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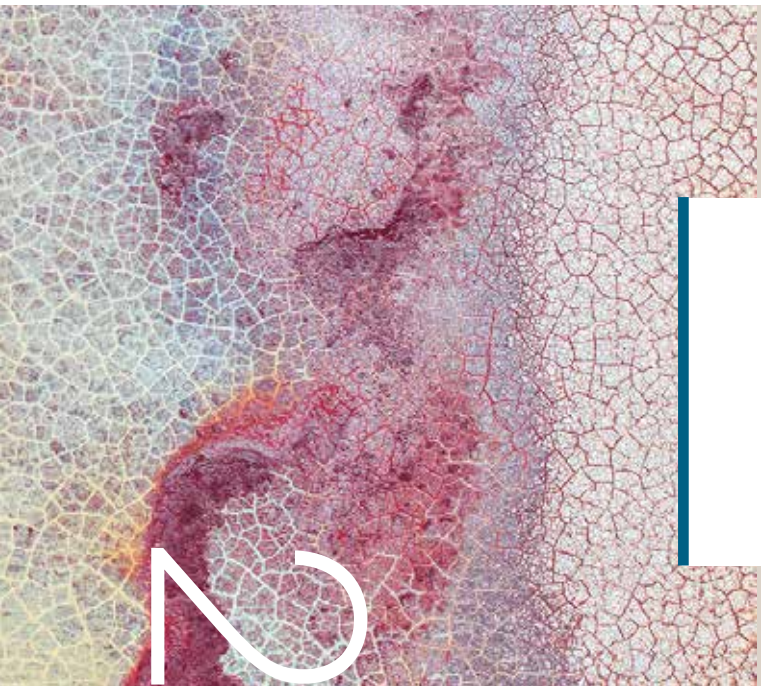

Newsletter

PHARMA & HEALTHCARE

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LEGISLATION AND LEGISLATIVE PROPOSALS

EUROPEAN UNION

Agreement on the pharmaceutical package

The Council and the European Parliament have reached an agreement on the pharmaceutical package and published the agreed texts in early March. The texts can be consulted on the Commission's website[1] and, although they are still awaiting formal endorsement by the Council and the Parliament, no further amendments are expected.

The pharmaceutical package is the name given to the texts reforming European pharmaceutical law, a reform process initiated by two Commission proposals: a) 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, — Document COM/2023/192 final, of 26 April 2023—; and b) 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, 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 — Document COM/2023/193 final, also of 26 April 2023.

Medical devices and harmonised standards

Regulation (EU) 2017/746 on in vitro diagnostic medical devices provides in Article 8(1) that "[d]evices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have

[1] See this *link*.

been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof."

On that basis, the following decisions have recently been adopted:

a) Commission Implementing Decision (EU) 2026/193 of 28 January 2026 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for neurosurgical implants, biological evaluation of medical devices, clinical investigation of medical devices for human subjects, non-active surgical implants, sterilization of health care products, biocompatibility evaluation of breathing gas pathways in healthcare applications and small-bore connectors for liquids and gases in healthcare applications[2].

b) And Commission Implementing Decision (EU) 2026/197 of 28 January 2026 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilization of health care products and information supplied by the manufacturer[3].

Procedures within the framework of the Health Security Committee

Commission Implementing Regulation (EU) 2026/220 of 29 January 2026 laying down the procedures necessary for the uniform implementation of the information exchange, consultation and coordination of response within the Health Security Committee and amending Implementing Decision (EU) 2017/253[4].

This new regulation forms part of the framework established by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health, a regulation that seeks to closely coordinate the response to serious cross-border threats to health within the framework of the Health Security Committee. It establishes the Early Warning and Response System as a tool for requesting consultation and coordination of the response to a serious cross-border health threat.

The purpose of the new implementing regulation is to standardise the way in which Member States share information and coordinate measures within the Health Security Committee to avoid fragmented responses.

[2] *Official Journal of the European Union* No 193, 30 January 2026; see this ***link***.

[3] *Official Journal of the European Union* No 197, 30 January 2026; see this ***link***.

[4] *Official Journal of the European Union* No 220, 30 January 2026; see this ***link***.

JUDGMENTS, RULINGS AND DECISIONS

EUROPEAN UNION

Supplementary protection certificate for medicinal products: marketing authorisation of a product as a medicinal product for human use and subsequent authorisation as a veterinary medicinal product

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, provides in Article 2 that any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in EU law may be the subject of a certificate.

The Court of Justice has ruled on the issue of authorisations for second or subsequent medical uses, which involves determining whether the *first authorisation* is that granted to the product containing the active ingredient for the first indication, or whether subsequent indications must be taken into account so that the concept refers to the first authorisation for a different indication. However, on this point, the case law of the Court in Luxembourg is inconsistent.

The current position is that set out in the judgment of 9 July 2020, *Santen* (C-673/18, ECLI:EU:C:2020:531), according to which "the fact that an active ingredient, or a combination of active ingredients, is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product where the same active ingredient, or the same combination of active ingredients, has been used for the purposes of a different, already known, therapeutic application" (para. 47).

In this way, the Court returns to the line taken in its earlier judgments in the *Pharmacia Italia*, *MIT* and *Yissum* cases[5] and corrects the position adopted in the judgment of 19 July 2012,

[5] *Pharmacia Italia* (C-31/03, EU:C:2004:641), *MIT* (C-431/04, EU:C:2006:291) and *Yissum* (C-202/05, EU:C:2007:214).

Neurim[6], in which the court held that the mere existence of a prior marketing authorisation obtained for the veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different use of the same product for which a marketing authorisation has been granted, provided that such use falls within the scope of protection conferred by the basic patent relied upon to support the application for a supplementary protection certificate.

However, the German Federal Patent Court *(Bundespatentgericht)* has just referred a matter to the Court of Justice for another preliminary ruling on this issue[7]. In particular, the question now put to the Court of Justice is as follows: "Is Article 3(d) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products to be interpreted as meaning that the marketing authorisation for a product as a veterinary medicinal product under Directive 2001/82/EC constitutes the first marketing authorisation for that product as a medicinal product, even if a marketing authorisation for the same active substance as a medicinal product for human use had previously been granted under Directive 2001/83/EC?"

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

The Court of Justice — in its Judgment of 19 March 2026, C-589/24, ECLI:EU:C:2026:217 — has ruled 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, as amended by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, must be interpreted as meaning that "legislation which provides that the preparation of medicinal products 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 is subject to a national authorisation requirement in cases where that preparation does not satisfy the condition that the medicinal products concerned must be intended for retail supply or supply in small quantities, that condition being expressed, in practice, in the form of a specific numerical criterion, does not come within the scope of that directive".

[6] Judgment of 19 July 2012, *Neurim* (C-130/11, EU:C:2012:489).

[7] See this ***link***.

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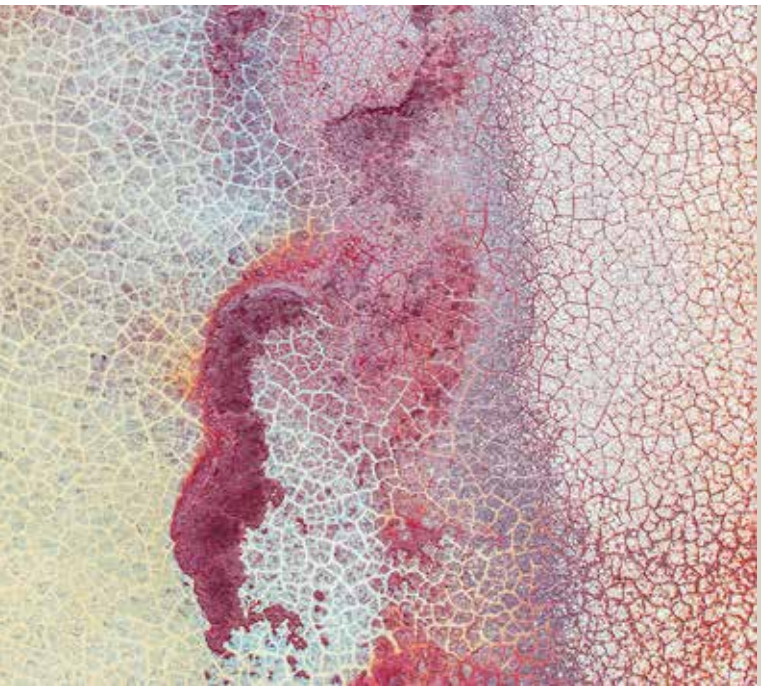

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