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Newsletter

PHARMA & HEALTHCARE

No. 47

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Regulation (EU) 2025/2645 of the European Parliament and of the Council on compulsory licensing for crisis management

Regulation (EU) 2025/2645 of the European Parliament and of the Council of 16 December 2025 on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006 has been adopted and published in the *Official Journal of the European Union*[1]. It lays down rules on the conditions and the procedure for granting a *Union compulsory licence* for intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a crisis or emergency mode. In particular, this Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States: *a*) patents and published patent applications; *b*) utility models and published applications for utility models; and *c*) supplementary protection certificates.

The main feature of this Regulation is that, as compulsory licences are configured as Union licences, they will not be granted by national patent authorities, but by the European Commission, which may do so only in response to certain crisis or emergency situations.

The centralisation of compulsory licensing is intended to avoid the lack of uniformity that could arise if a particular patent (or other right falling within the scope of the Regulation) were subject to compulsory licensing in one Member State but not in another, or if the conditions of the licences in several States were divergent. The aim is to ensure that the Commission's decision is enforced in all Member States where a particular technology (necessary to deal with the crisis or emergency situation) is protected and that this is done under the same conditions; notwithstanding, the granting of the licence by the Commission must be preceded by the possibility for third parties to submit comments, as well as by an opinion from the advisory body competent under the Union crisis or emergency mechanism in question (or, in the absence of a competent advisory body, from an ad hoc advisory body set up by the Commission in which each Member State shall have the right to be represented).

[1] *Official Journal of the European Union* No. 2645, 30 December 2025. See this ***link***.

Furthermore, the limitation of the cases in which *Union compulsory licences* will apply means that national authorities will still be able to grant compulsory licences when these are not granted in response to any of the crises or emergencies referred to above.

Agreement between the Council and the European Parliament on the reform of EU pharmaceutical rules (the so-called *pharma package*)

On 11 December 2025, the Council and the European Parliament reached an agreement on the final shape of the *pharma package*, the name given to the regulatory proposals for reforming the EU's pharmaceutical legislation: on the one hand, the "Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006" [COM(2023) 193 final]; and, on the other hand, the "Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC" [COM(2023) 192 final].

Two points in the joint position of both institutions are particularly noteworthy at this stage: those relating to the Bolar clause and data protection:

a) With regard to the *Bolar clause*, the agreement consolidates the broadening of the scope of the clause by extending the exemption to patent rights — among other cases — to acts consisting of submitting a tender in public procurement procedures, in accordance with Union and national law, insofar as this does not involve the sale, offer for sale or marketing of the medicinal product in question during the period of protection conferred by the patent rights or the supplementary protection certificate. This is a debatable measure because extending the exemption to cover tenders in public procurement procedures may constitute an infringement of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"), contained in Annex 1C of the Marrakesh Agreement establishing the World Trade Organisation of 15 April 1994.

b) With regard to *data protection*, the Commission's proposal provided for the duration of protection to be reduced from the current eight years to six years from the date on which the marketing authorisation for the medicinal product was granted. This period of data protection would be followed by the period of market exclusivity or protection, which remained unchanged. However, despite this reduction in the duration of the data protection period, the Commission's proposal included a number of cases in which these six years could be extended for different periods of time.

However, following various amendments during the legislative procedure, the agreement between the Parliament and the Commission stipulates that companies introducing a new medicine onto the market will retain exclusivity over the information generated in the preclinical and clinical phases for eight years, preventing third parties from using this data during that period. An additional year of market protection is

also provided for after marketing authorisation.

It is also envisaged that companies in the pharmaceutical sector will be able to access additional extensions of market protection in various scenarios. In particular, they will be able to obtain an extra twelve months when the medicinal product provides a response to an unmet medical need. They may also receive a further twelve-month period if the medicinal product incorporates a novel active substance and meets certain requirements relating to the conduct of comparative clinical trials, studies carried out in different Member States and the obligation to apply for marketing authorisation within ninety days of the first application outside the European Union. Finally, a similar extension is permitted when the company obtains authorisation for one or more new therapeutic indications that provide a clinically relevant improvement over existing treatments.

However, the text sets a cap: all these extensions together may not exceed eleven years of regulatory protection. As a result, it specifies that innovative orphan medicinal products, intended for diseases with no available therapeutic alternatives, may enjoy up to eleven years of market exclusivity.

Proposed amendment of regulations on medical devices

On 16 December 2025, the European Commission presented the "Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I" [COM(2025) 1023 final][2].

The European Commission intends to reform the regulatory framework for medical devices and in vitro diagnostic medical devices in order to make it simpler, more proportionate and more predictable. Various measures are therefore planned to simplify administrative procedures and allow for more flexibility in the demonstration of clinical evidence, in addition to the removal of obligations considered disproportionate. The rules for classifying devices are also revised in some respects.

Proposal for a regulation establishing a framework of measures for strengthening the Union's biotechnology and biomanufacturing sectors

On 16 December 2025, the European Commission published its "Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)" [COM(2025) 1022 final][3].

[2] See this *link*.

[3] See this *link*.

This new Regulation aims to establish a framework to strengthen the competitiveness of the health biotechnology sector in the Union and create and reinforce favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

In particular, and as already stated in its first article, the Regulation lays down measures regarding:

a) the establishment of a framework for the recognition of, and support measures for, health biotechnology strategic projects and high impact health biotechnology strategic projects;

b) novel health biotechnology products and regulatory sandboxes to support innovation and take into account technological and scientific developments and progress;

c) the support to promoters of biotechnology projects, SMEs, start-ups and scale-ups and non-profit developers of biotechnology products, by establishing an EU Health Biotechnology Support Network;

d) the support for funding of, investments in, and access to capital for biotechnology companies and projects;

e) the enhancement of the manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;

f) the application in a facilitated manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;

g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures;

h) the prevention of the misuse of biotechnologies and the strengthening of biodefence capabilities, without prejudice to, and in complementarity with, activities financed under any defence related Union funding programmes and instruments.

Judgments, rulings and decisions

European Union

Online sale of medicinal products

1. As is well known, Article 85c of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, permits the sale at a distance of non-prescription medicinal products by means of information society services, provided that a number of conditions are met.

   On that basis, in Case C-604/24, *Farmakeio YZ*, the Court of Justice is asked whether national legislation may allow the sale at a distance of only certain medicinal products not subject to medical prescription, but not all of them, on grounds of public health protection (combating overmedication and the trafficking of counterfeit or inappropriate medicinal products, and so forth).

2. In Opinion delivered on 18 December 2025 (ECLI:EU:C:2025:1007), Advocate General Maciej Szpunar proposes that the Court of Justice declare that Article 85c(1) and (2) of Directive 2001/83/EC "must be interpreted as meaning that it precludes a national provision prohibiting electronic pharmacy establishments from selling to the public, by means of information society services, certain non-prescription medicinal products, on grounds of public health protection".

The Court of Justice interprets the legal concept of 'biocidal product'

In its judgment of 11 December 2025, in case C-473/24, *Speyer*, the Court of Justice has ruled that, for a product to fall within the concept of 'biocidal product', as defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May concerning the making available on the market and use of biocidal products (Article 3(1)(a)), that product does not necessarily have to be intended for use exclusively or primarily as a biocide, as such use may also be incidental to other intended uses.

The Court of Justice also states that "a biocidal product which is intended for cleaning and disinfecting foodstuffs does not fall within the scope of that regulation".

Marketing authorisation for generic medicines

In the Advocate General's Opinion in Case C-118/24, *Laboratoires Eurogenerics and Theramex France*, delivered on 25 October 2025

(ECLI:EU:C:2025:815), it is proposed that the Court of Justice declare that Articles 28 and 29 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, "must be interpreted as meaning that they do not preclude a court of a Member State, involved in a decentralised marketing authorisation procedure, without being the reference Member State, which has jurisdiction to hear an action brought against the decision granting a marketing authorisation adopted by the competent authority of that Member State, from verifying whether the medicinal product whose marketing was authorised can be considered a 'generic medicinal product' within the meaning of Article 10(2)(b) of Directive 2001/83".

Similarly, it is also proposed that Article 10(2)(b) of Directive 2001/83/EC "must be interpreted as meaning that it does not preclude a marketing authorisation from being granted for a chemical medicinal product, in accordance with the abridged procedure laid down in Article 10(1) of that directive, where the reference medicinal product is a biological medicinal product, provided that the conditions under which the former can be considered a generic of the latter laid down in Article 10(2)(b) of Directive 2001/83 are satisfied".

Medicinal products prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia

In the Opinion of Advocate General Maciej Szpunar in Case C-589/24, *Almirall*, delivered on 9 October 2025 (ECLI:EU:C:2025:776), it is proposed that the Court of Justice declare that Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Art. 3(2)), must be interpreted as "not precluding national legislation which exempts the officinal formula, that is to say, medicinal products prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question, from the requirement to obtain a marketing authorisation and a manufacturing authorisation, provided that the monthly number of patients served by that pharmacy does not exceed the limit determined using a numerical criterion".

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