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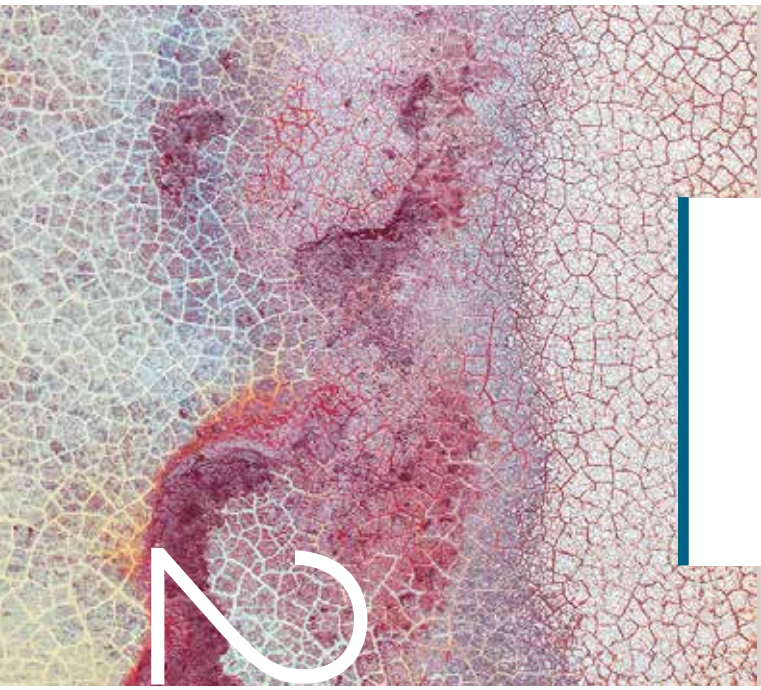

Newsletter

PHARMA & HEALTHCARE

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Ángel García Vidal

Professor of Corporate & Commercial Law, University of Santiago de Compostela
'Academic Counsel', Gómez-Acebo & Pombo

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Implantable devices exempted from the obligation to perform clinical investigations or an assessment of the technical documentation for every device during the conformity assessment procedure

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, the European Commission may amend the list of implantable devices and class III devices that are exempted from the obligation to perform clinical investigations. On this basis, Commission Delegated Regulation (EU) 2026/1451 of 20 March 2026 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of implantable devices and class III devices exempted from the obligation to perform clinical investigations, has been adopted[1].

Similarly, Regulation (EU) 2017/745 also allows the Commission to amend the list of types of class IIb implantable devices that are exempted from the obligation to perform an assessment of the technical documentation for every device during the conformity assessment procedure. This explains the recent adoption of Commission Delegated Regulation (EU) 2026/1359 of 20 March 2026 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of class IIb implantable devices exempted from the obligation to perform an assessment of the technical documentation for every device[2].

EFPIA practical guide on the importance of effective communication materials in the pharmaceutical industry

[1] *Official Journal of the European Union* No 1451, 29 June 2026; see this ***link***.

[2] *Official Journal of the European Union* No 1359, 29 June 2026; see this ***link***.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has published a practical guide to enhance patients' understanding of the information provided by the pharmaceutical industry ('Enhancing understanding: the importance of effective communication materials in the pharmaceutical industry. A practical guide'[3]). With this in mind, the guide outlines core principles of health literacy, such as accuracy, accessibility, inclusivity and actionability of medical information, and introduces the concept of plain language as a key tool for achieving clear and comprehensible patient communication.

The document also sets out the general principles of patient-centred communication, highlighting the importance of clear wording, the appropriate structure and format of written documents, the correct use of numbers and visuals, as well as the importance of accessibility and consistency of information.

[3] See this *link*.

JUDGMENTS, RULINGS AND DECISIONS

EUROPEAN UNION

The concept of *medical device* in patient identification systems

In its judgment of 2 July 2026, Case C-427/24, the Court of Justice ruled that Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Article 2(1) and (12)) must be interpreted as meaning that "patient identification wristbands manufactured from a thermoplastic resin and intended to be worn by patients in the healthcare sector, which, although they can be printed individually with letters, digits and/or a barcode in order to identify the patient concerned and to save other data relating to him or her, have been supplied completely blank, cannot be classified as 'medical devices'".

Labelling of medicinal products imported in parallel

In his Opinion delivered on 11 June 2026 in Case C-354/25, Advocate General Szpunar proposes that the Court of Justice rule 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, must be interpreted "as meaning that the labelling requirements contained in those provisions apply to a medicinal product for which a marketing authorisation has been issued in a Member State and the importation of which into another Member State constitutes a parallel import in relation to a medicinal product already covered by a marketing authorisation in that second Member State".

It also proposes that it be declared that Articles 34 and 36 of the Treaty on the Functioning of the European Union "must be interpreted as precluding the application of national legislation which requires the labelling of the immediate packaging of a medicinal product for human use imported by means of parallel trade to include certain information in the language of the Member State of importation, where relabelling would substantially affect the stability of that medicinal product".

Obligation to act with due care incumbent on the distributor of medical devices

The Judgment of the Court of Justice of 4 June 2026, *Dürr Dental*, C-10/24 (ECLI:EU:C:2026::443), examines the duty of care of distributors of medical devices as laid down in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Regulation (EU) 2017/745 imposes a duty of care on distributors of medical devices, requiring them to verify formal requirements such as the CE marking and the accompanying documentation before making the devices available on the market. The Court of Justice interprets this obligation, stating that it does not entail a technical verification of the device's conformity or classification, although the distributor must act if there are indications of non-compliance, by assessing the available information and, where appropriate, refraining from placing the product on the market.

In the words of the Court of Justice, "as part of its obligation to act with due care, a distributor must verify, in the light of the information at its disposal, whether the CE marking and the EU declaration of conformity for the product that it makes available on the market clearly concern a device falling within the scope of that regulation".

Furthermore, "a distributor is not obliged to verify whether the device it makes available on the market must be classified in risk class IIa, within the meaning of that regulation. However, if the information available to that distributor indicates that that device is classified by the manufacturer in a risk class necessarily entailing the involvement of a notified body, the distributor's obligation to act with due care includes verification that the four-digit identification number of that body is indicated".

Finally, "a distributor may have reason to believe that a product is not in conformity with Regulation 2017/745 where a letter of formal notice has been sent to it by a competitor concerning the non-compliance of that product. If the manufacturer, when questioned by the distributor, is of the opinion that the alleged non-compliance is unfounded, the distributor cannot be held to have breached its obligations under that provision by following the opinion issued by the manufacturer, unless that opinion appears to the distributor to be manifestly unfounded. Where the distributor has informed the competent national authority pursuant to that provision, the doubts thus expressed as to the conformity of the product concerned are dispelled without reservation by the reasoned and clear opinion of that authority refuting the alleged non-compliance".

Likelihood of confusion between pharmaceutical trade marks: the level of attention paid by health professionals and consumers is high

In its judgment of 1 July 2026, T-591/24, the General Court reaffirms European case law according to which, when assessing the existence of a likelihood of confusion in relation to pharmaceutical trade marks, it must be assumed that the level of attention paid by health professionals and consumers is high. According to the General Court, where medicines can be purchased without a prescription, the level of attention of consumers is relatively high, since these are products that affect their

health. This circumstance makes it less likely that they will confuse different versions of such products Furthermore, even assuming that a medical prescription is mandatory, consumers are likely to have a high level of attention when the goods at issue are prescribed, in the light of the fact that those goods are pharmaceutical products. Thus medicines, whether or not issued on prescription, can be regarded as receiving a heightened level of attention on the part of consumers who are reasonably well informed and reasonably observant and circumspect.

The General Court extends this case law to trade marks for tinctures, medicinal herbs, herbal medicine and decoctions of medicinal herb, which strictly speaking are not medicines, but nevertheless constitute goods in the field of health, since in general they are intended to improve health. It can therefore be understood that consumers also pay a high degree of attention to these products.

Furthermore, in the judgment under review, the General Court rejects the appellant's argument that both consumers and health professionals may, in certain circumstances, pay less attention and confuse medicines with similar trade marks. According to the General Court, in the assessment of the likelihood of confusion, account should be taken of the average behaviour of a reasonably well informed, observant and circumspect consumer; it is therefore not appropriate to take into account each of the circumstances of the specific case.

Partial prohibitions of the sale at a distance of non-prescription medicinal products do not comply with European Union law

In its judgment of 21 May 2026, *Farmakeio YZ*, C-604/24, the Court of Justice interprets Article 85c of Directive 2001/83/EC on the sale at a distance of medicinal products and examines whether a Member State may prohibit the marketing of certain types of non-prescription medicinal products in this manner.

According to the Court of Justice, Article 85c(1) and (2) of Directive 2001/83/EC must be interpreted as "precluding national legislation that, on grounds of public health protection, prohibits the sale at a distance to the public, by online pharmacy establishments using information society services, of non-prescription medicinal products, with the exception of a subcategory thereof".

The Court of Justice bases its reasoning, first and foremost, on the literal wording of Article 85c(1), emphasising that it provides that "Member States are required to ensure that 'medicinal products' are offered for sale at a distance to the public by means of information society services. The general nature of that wording and the use of the definite article in certain linguistic versions, such as the Spanish-, Greek-, French-, Italian- and Portuguese-language versions, indicates that the obligation thereby imposed on Member States covers all medicinal products. That second part of the provision offers no reason to believe that the intention of the EU legislature was to distinguish between possible categories of medical products".

The exclusion of surgical methods from patentability

The Convention on the Grant of European Patents ('EPC'), in its current version following the Act revising the EPC of 29 November

2000, prohibits the grant of European patents for "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods" (Article 53(c)).

Decision T 0941/24 of the European Patent Office clarifies the scope of this exclusion of surgical methods from patentability. According to this decision, a claim is not excluded merely because the method may be used in surgery, but only where it comprises, expressly or implicitly, a step constituting a surgical treatment of the human or animal body.

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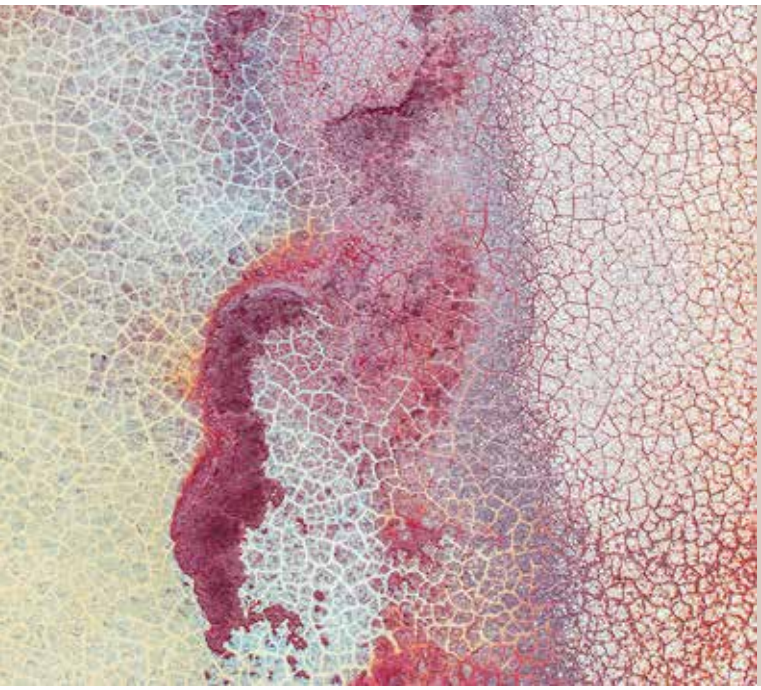

If you have any questions regarding the contents of this document, please contact any one of the following GA_P lawyers:

Irene Fernández Puyol
Tel.: (+34) 91 582 91 00
ifernandez@ga-p.com

Estibaliz Aranburu Uribarri
Tel.: (+34) 91 582 91 00
earanburu@ga-p.com

Rais Amils Arnal
Tel.: (+34) 93 415 74 00
ramils@ga-p.com

Eduardo Gómez de la Cruz
Tel.: (+34) 91 582 91 00
e.gomez@ga-p.com