiff became aware or should have become aware of the damage, the defect and the identity of the producer (article 10, paragraph 1 of the Product Liability Directive). Further, the rights of the injured party pursuant to this Directive expire 10 years from the date on which the producer put into circulation the product that caused the damage, unless the injured party has commenced legal proceedings against the producer in the meantime (article 11 of the Product Liability Directive).

According to article 13 of the Product Liability Directive, its provisions do not affect any rights an injured party may have under the rules of contractual and non-contractual liability or under any special liability regime existing at the time of notification of this Directive. This applies, for example, to the strict liability rule under section 84 of the German Medicinal Products Act.

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The European Commission published a draft for a new Product Liability Directive on 28 September 2022. Among other things, the draft provides for (further) facilitations of evidence for injured parties.

For example, according to article 9, paragraph 2 of the draft, the defectiveness of the product will be presumed if the claimant proves that the product does not comply with mandatory safety requirements under EU or national law intended to provide protection against the risk of harm that has occurred. Further, the product will be regarded as defective if the claimant proves that the damage was caused by an obvious malfunction of the product during normal use or under normal circumstances.

In addition, companies will be obligated to disclose relevant evidence in their possession if certain conditions are met. Such disclosure obligations are unfamiliar to many member states, such as Germany. If the company does not fulfil its obligation to disclose relevant evidence, the product is also presumed to be defective according to article 9, paragraph 2 of the draft.

However, the defendant has the right to rebut said presumptions (see article 2, paragraph 5 of the Draft Product Liability Directive).

The Medical Device Regulation (Regulation (EU) 2017/745) also contains provisions on liability for defective products.

With regard to compensation claims arising due to the defectiveness of a product, the MDR refers to applicable EU and national law (article 10, paragraph 16 of the MDR).

Also, the authorised representative is legally liable for defective devices on the same basis as the manufacturer, jointly and severally with the latter, if the manufacturer is not established in a member state and has not fulfilled its obligations under the MDR (article 11, paragraph 5 of the MDR).

Notified bodies may also be liable under national law due to a culpable failure to fulfil their obligations in connection with the declaration of conformity procedures (CJEU, judgment of 16 February 2017, Case C-219/15).

In addition to the legal grounds set out in these Directives, the law of the respective member state may provide further grounds for purchasers or users of pharmaceuticals or medical devices to seek recourse in case of regulatory or legal infringements.

The availability of class and collective actions varies across the member states. However, a directive on representative actions was recently adopted in the European Union. The Representative Actions Directive (Directive (EU) 2020/1828) came into force on 24 December 2020 to protect the collective interests of consumers. The member states were obliged to implement the Directive into national law by 25 December 2022. Laws, regulations and administrative provisions based on the Directive must be applied by 25 June 2023.

Pursuant to the Directive, member states must ensure that representative actions may be brought by qualified entities. A 'qualified entity' as defined in the Directive is any organisation or public body representing consumers' interests designated by a member state as

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qualified to bring representative actions in accordance with this Directive (article 3, paragraph 4 of the Representative Action Directive).

According to article 2, paragraph 1 of the Representative Actions Directive, representative actions may be brought against infringements by traders of certain provisions of EU law, including provisions implementing these EU laws, which affect or threaten to affect the collective interests of consumers.

The scope of representative actions also covers health law regulations such as the Product Liability Directive, the MDR and Directive 2001/83/EC, also known as the Community code relating to medicinal products for human use (Annex I of the Representative Action Directive).

Qualified entities shall be entitled to sue at least for injunctive and redress measures such as compensation, repair, replacement, price reduction, contract termination or reimbursement of the price paid, but only to the extent provided for by EU or national law (articles 8 and 9 of the Representative Action Directive).

The Directive also entails cross-border representative actions. Member states must ensure that qualified entities designated in advance in another member state for the purpose of bringing cross-border representative actions can bring such representative actions before courts or administrative authorities (article 6 of the Representative Action Directive).

All in all, the Representative Action Directive will strengthen private enforcement, including in the field of healthcare law. The directive will harmonise the regulations in member states on representative actions and enable cross-border representative action. The directive also provides that entities qualified to bring representative action can sue for remedial decisions. This is particularly important for consumers in those member states in which this is not possible currently.

At EU level, the Directive on the protection of persons who report breaches of Union law (Directive (EU) 2019/1937) was created on 23 October 2019. The Directive aims to ensure a high level of protection for whistleblowers with regard to breaches of EU law by setting common minimum standards. The material scope of application also includes EU acts relating to public health, such as Directive 2001/83/EC.

A whistleblower is entitled to protection under article 6 of Directive (EU) 2019/1937 if the whistleblower had reasonable grounds to believe that the reported information about breaches was true at the time of the report and that the information fell within the scope of the Directive and, in addition, either made an internal or external report or disclosed the information. Three forms of reporting are therefore protected:

- article 8 of Directive (EU) 2019/1937 provides that in the internal reporting procedure, the information on infringements is transmitted to a legal person governed by public or private law. Member states shall ensure that legal persons in the private and public sectors establish internal channels and procedures for reporting and follow-up. In any case, all private companies with more than 50 employees are obliged to do so. According to article 8, paragraph 5 of Directive (EU) 2019/1937, the reporting channels can be provided by a person or department designated for this purpose or externally by a

third party. The whistleblower should receive an acknowledgement of receipt of internal reports within a maximum of three months.

- In the external reporting procedure, the whistleblower contacts the competent authorities directly. To this end, the member states must ensure that the competent authorities authorised to receive these reports provide feedback on them and take appropriate follow-up action. In addition, member states must ensure that independent and autonomous external reporting channels are established for receiving and processing information submitted by whistleblowers (article 11, paragraph 2 of Directive (EU) 2019/1937). The whistleblower should receive an acknowledgement of receipt of external reports within a maximum of three months (article 11, paragraph 2 lit. d of Directive (EU) 2019/1937).
- Public disclosure is understood to mean 'the making of information on breaches available in the public domain', pursuant to article 5, paragraph 6 of Directive (EU) 2019/1937. This includes disclosure to the press if no appropriate measures have been taken in the internal and external reporting procedure or if there is a special reason for the disclosure, such as fear of retaliation in the case of an external report.

Directive (EU) 2019/1937 aims to preserve the confidentiality of the identity of whistleblowers. According to article 16 of Directive (EU) 2019/1937, a whistleblower's identity may only be disclosed without his or her explicit consent if this is a necessary and proportionate measure under EU or national law in the context of investigations by national authorities or judicial proceedings. In addition, the whistleblower should be protected from retaliation. For this purpose, article 19 of Directive (EU) 2019/1937 contains a wide, standardised catalogue of reprisals. In addition, article 21 of Directive (EU) 2019/1937 provides that a wide exclusion of whistleblowers' liability is to be regulated, whereby liability in court proceedings for defamation, breach of copyright, breach of secrecy, breach of data protection rules or disclosure of trade secrets, or for compensation claims, is excluded.

According to articles 25 and 26 of Directive (EU) 2019/1937, the provisions of the Directive must be transposed into national law by 17 December 2021 but may deviate from its regulations in favour of the rights of whistleblowers. Despite this deadline, only eight EU member states transposed Directive (EU) 2019/1937 into national law in time. There are still four EU member states that have not adopted a national act to transpose Directive (EU) 2019/1937. Meanwhile, the European Commission has initiated infringement proceedings against 19 EU member states.

Cross-border enforcement and extraterritoriality

In general, EU authorities cannot investigate violations of healthcare laws and other legal provisions independently, as this is the responsibility of the law enforcement authorities of the member states.

Although the European Public Prosecutor's Office has been conducting its own investigation procedures since 1 June 2021, it only investigates (cross-border) crimes against the financial interests of the European Union (eg, corruption, certain forms of subsidy fraud).

To fight cross-border crimes, member states are cooperating and the EU facilitates such cooperation. For example, Europol assists member states in countering crime and facilitates police cooperation among member states. Its competence extends to organised crime,

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terrorism, forms of crime that violate a common interest that is the subject of an EU policy or other forms of serious crime where two or more EU member states are involved.

Tasks of Europol include gathering and exchanging data, coordinating investigative activities and working on joint investigations. Nonetheless, Europol has no investigative or enforcement powers of its own. Further, Eurojust supports coordination and cooperation between national law enforcement authorities with regard to serious crimes affecting two or more member states or requiring prosecution on a common basis.

However, the focus is on certain serious crimes such as terrorism, cybercrime, drug trafficking and human trafficking.

Update and trends

On 26 April 2023, the European Commission presented a legislative proposal for the revision of the EU medicinal products legislation: Firstly, the Commission submitted a proposal for a Directive of the European Parliament and of the Council on the EU code relating to medicinal products for human use (Directive 2023/0132 (COD)). Second, the Commission introduced a proposal for a Regulation of the European Parliament and of the Council laying down EU procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (Regulation 2023/0131 (COD)). The proposals intend to repeal several European legal acts, such as Directive 2001/83/EC and Regulation (EC) 726/2004.

This revision is part of the implementation of the Pharmaceutical Strategy for Europe and aims to promote innovation while reducing the regulatory burden and environmental impact of medicinal products. In particular, it aims to ensure access to innovative and proven medicinal products for patients, with a particular focus on improving security of supply and managing supply shortages. The proposed reform of pharmaceutical legislation intends to respect the exclusive competence of member states for the provision of health services, including pricing and reimbursement policies and related decisions, and avoids harmonising these issues.

The proposal for Directive 2023/0132 (COD), among other things, provides amendments with respect to the system of supervision and inspections due to ensure compliance with the principles of good manufacturing practice and good distribution practices. In principle, the competent authorities of the EU member states remain responsible for supervision of pharmaceutical companies and wholesale distributors. However, upon request by one or more competent authorities, inspections of premises or activities of manufacturers of medicinal products or active substances located in the European Union or in third countries, or premises of distributors of medicinal products or active substances or marketing authorisation holders, may be carried out by official representatives from more than one member state together with the inspectors of EMA.

The legislative proposals are currently undergoing the ordinary legislative procedure. It is not yet foreseeable when the Commission will conclude this procedure. Moreover, the proposals currently provide that member states shall transpose Directive 2023/0132 (COD) 18 months after the date of entering into force and that Regulation 2023/0131 (COD) shall

apply 18 months after its entry into force. Thus, it will take a while for the proposals to unleash their legal effect.

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