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## Medicines

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### **A. Introduction and Definitions of Medicines in EU Law**

- 1 Medicines or ‘medicinal products’ are regulated by a dense web of European Union (EU) legislation, supplemented by delegated and implementing acts, and interpreted by many rulings of the Court of Justice of the EU (CJEU). EU medicines law is developed and applied by a complex network of institutional actors, both within the EU’s institutional structures and within Member States.
- 2 A ‘medicine’ in EU law is defined in Article 1(2) Directive 2001/83/EC (‘Community Code’) (to be replaced by the Art. 4 COM(2023) 192 final (‘Proposed new Medicines Directive’) identical wording), as follows. It must be ‘any substance or combination of substances’ that either ‘is presented as having properties for treating or preventing disease in human beings’, or ‘may be used in or administered to human beings with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis’. The definition is often summarized as being by presentation and function, and either of the two is sufficient for a product (→ *health products*) to be classified as a medicine.
- 3 The obligations in the Community Code do not apply to all medicines. In essence, although matters are complex, the EU’s medicines legislation applies to mass-produced medicines, ‘either prepared industrially or manufactured by a method involving an industrial process’ (Art. 2(1) Community Code) intended to be placed on the market in the EU.
- 4 Some medicines are excluded from the scope of the Community Code but are subject to other specific EU legislation. Specific EU rules apply to substances of human origin (→ *Blood*; → *Human Tissues and Cells*), but when such a substance is transformed into a medicine, it falls within the scope of the Community Code. Specific EU rules apply to radiopharmaceuticals, but not to ‘radionuclides in the form of sealed sources’ which are excluded from the scope of the Community Code (Art. 3(5)).
- 5 The Community Code does not apply to medicines ‘prepared in a pharmacy in accordance with a medical prescription for an individual patient’ (known as magistral formula); or ‘supplied in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question’ (known as officinal formula); or ‘advanced therapy medicinal products’ prepared on a ‘non-routine basis ... in a hospital under the exclusive professional responsibility of a medical practitioner’ (known as the ATMP hospital exemption). There are also exemptions for compassionate use (Art. 5(1)

Community Code; Art. 83 of Regulation 2004/726). Nor does the Community Code apply to products being used as part of a clinical trial. Such products are covered by specific EU rules on → clinical trials (Art. 3(3) Community Code).

- 6 Not all obligations in the Community Code apply to ‘intermediate products’, which are ‘intended for further processing’ (Art. 3(4) Community Code), for example, a partly processed material that must undergo further processing steps before it becomes the final product, for example, a solution prior to filling, granulates, or uncoated tablets, although the obligations concerning manufacturing and import do apply. Further, Member States have the power to temporarily authorize an unauthorized medicine, ‘in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation’ (Art. 5(2) Community Code).
- 7 Medicines in EU law are subject to a complex legal taxonomy, with different obligations and opportunities for manufacturers, importers, distributors, or retailers of different types of medicines. In addition to classical or general medicines, EU law covers → homeopathic and traditional herbal medicinal products; → advanced therapy medicinal products; → generics and biosimilars; → paediatric medicines; and → orphan medicines (used to treat rare diseases). Specific requirements apply to radiopharmaceuticals; biological and biotechnological medicines; blood and plasma-derived medicines; and immunological medicinal products.
- 8 The current proposals for reform of EU medicines law (Proposed new Medicines Directive and COM(2023) 193 final (‘Proposed new Medicines Regulation’)) restructure the EU legal definitions of medicines. The proposals introduce new concepts, such as a ‘critical medicinal product’ (defined by EU law but identified and managed by national competent authorities in accordance with a common methodology developed by the → European Medicines Agency) (Arts 2(13), 127, and 130(1) Proposed new Medicines Regulation) and a ‘Union list of critical medicinal products’ (Art. 131 Proposed new Medicines Regulation). The proposals also bring forward new obligations and incentives for antimicrobial medicines, especially ‘priority antimicrobials’ (Art. 17 Proposed new Medicines Directive; Art. 40 Proposed new Medicines Regulation), and strengthen legislative support for development of ‘priority medicinal products’ (Art. 60 Proposed new Medicines Regulation) and ‘medicinal products addressing an unmet medical need’ (Art. 83 Proposed new Medicines Directive).

## **B. History of EU Medicines Law**

- 9 EU medicines law covers the entire ‘regulatory life cycle’ (see further below at Section C.) for medicines, starting from research and ending at post-market surveillance, including access to medicines along the way. Most aspects of the relevant law involve competences shared between EU and national institutions. As we would expect, much of EU medicines law is justified by the imperatives and virtues of the single European market (→ *internal market*): the benefits of sharing in a larger geographical space, and that flow from removing redundant regulatory duplication and barriers to the free movement of medicines within the EU (Art. 114 Treaty on the Functioning of the European Union (TFEU)). Nevertheless, EU

medicines law has also been progressively justified by the objectives of ensuring a high level of protection of human health, especially regarding the common safety concerns of meeting high standards for the quality and safety of medicines (Art. 168(4)(c) TFEU). The history of EU medicines law may be understood within three broad phases: an initial and a consolidation phase both focused on quality, safety, and efficacy, and then a more recent complementary phase extending the focus also to access to and affordability of medicines within the EU.

### 1. Initial phase 1960s–2000s

- 10 The initial phase began in the 1960s. The first EU legislation on medicines (Directive 65/65/EEC on approximation of laws relating to proprietary medicinal products, no longer in force) was adopted in response to the global Thalidomide tragedy. Medicine sold under the brand names ‘Contergan’ and ‘Thalomid’ was used to treat morning sickness in pregnant women, resulting in the deaths of many babies, and leaving many others with serious limb, eye, urinary tract, and heart defects. The Directive required all Member States to establish medicines marketing authorization (licensing) obligations for medicines manufactured on an industrial scale and intended to be placed on the market in Member States. No medicines could lawfully be marketed within the EU without compliance with those national marketing authorizations. Marketing authorizations were intended to establish that medicines are safe and efficacious, taking into account that safety is possible only if quality criteria are met and that the benefits/risks balance of their safety and efficacy is positive.
- 11 From this beginning, the EU adopted a large number of detailed provisions of secondary legislation, covering all industrially produced medicines, including vaccines, serums, radiopharmaceuticals, and so on. Quality and safety measures also include detailed procedures notably for assessment and inspections, good laboratory/manufacturing/clinical/distribution practice, labelling and packaging, and advertising. The internal market law obligation of mutual recognition of → indistinctly applicable rules applies to national measures in this domain.
- 12 In the early 1990s, the EU added to the national ‘decentralized’ marketing authorization route by establishing its own laws, institutions, and procedures to provide an EU/EEA-level ‘centralized’ marketing authorization for certain medicines (→ *Centralized Authorization of Medicines Marketing*). Regulation 2309/93/EEC provided a complete procedure for a mandatory marketing authorization of ‘medicinal products developed by means of [certain] biotechnological processes’; and an optional marketing authorisation for other new medicines constituting a ‘significant innovation’ or ‘of significant therapeutic interest’ (Annex Part A Regulation 2309/93/EEC). Together, these cover the vast majority of truly novel medicines. The centralized procedure involves the then-newly created European Agency for the Evaluation of Medicinal Products and its two scientific committees (for medicines for human use and veterinary uses) in charge of the scientific assessment of those medicines. Formally speaking, the European Commission decides whether or not to grant the marketing authorization. (This has important ramifications for → *judicial review*.)

13 Regulation 2309/93/EEC was an important step in bringing the assessment of the quality, safety, and efficacy of certain medicines to the European Union level. Detailed requirements for submission and examination of the application, authorization (including granting, variation, renewal, suspension, and withdrawal of an authorization), and pharmacovigilance, as well as linked timelines, are set out in the Regulation.

## **2. Quality, safety, and efficacy consolidation phase: 2000s–2010s**

14 In the second phase of the history of EU medicines law, broadly speaking from the 2000s to the mid-2010s, EU law on quality, safety, and efficacy of medicines was consolidated. The EU legislature brought together many provisions of EU medicines law into what is now known as the ‘Community Code’. The main objective here was to clarify and rationalize all the existing provisions on the sale, production, labelling, classification, distribution, and advertising of medicinal products for human use by assembling them into a single text as the starting point of a major codification process. As we will see, however, the codification remains incomplete.

15 A legislative package in 2004 sought to eliminate the remaining obstacles to the free movement of medicines. The EU level ‘centralized’ marketing authorization provisions were consolidated (Regulation 726/2004/EC), establishing new rules for manufacturing, import, marketing authorization, distribution, and surveillance of certain medicines. The scope of centralized authorization was extended to orphan medicines. The new legislation also provides new responsibilities and administrative structure for the renamed European Medicines Agency. Two new scientific committees, for herbal medicines and orphan medicines, were established.

16 The 2004 legislative package also includes clarification of the definition of medicines (which has remained in place) and homeopathic medicines, and new rules for biosimilars, previously not explicitly covered by EU law (Directive 2004/27/EC), as well as the introduction of a definition and a legal regime for herbal medicines (Directive 2004/24/EC).

17 Throughout the following years, an extremely dense body of EU legislative and non-legislative acts covering medicines has been adopted, especially by the European Commission in accordance with delegated powers (→ *delegated legislation*; Directive 2008/29/EC). Most stages of the regulatory life cycle for medicines (from clinical trials to pharmacovigilance) are covered by EU law, and all those concerning quality, safety, and efficacy are currently included.

18 Thus, EU law covers the conditions for the conduct of clinical trials of new medicines, securing compliance with → good clinical practice (Directive 2001/20/EC; Commission Directive 2005/28/EC), with a major amendment in 2014 to simplify and speed up the procedures for authorizing clinical trials (→ *clinical trial authorization*) through a single application via an EU-supported electronic portal and enhanced cooperation between Member States for safety assessment, leaving ethical assessment (→ *clinical trial ethical*

*review*) to the national level (Regulation 536/2014/EU ('Clinical Trials Regulation')). The Regulation will repeal the 2001 Directive by 31 January 2025 following the transition period.

- 19 As well as requiring a valid marketing authorization (see above) for all medicines made in or imported into the EU, EU law covers a variation of the terms of medicines marketing authorizations (Commission Regulation 1234/2008/EC, Directive 2009/53/EC), and conditional marketing authorization (Commission Regulation 507/2006/EC). Fees payable to the European Medicines Agency are set by EU law (Regulation 1905/2005; Commission Regulation 2049/2005; Regulation 658/2014). So are financial penalties for infringement of obligations imposed by marketing authorizations (Regulation 658/2007/EC; Regulation No 488/2012/EU).
- 20 Some third countries, such as Australia, Brazil, Canada, Japan, Switzerland, and the United States (US), are recognized as having an equivalent regulatory framework to the EU's for active substances used to manufacture medicines, allowing for easier importation of those substances to the EU (Commission Implementing Decision 2012/715/EU). EU law covers good manufacturing practice (→ *manufacturing and batch control of medicines*) (originally Commission Directive 2003/94/EC, now Commission Directive 2017/1572/EU, Commission Delegated Regulation 1252/2014/EU), including addition of colourants (Directive 2009/35/EC). → Distribution of medicines is also covered.
- 21 Mandatory labelling and packaging rules (→ *Packaging and Labelling of Medicines*) (Commission Delegated Regulation 2016/161/EU) include detailed rules on safety features, inter alia to tackle concerns about falsified medicines (→ *Falsified Medicines Regulation*) circulating within the EU (Directive 2011/62/EU).
- 22 Distance sales of medicines to the public are covered both by EU internal market litigation (eg *DocMorris*) and legislation (Commission Implementing Regulation 699/2014/EU).
- 23 At the end of the regulatory life cycle, EU law covers → *pharmacovigilance* (Directive 2010/84/EU, Regulation 1235/2010/EU; Directive 2012/26/EU, Regulation 1027/2012/EU, Commission Implementing Regulation 520/2012/EU), with the 2012 amendments adopted because the medicine 'Mediator' (benfluorex) should have been withdrawn from the market before 2009, given reports of harmful effects on patients from 1999. It also covers additional monitoring (Commission Implementing Regulation 198/2013/EU) and post-authorization efficacy studies (Commission Delegated Regulation 357/2014/EU).
- 24 In addition, the quality and safety consolidation phase is also characterized by incentivization of certain behaviours from the global pharmaceutical industry. EU law seeks to incentivize novel medicinal inventions, by offering enhanced → *intellectual property rights* (→ *Health products and IP in EU law*) known as the 'supplementary protection certificate' for medicines (Regulation 469/2009/EC). *Lex specialis* Regulations (expressing the EU's desire to harmonize these matters as strongly as possible) specifically cover particular patient populations or types of medicines (→ *orphan medicines for rare diseases* (Regulation

141/2000/EC); → *paediatric medicines* (Regulation 1901/2006/EC); and → *advanced therapy medicinal products* (Regulation 1394/2007/EC)) to incentivize their development, including through offering extended exclusive marketing rights. In the former two, the EU lagged behind the other global regulators for medicines, the US and Japan, but in the latter, the EU was the global regulatory first-mover. Three dedicated scientific committees in the European Medicines Agency oversee matters concerning these medicines.

25 The entire set of legislative and non-legislative acts as well as EU guidelines applicable to medicines was assembled on Eudralex organized into ten volumes.

### **3. Complementary extension phase 2010s–onward**

26 A third new phase of EU medicines law can be traced to the late 2010s, but was really accelerated by the 2020 COVID-19 pandemic, when the supply of critical medicines, especially vaccines, to the EU, and the equitable sharing of such vaccines, challenged a legal structure that is effective for market supply of high quality, safe and effective medicines, but not for equitable access to medicines.

27 The new dynamic can be seen from public consultations in → Health Technology Assessment ('HTA') (2016–17), and the adoption process (2018–21) of Regulation 2021/2282/EU ('→ *Health Technology Assessment Regulation*'). Deploying the significant legal tool of a Regulation, enhanced cooperation on HTA has been recognized as key to improving patients' access to innovation and medicines both by the Council and the European Parliament (Recitals (8) and (9) Health Technology Assessment Regulation). It is now obligatory for Member States to work collaboratively through joint clinical assessments of health technologies, although there is no obligation to adopt any particular outcome from that collaborative work, and cooperation on non-clinical assessments of health technologies remains voluntary.

28 The European Commission capitalized on a change in support from other institutions to propose a new phase for EU medicines legislation. Work towards the legislative proposals had begun in the mid-2010s, with what the Commission presented as significant multi-stakeholder consultations. The centrepieces of the proposed reforms are a new Regulation (COM(2023) 193 final) and a new Medicines Directive (COM(2023)192 final). According to the Explanatory Memoranda, the ambitious 'overarching aims' of the reform are 'timely and equitable' access to safe, effective, and affordable medicines for all patients across the EU; to secure medicines supply; to promote environmentally sustainable biomedical research, medicines production, and use of medicines within the EU, including by addressing antimicrobial resistance. The proposals recognize that the objective of quality, safety, and efficacy of medicines has been 'achieved to the largest extent'; whereas the 'competitive functioning of the internal market and attractiveness in a global context' has been 'achieved to a moderate extent'. By contrast, patient access to medicines has been achieved 'only to a limited extent'.

- 29 The Proposed new Medicines Regulation and the Proposed new Medicines Directive will be based on Articles 114(1) and 168(4)(c) TFEU, reflecting their place within both EU internal market law and EU health law. This dual legal basis follows other more recent EU medicines legislation, and the Patients' Rights Directive (→ *Article 56 TFEU*; → *Patients' Rights Directive*). Use of a dual legal basis remains unchallenged in EU medicines law, despite CJEU rulings on → choice of legal basis (see eg *Titanium Dioxide*). This is probably explained by the evolution of the EU competence in public health following the adoption of the Lisbon Treaty. The EU legislature obtained a *formal* shared competence to meet common safety concerns for 'high standards of quality and safety for medicinal products' (Art. 168(4)(c) TFEU) towards the end of the consolidation phase, at which point the European Commission had already begun to move from access of safe and high quality of medicines to the market towards equitable patients' access to medicines.
- 30 Within the new phase, further hard and soft law provisions on → antimicrobial resistance are also envisaged (COM(2023) 190&191 final). Antimicrobial resistance has been identified as one of the most serious cross-border health threats for the EU by the → Health Emergency Preparedness and Response Authority ('HERA') established in 2022 and the Member States. The proposals envisage transferable data exclusivity vouchers, to incentivize antimicrobial development; that antimicrobials become prescription medicines across the EU; and marketing authorizations to be conditional on 'stewardship plans' to ensure detrimental environmental impacts are minimized.
- 31 The proposed reforms, when/if adopted, would (confusingly) both revise and replace existing general medicines legislation. The Proposed new Medicines Regulation repeals and replaces Regulation 726/2004/EC, Regulation 141/2000/EC, and Regulation 1901/2006/EC, while the Proposed new Medicines Directive repeals and replaces the Community Code and Directive 2009/35/EC. Provisions on falsified, homeopathic, and traditional herbal medicines remain. The provisions of the current → paediatric medicines Regulation 1901/2006/EC are incorporated and amended into both the Proposed new Medicines Regulation and the Proposed new Medicines Directive, while the provisions of the current → orphan medicines Regulation 141/2000/EC are incorporated and amended within the Proposed new Medicines Regulation only. From a general framing point of view, the merger of the current orphan and paediatric regulations with the general medicines legislation, justified by the European Commission on the basis of 'simplification and increased coherence' would enhance the particularity of → advanced therapy medicinal products, their regulation being the sole remaining *lex specialis* in the proposed new medicines legislation landscape.
- 32 The coming into force of the proposals would herald a new phase of EU medicines regulation. They would clarify some matters of scope and definition. They would include institutional consolidation: for example, most of the European Medicines Agency's specialist committees would become working parties (with representation by experience, not nationality), in the name of efficiency. They would embed the EMA's 'priority medicines'

scheme in legislation. They would also include enhanced support for the EU pharmaceutical industry in terms of regulatory flexibility, including the concept of ‘regulatory sandbox’ (see below C.11.).

### **C. The ‘Regulatory Life Cycle’ for Medicines in EU Law**

- 33 To understand EU law on medicines, it is useful to adopt a model or typology. The ‘regulatory life cycle’ for medicines is regularly used in this regard, and also in the context of other jurisdictions. The ‘regulatory life cycle’ follows a medicine from its inception in bench science, through all the stages until it is in use with a population of patients, available under the ‘basket of care’ provided by a national health (insurance) system. The EU’s ‘regulatory life cycle’ approach now implies regulation beyond quality, safety, and efficacy, to include access to medicines. It also involves enhanced collaboration of various actors: regulators, health technology assessors, national health (insurance) entities, research scientists, healthcare professionals, industry, patients’ representatives, and patients themselves.
- 34 We have divided the regulatory life cycle into ten phases: research and innovation; clinical trials; marketing authorization (also known as ‘licensing’); manufacturing and testing; packaging and labelling; selling arrangements (including prescriptions, direct to consumer sales, online sales, advertising); falsified medicines; pricing and reimbursement of patients by national health systems; availability in a national health system; post-market oversight. Each stage is associated with at least some EU law, and covered in more detail in other Encyclopaedia entries. Each stage also involves national competence, and therefore national law. Note that the regulatory life cycle is a model, used for analytical purposes. In real-time or real-life examples, depending on the circumstances, the phases overlap or do not necessarily occur in this order.

#### **1. Research and innovation**

- 35 EU law does not attempt to systematically harmonize rules for medical research activities in general. It is an area of → shared legislative competence, where both competences are exercised in parallel (M Blanquet, *Fascicule 170: Compétence de l’Union - Architecture générale* JurisClasseur Europe Traité January 2012, para. 81), rather than the exercise of EU competence displacing national competence. Much regulation of bench research and innovative science thus remains determined at national level within each EU Member State.
- 36 But EU law does work to incentivise, through funding and support for collaborative research in biomedicine, including research and development activities which eventually result in new medicines. Prominent funding schemes through which the EU operates in this regard include Horizon Europe (Regulation 2021/695/EU); EU4health (Regulation 2021/522/EU); and the European Reference Groups for research into rare diseases (Patients’ Rights Directive and Commission Delegated Decision 2014/286/EU). Other important examples of EU funding for medicines research include the European Research Infrastructure Consortia in the area of biomedicine broadly defined (Art. 6(3) Regulation 723/2009/EC; Commission Implementing Decision 2013/701/EU; Commission Implementing Decision 2019/1854/EU; and

Commission Implementing Decision 2022/1204/EU). These EU-supported research consortia bring together the main players from the relevant field (biobanking, bioimaging, microbial research)—researchers, biobanks, industry, and patients—to boost research in the field at EU level. There are also European Research Infrastructure Consortia on Clinical Research (Commission Implementing Decision 2013/713/EU) and Advanced Translational Research in Medicine (Commission Implementing Decision 2013/640/EU).

## **2. Clinical trials**

37 Aspects of clinical research falling within the scope of the EU's Clinical Trials Regulation are harmonized at EU level. Clinical trials taking place in the EU (Art. 1 Clinical Trials Regulation) must be authorized (Arts 4–11 Clinical Trials Regulation), modified (Arts 14–24 Clinical Trials Regulation), and withdrawn (Art. 13 Clinical Trials Regulation) in accordance with the requirements of the Regulation, including both scientific and ethical review. Trials are only permitted in the EU if they meet the requirements specified in the Regulation, including that the risks of the trial must be proportionate to the benefits to society; medical care provided to patients/research subjects must be the responsibility of a qualified medical professional (Art. 28 Clinical Trials Regulation); patients/research subjects must give informed consent (→ *Consent in Clinical Trials*); and → clinical trial transparency requirements are followed. Each clinical trial must have at least one formal trial sponsor, established in the EU, with formal legal obligations (→ *Clinical Trial Sponsor Obligations*) under the Regulation.

## **3. Marketing authorization**

38 Medicines sold in the EU, whether made there or imported, must have a marketing authorization. That authorization could be from a national competent authority (→ *Decentralised Marketing Authorization*), or from the European Commission after assessment by the European Medicines Agency. Separate rules apply to → marketing authorizations for generics and biosimilars; → herbal medicines; and → homeopathic medicines. Under the Proposed new Medicines Regulation (Annex I), as currently, a centralized marketing authorization would be required for certain biotechnological medicines; → advanced therapy medicinal products; products containing an unauthorized active substance; → orphan medicines. The Proposed new Medicines Regulation would extend the requirement to → paediatric medicines; and priority → antimicrobials. Decentralized/national marketing authorizations must be mutually recognized (→ *mutual recognition*). Specific rules also apply to → marketing authorizations for generics and biosimilars; → herbal medicines; and → homeopathic medicines.

## **4. Manufacturing standards, batch testing**

39 For access to the EU market—rules apply to imports and medicines produced in the EU—medicines must have a manufacturing or import authorization, showing compliance with good manufacturing practice standards, and rules on batch testing set at EU-level. EU rules cover good manufacturing practice of both authorized medicines (Commission Directive 2017/1572/EU) and investigational medicines (Commission Delegated Regulation 2017/1569/EU). New therapeutic approaches have enabled decentralized manufacturing or testing steps, especially for short shelf lives or highly personalized medicines. The Proposed new Medicines Directive would establish a risk-based and flexible approach for the manufacture or testing of a wide range of medicinal products in close proximity to the patient.

## **5. Packaging and labelling**

40 For access to the EU market—rules apply to imports and medicines produced in the EU—medicines must comply with rules on → packaging and labelling of medicines, set at EU level.

41 Medicines, being considered as including both a product and its related information, must comply with rules on packaging and labelling in order to promote the accessibility, intelligibility, and transparency of information with regard to the risks associated with the medicines for their correct use. The applicable requirements are part of the marketing authorization application file, thus assessed by the competent authorities during the evaluation process for marketing authorization. The current proposals for revision of the pharmaceutical legislation take into account digital progress as regards as packaging and labelling of medicines (eg, Recital 128 Proposed new Medicines Directive), especially for the package leaflet (Recital 129 and Article 63(3) Proposed new Medicines Directive).

## **6. Selling arrangements (including prescriptions, direct to consumer sales, online sales, advertising)**

42 Some → rules relating to selling arrangements for medicines are covered by EU law; others remain at a national level. EU law covers the distribution of medicines. Whether a medicine is prescription-only; may only be sold by a qualified pharmacist; or is available freely ‘over the counter’ in supermarkets and other retail venues or indeed via distance sales using the internet, is a matter of national law, although subject to EU law on ‘e-commerce’ (Directive 2000/31/EC). That said, some such national rules may breach EU law on → free movement of goods. Advertising of medicines is regulated by EU law when directed both to the general public and to persons qualified to prescribe or supply medicines. While EU law prohibits any advertising of medicine in respect of which a marketing authorization has not been granted (Art. 87.1 Community Code), it also prohibits → direct to consumer advertising of certain medicines (those available on prescription only or containing psychotropic or narcotic substances: Art. 88 Community Code). While the category of medicine on prescription only would be extended to antimicrobials, and to medicines containing a persistent, bioaccumulative, and toxic active substance as a risk minimization measure with regard to the environment (Article 51(1) Proposed new Medicines Directive), advertising is one of the

few areas that would not be affected by the current proposals for revision of the EU medicines legislation.

### **7. Falsified medicines**

- 43 For access to the EU market—rules apply to imports and medicines produced in the EU—medicines must comply with rules on → falsified medicines, set at EU level, in order to improve the security of the supply chain. Falsified medicines is another of the few areas that would not be affected by the current proposals for revision of the EU medicines legislation.

### **8. Medicines pricing and reimbursement**

- 44 In principle, the price at which a national health system will purchase a medicine, and thus keep public expenditure on medicines under control, is a matter of national law (and policy) within the EU. This is why there is a considerable body of EU case law on → parallel trade in medicines: the cost-containment measures adopted by Member States, which make sense from the point of view of health protection, are ‘measures having equivalent effect to quantitative restrictions’ from the point of view of EU free movement of goods law. In general, the CJEU gave a wide margin of discretion to measures protecting human health, but stricter scrutiny followed (Hervey and McHale, 2004, 320). However, the European Commission Decision of 2018 suggests a new approach is coming (Mulder): the Commission points out that parallel trade drives medicines shortages, especially in lower-income countries, and undermines access to medicines.
- 45 The EU’s only mandatory legislative intervention (→ *Transparency of Medicines Pricing and Reimbursement*) to date (Council Directive 89/105/EEC) requires only that Member States must publish information and time limits for examining applications on the price controls they operate, as well as on which medicines are included in the scope of national health (insurance) systems (the ‘basket of care’). Despite several attempts to undertake revisions of this Directive, especially from the European Parliament, these rules have remained unchanged for more than thirty years.
- 46 EU law on parallel imports intersects with health products and intellectual property in EU law and with EU competition law (→ *Monopolies in Health Institutions*). During the period of patent protection of a novel medicine, parallel imports are the only available mechanism of direct price competition. The Proposed new Medicines Regulation includes variable intellectual property incentives, such as market exclusivity for ten, nine, and five years, for novel medicines in areas of unmet needs, such as paediatric medicines, to try to ensure that the medicines industry supplies national health systems across the EU at a ‘fair’ or ‘good’ price.

### **9. Availability in national health systems**

- 47 In principle, reimbursement of medicines within a national health system is a matter of national law (and policy) within the EU. Both the Patients’ Rights Directive and the Health

Technology Assessment Regulation involve the coordination of national decisions on reimbursement, the latter going a step further in making obligatory joint clinical assessments of health technologies, although their outcome is not binding on Member States.

- 48 The Proposed new Medicines Regulation (Art. 116) would impose an obligation on marketing authorization holders to notify disruptions to supply, as well as to establish shortage prevention plans, as matters of EU law. These obligations are already imposed on suppliers as a matter of national law. A new system of collaboration between national authorities and the EMA is envisaged to manage shortages of supply in ‘critical medicinal products’— a new concept in EU law (Art. 127 and Art. 2(13) Proposed new Medicines Regulation). A ‘critical medicinal product’ would mean a ‘medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients’ (Art. 2(13) Proposed new Medicines Regulation). The products themselves are to be determined by national authorities, which thus retain control over the ‘basket of care’, including which medicines are available within their health systems. But the risk is to be identified using a methodology set by EU law (Art. 130 Proposed new Medicines Regulation), and using an EMA ‘Working Party’, established in the EU’s crisis preparedness legislation (Regulation 2022/123/EU).

#### **10. Post-market: surveillance, pharmacovigilance, urgent procedure for withdrawal, liability for harm**

- 49 For access to the EU market—rules apply to imports and medicines produced in the EU— medicines must comply with rules on post-marketing surveillance and pharmacovigilance, set at the EU-level. The EU-level rules involve the EMA’s Pharmacovigilance Risk Assessment Committee, the main safety committee and the only Committee that would be maintained, along with the Committee for Medicinal Products for Human Use (‘CHMP’) regarding human medicines, in accordance with the Proposed new Medicines Regulation.
- 50 Member States are entitled to withdraw → marketing authorizations under an urgent procedure set out in the Community Code (Art. 107i) ‘where urgent action is necessary to protect public health’. The EMA’s Pharmacovigilance Risk Assessment Committee must assess the relevant data and reach a recommendation within a prescribed period of time (Art. 107j Community Code). Where a centralized marketing authorisation is at issue, the EMA’s Committee for Medicinal Products for Human Use must issue an Opinion, which in turn forms the basis for a Commission Decision (Art. 107k Community Code).
- 51 EU law also covers → liability for harm, protecting those who use medicines under the general EU legislation on liability for defective products (Council Directive 85/374/EEC), which is undergoing revision (COM/2022/495 final). The obligations and liability of the marketing authorization holder would be strengthened in the Proposed new Medicines Directive (Chapter V).

#### **11. Flexibilities within the EU’s regulatory life cycle**

- 52 In addition to the standard or ordinary regulatory life cycle for medicines, the EU has promoted or is attempting to promote some deviations, designed to provide a more patient-focused regulatory approach, and one seeking to be more sympathetic to the development and launch of novel medicines in the EU, while using the same criteria of quality, safety, and efficacy. One is sometimes called the ‘expediting regulatory pathway’, or, according to the EMA ‘support for early access’. It excludes specific legislative schemes such as conditional marketing authorization or compassionate use of medicines. Among these, the ‘PRIority Medicines’ scheme, which was launched by the EMA in 2016 to provide an early and enhanced regulatory and scientific support for certain medicines having the potential to address significant unmet medical needs, based on early evidence, would be embedded at the legislative level (Art. 60 Proposed new Medicines Regulation).
- 53 Moreover, part of the Proposed new Medicines Regulation (Arts 2(12), 113–115), is the ‘regulatory sandbox’ (also known as a ‘living lab’ or ‘testbed’), which allows time-limited experimentation with novel technology in a real-world situation, under regulatory supervision, aimed to facilitate innovation. This regulatory framework would allow a new technology/product/service to be tested on a case-by-case basis, without incurring all the normal regulatory obligations, but without lowering standards of quality, safety, and efficacy. The concept was first developed in Fintech in the UK in 2016 (Leckenby and others) and since then has been extended to medicines regulation in several jurisdictions.

#### **D. Conclusions**

- 54 EU law on medicines—as in all jurisdictions—has to balance many different interests: patients, national health (insurance) systems, the pharmaceutical industry globally, domestic pharmaceutical companies in Member States, generic producers, and so on. The EU legislature has done so predominantly based on the idea of an EU internal market based on ‘European’ ideas of quality, safety, and efficacy of medicines, which tend to be associated with precaution (Hervey and McHale, 2015). Recent developments suggest a legislative move towards access to medicines on a more equitable basis across the EU. Consolidation and clarification of EU legislation is a constant preoccupation of what is a highly complex legislative landscape, where the interfaces between product-specific legislation and thematic legislation have to be carefully navigated. The latest proposed legislative reform, if adopted, would move towards greater general thematic legislation, while keeping advanced therapy medicinal products subject to a discrete Regulation.
- 55 In its legislative processes, as well as in the administration of medicines regulation through powers devolved to the European Commission, the EU legislature works within a shared competence model. This model is important, for where the balance of competences lies matters for industry behaviour, the interfaces with national health systems which are the primary purchasers of medicines across the EU, and, ultimately, in terms of outcomes for patients.
- 56 In terms of legislative *form*, over time we discern a movement towards greater use of Regulations as opposed to Directives. However, the sheer volume of EU legislation, especially tertiary legislation (Commission Directives), and also soft law in the form of

EMA/Commission Guidelines, suggests a significant and ever-increasing role for EU competence at a granular level in this field. Over time, non-mandatory Guidelines, or pilot regulatory tools, developed by the EMA and/or European Commission are later embedded into hard law. Such a model is standard in EU law for a regulatory area of significant technological complexity. Scientific and technical progress leads to the emergence of innovative and complex medicines. A one-size-fits-all regulatory model would struggle to respond to this complexity, especially when taking into account a desire to secure patient access to medicines, especially where there are unmet medical needs.

- 57 While some EU medicines legislation imposes *obligations*, much of it determines *options* for the multiple actors in this complex regulatory field. Although the Proposed new Medicines Regulation and Proposed new Medicines Directive would herald a new complementary direction for EU medicines law, they would do so while respecting the existing shared competences model.
- 58 The Proposed new Medicines Regulation ‘shall not affect the powers of Member States’ authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions. Member States may choose from the particulars shown in the marketing authorization those therapeutic indications and pack sizes that will be covered by their social security bodies’ (Article 1 Proposed new Medicines Regulation). The Proposed new Medicines Directive ‘shall not affect the powers of the Member States’ authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions’ (Article 1(9) Proposed new Medicines Directive). Changes to equitable access to medicines across the EU are thus expected to take place as an *indirect* consequence of the new Regulation and Directive, alongside other legislative forms, such as in IP, HTA, and transparency of pricing, not directly. While the ‘powers’ of the Member States will not be formally affected, the hope and intention is that the new focus of EU medicines regulation not only on safety and efficacy, but also on access and affordability, will lead to changes in national practice that are not mandated by law, but flow from the new regulatory environment.

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