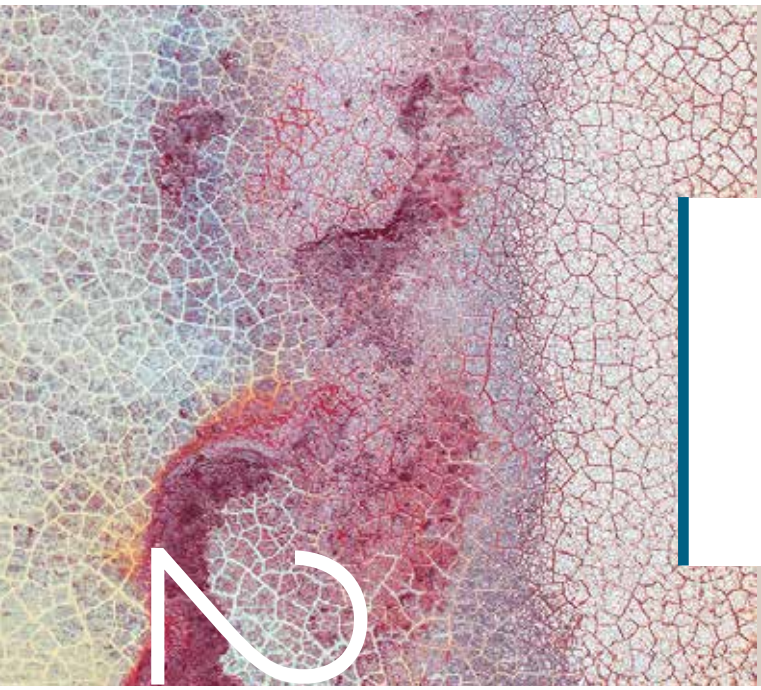
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Newsletter

# *PHARMA & HEALTHCARE*

2026

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# *LEGISLATION AND LEGISLATIVE PROPOSALS*

## EUROPEAN UNION

### The Council of the European Union takes another step toward the adoption of the European pharmaceutical reform

On 16 October 2026, the *Official Journal of the European Union*, Series C, published the positions adopted at first reading on 28 September of the same year by the Council regarding the pieces of legislation that make up the so-called *pharmaceutical package*. They are as follows:

*a*) Position (EU) No. 11/2026 of the Council at first reading with a view to the adoption of a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC[1]; the statement of the Council's reasons is also attached[2];

*b*) Position (EU) No 12/2026 of the Council at first reading with a view to the adoption of 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 Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006[3]; it is also accompanied by the statement of the Council's reasons[4].

[1] See this ***link.***

[2] See this ***link***.

[3] See this ***link***.

[4] See this ***link***.

The European Parliament's second reading is now pending. However, no major changes are expected, given that the texts included in the Council's positions are the result of prior negotiations between the Council and Parliament, as set out in Council of the European Union document ST 6367/26, dated 24 February 2026.

## The new *Critical Medicines Act* is in the final stages of the legislative process

As with the "*pharmaceutical package*" just mentioned, the legislative process for the Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 — a proposal more commonly known as the *Critical Medicines Act*.

This proposal, which aims to increase the availability and security of supply of critical medicines (particularly antibiotics, insulin, and pain relievers) in the European Union, was the subject of a political agreement between the Council and the Parliament and has already been approved by the Council, Coreper (Committee of Permanent Representatives), and the Parliament's Committee on Public Health (SANT).

The legislation must still pass a final vote in the European Parliament's plenary session, be formally adopted by the Council of the European Union, and be signed by both institutions before it is definitively published in the *Official Journal of the European Union* and it enters into force.



# *JUDGMENTS, RULINGS AND DECISIONS*

## EUROPEAN UNION

### Mandatory information that must accompany health claims made on foods

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, provides in Article 10(2) that health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

*a*) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;

*b*) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

*c*) where appropriate, a statement addressed to persons who should avoid using the food; and

*d*) an appropriate warning for products that are likely to present a health risk if consumed to excess.

The Court of Justice, in its judgment of 17 September 2026, *Kyberg Pharma*, C-657/24, held that there is no exact correspondence between the concepts of 'labelling' and 'advertising', stating that Regulation No 1924/2006 "operates a systematic distinction between those two concepts, and the first concept cannot be considered to encompass the second". Consequently, when the Regulation requires that certain information — such as that listed in Article 10(2) — appear on the label, that requirement is not met if the information is reproduced in a separate written advertising message.

Furthermore, the aforementioned Article 10(2) clearly states that this information must appear on product labelling, provided that such labelling exists, and only in the absence of labelling will it appear on the product packaging "and" in advertising. Consequently, where labelling exists, it is not necessary to reproduce the information in the product's advertising. This follows from the literal wording of the provision and has been confirmed by the Court of Justice in *Kyberg Pharma*, holding that "Article

10(2) of Regulation No 1924/2006 must be interpreted as meaning that the mandatory information listed in that provision does not have to be included in written advertising to promote a food supplement if that information is included in the labelling of that supplement". Therefore, the mandatory information listed in Article 10(2) of the Regulation must appear in advertising and on the packaging ('presentation') only when the product is not labelled.

## Statements relating to the frequency of intake and/or the route of administration of a food may constitute health claims

In Case C-721/24, *Vista-Life Pharma and Vista-Life Pharma Belgium*, before the Court of Justice, the issue arises as to whether statements relating to the frequency of intake and/or the route of administration of a food supplement may be construed as falling within the concept of *health claims* established by Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. According to Article 2(2)(5) of the Regulation, a health claim is "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

The question arises in connection with a dispute in Belgium concerning the use, in the advertising of a food supplement, of the phrase "daily better than single dose" in reference to the frequency of intake, accompanied by the statements "stable plasma levels", "more rapid absorption" and "avoiding the first-pass effect in the liver", as well as the claim "the best possible absorption for all patients" regarding the product's sublingual route of administration.

In Case C-721/24 (ECLI:EU:C:2026:775), the Court of Justice held that such statements regarding the frequency of intake and/or the route of administration may constitute a health claim when they are presented as having health benefits. In its view, the reference to the 'particular characteristics' of a food should not be construed as being limited to the intrinsic properties of that food, such as its composition or content. Rather, it "also covers the way in which that food is intended to be consumed, where this is presented as being relevant to the characteristics attributed to that food". Consequently, "statements relating to the frequency of intake of a food supplement, such as 'daily better than single dose', or to the method of its administration, such as 'sublingual', are capable of attributing particular characteristics, within the meaning of Article 2(2)(1) of Regulation No 1924/2006, to that food supplement"; and may therefore constitute "claims".

And, on that basis, these statements "can, where presented as being relevant to the attainment of a beneficial effect on health or to the absence or reduction of an effect that is adverse to health that might result from a different frequency of intake or another method of administration, fall within the concept of 'health claim' within the meaning of Article 2(2)(5) of Regulation No 1924/2006". However, if these statements are limited to "providing consumers with purely practical information on how the product in question is to be consumed, without any explicit or implicit reference to an effect on health", they are not covered by the concept of health claim.

Therefore, each specific case must be examined to assess what an average consumer might understand, bearing in mind that what matters is not merely that the manner of consumption of the food is referred to, but rather that such reference is presented in connection with health.

For this reason — and as Advocate General Andrea Biondi stated in his opinion presented on 29 January 2026 (ECLI:EU:C:2026:56) — "instructions for use, with no persuasive health-related content (for example, 'take with water', 'one tablet per day'), [...] when not accompanied by any explicit or implicit reference to benefits or risks", will not be considered health claims. However, "statements relating to the method of administration and the frequency of consumption are included within the definition of 'health claim' where, by virtue of their wording, graphic presentation, accompanying indications or images, they attribute to those methods a role in the attainment of a beneficial health effect (for example, 'stable plasma levels', 'better absorption' and 'avoids the first-pass effect in the liver')".

# INTERNATIONAL

## Adapting the description to the amended claims of a European patent: Decision G 1/25 of the Enlarged Board of Appeal puts an end to the debate

The European Patent Convention (EPC) expressly provides for the possibility of amending the claims of a European patent application or a patent already granted, and permits this in administrative proceedings —such as opposition, appeal, or limitation proceedings — as well as in court proceedings.

Changes made to the wording of the claims can take various forms (deleting or adding words to a claim, deleting one or more claims, or combining several claims into a single one), but a series of general requirements must always be met, regardless of the procedure in which the patent amendment is sought: the subject matter of the amended claim may not extend beyond the content of the application as filed, nor may the scope of protection conferred by the patent be extended (Art. 123 EPC).

Furthermore, amended claims must also meet the general requirement applicable to all claims to be clear and concise, as well as being supported by the description (Art. 84 EPC). And, regarding this requirement, in recent years there has been a debate among the various Boards of Appeal of the European Patent Office (EPO) over whether amendments to the claims also require changes to the description of the invention to bring it into line with the new, amended text of the claims.

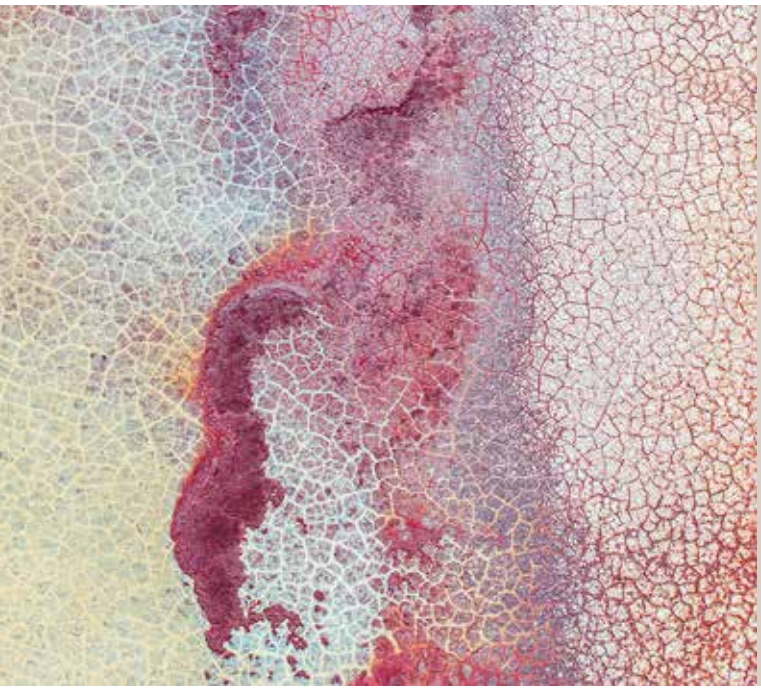
In its Decision of 3 September 2026, G 1/25[5], the Enlarged Board of Appeal of the European Patent Office (EPO) resolves the existing controversy over whether an amendment to the claims always requires an adaptation of the patent description. The decision rejects a requirement for purely formal concordance and limits this obligation to cases where the inconsistency leads to non-compliance with one or more requirements of the EPC.

Thus, Article 84 does not require absolute formal concordance between the description and the claims, nor does it require the removal of all matter not reflected in the claims; however, it does require the correction of any contra-

[5] ECLI:EP:BA:2026:G000125.20260903.

dictions that raise doubts as to which embodiments or technical teachings are covered by the claim. Furthermore, the description must be amended when it contains statements that suggest an understanding of the claims incompatible with the assessment of patentability made during examination, for example, with regard to an invention. This requirement takes on particular significance in light of the precedent-setting decision G 1/24, which confirms that the description and drawings must always be consulted when interpreting the claims. Furthermore, although less frequently, inconsistencies may also raise issues regarding the sufficiency of the description (Art. 83), divisional applications (Art. 76(1)), or the prohibition on adding matter or extending the scope of protection (Art. 123 EPC).

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