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Newsletter

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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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Changes to the regulation on the performance of pharmacovigilance activities

Commission Implementing Regulation (EU) 2025/1466 of 22 July[1] has amended Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.

The changes introduced include the simplification of the pharmacovigilance system master file because, as highlighted in the recitals, "[t]o avoid unnecessary administrative burden for applicants and competent authorities, only significant deviations from the pharmacovigilance procedures, their impact and their management should be documented in the pharmacovigilance system master file until resolved".

Similarly, pharmacovigilance tasks may be outsourced (for instance, to specialised service providers), clearly documenting the delegation arrangements, each party's responsibilities, and audit and inspection arrangements. In addition, third parties must agree to be audited by or on behalf of marketing authorisation holders and to be inspected by the competent authorities to ensure and verify compliance with all aspects of the pharmacovigilance system.

Electronic instructions for use of medical devices

Commission Implementing Regulation (EU) 2021/2226 of 14 December laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices, sets out the conditions under which information in the instructions for use may be provided by manufacturers in electronic form. However, the scope of Implementing Regulation (EU) 2021/2226 is limited to certain medical devices and their accessories.

In order to meet the preference among healthcare professionals for receiving instructions for use in electronic form, Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for

[1] Official Journal L, 2025/1466, of 23 July 2025. See this *link*.

which the instructions for use may be provided in electronic form[2] has been adopted, thereby extending the scope of Implementing Regulation (EU) No 2021/2226 to all medical devices and their accessories covered by Regulation (EU) 2017/745 that are intended for professional users, as well as to devices without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745, provided that they are intended for professional use.

Restriction of access of economic operators and medical devices originating in the People's Republic of China to the EU public procurement market for medical devices

Commission Implementing Regulation (EU) 2025/1197 of 19 June 2025 imposing an International Procurement Instrument measure restricting the access of economic operators and medical devices originating in the People's Republic of China to the European Union public procurement market for medical devices pursuant to Regulation (EU) 2022/1031 of the European Parliament and of the Council[3] has been published.

This regulation is the European response to measures and practices by the People's Republic of China that have seriously and repeatedly impeded access by Union economic operators, goods and services to the Chinese public procurement market for medical devices.

EU SoHO Platform to exchange information concerning substances of human origin intended for human application

Commission Implementing Regulation (EU) 2025/1467 of 18 July 2025 laying down rules for the application of Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards the technical specifications for the EU SoHO Platform to exchange information concerning substances of human origin intended for human application[4] has been adopted and published. Of note is the regulation of the processing of sensitive personal data, including data concerning health, with strict security measures, including pseudonymised donor identification in the case of rapid alerts and clinical-outcome monitoring with pseudonymised clinical data.

Strategy for European life sciences

The European Commission has published a communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entitled 'Choose Europe for life sciences. A strategy to position the EU as the world's most attractive place for life sciences by 2030' [COM(2025) 525 final, 2 July 2025][5].

The Commission's strategy proposes, among other things, to reinforce European R&I in this

[2] Official Journal L, 2025/1234, of 26 June 2025. See this *link*.

[3] Official Journal L, 2025/1197, of 20 June 2025. See this *link*.

[4] Official Journal L, 2025/1467, of 21 July 2025. See this *link*.

[5] See this *link*.

field, promote a holistic approach to life sciences, unlock the power of data and artificial intelligence for breakthrough innovation, strengthen skills and careers for competitive European life sciences, and promote innovation-responsive regulation. In relation to the latter issue, it highlights the objective of adopting, by 2026 at the latest, an EU Biotech Act, as well as regulatory simplification for medical devices and in vitro diagnostics.

New guidelines from the Medical Device Coordination Group

The Medical Device Coordination Group has published several guidelines of interest:

a) Revision No. 1 of the document 'Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746'[6], which, among other changes, takes into account the recent approval of the European Health Data Space.

b) The document 'Guidance on the safe making available of medical device software (MDSW) apps on online platforms'[7]. This guidance aims to describe the obligations of app platform providers and their respective responsibilities under Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as well as under the Digital Services Act (DSA), which introduces requirements for online intermediary service providers.

c) The document 'FAQ on Interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act'[8].

[6] 'Update MDCG 2019-11 Rev.1 - Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (June 2025)'. See this ***link***.

[7] MDCG 2025-4 — 'Guidance on the safe making available of medical device software (MDSW) apps on online platforms (June 2025)'. See this ***link***.

[8] MDCG 2025-6 — 'FAQ on Interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act (June 2025)'. See this ***link***.

Absolute prohibition on pharmacy advertising is contrary to EU law

European Union

The prohibition on pharmacy advertising is contrary to EU law

In its judgment of 19 June 2025, European Commission v Republic of Poland, C-200/24, ECLI:EU:C:2025:459, the Court of Justice of the European Union (CJEU) examines whether the introduction by national legislation of an absolute prohibition on pharmacy advertising is contrary to EU law[9].

The question was referred to the court in connection with the provision contained in the Polish Pharmaceutical Act, which provides (Article 94(a)(1)) that "[a]dvertising for pharmacies and pharmaceutical outlets and the activities thereof shall be prohibited", although it adds that "[i]nformation relating to the location and opening hours of pharmacies or pharmaceutical outlets shall not constitute advertising". Specifically, the court is asked to determine whether such a prohibition complies with the Directive on electronic commerce (Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market), as well as with Articles 49 and 56 of the Treaty on the Functioning of the European Union on the freedom of establishment and the freedom to provide services, respectively.

According to the court, the absolute prohibition on advertising by pharmacies is contrary to the general principle of allowing commercial communications by a regulated profession, as well as to the principles of freedom of establishment and freedom to provide services. In this regard, the court rejects Poland's claims that there are public health reasons justifying such restrictions, since pharmacy customers are a category of consumers particularly susceptible to advertising, who should be protected against techniques intended to incite them to make more purchases (including non-prescription medicinal products and food supplements). In the court's view, pharmacy advertising "may benefit individuals who are likely to purchase

[9] Further details in the *GA_P Analysis*: Ángel GARCÍA VIDAL, 'Absolute prohibitions on pharmacy advertising are contrary to EU law', See this ***link***.

medicinal products, inasmuch as it allows them to be informed of lower prices or additional services offered by a specific pharmacy. Thus, further to such advertising, those individuals may decide to purchase their usual medicinal products from a pharmacy other than that where they were customers before, without that giving rise to an increase in the quantities of medicinal products purchased by those individuals". By contrast, the prohibition on such advertising "runs the risk of favouring pharmacies that have been present on the market for many years, to the detriment of those wishing to enter that market and offer more or better quality services".

The CJEU rules on health claims 'pending'

The CJEU, in its judgment of 30 April 2025 (*Novel Nutriology* case, C-386/23, ECLI:EU:C:2025:304), addresses the legal regime for health claims pending completion of evaluation, pursuant to 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. In particular, the national court asks the CJEU whether, pending completion of the evaluation by the European Food Safety Authority and the examination by the Commission of the inclusion of the claims notified in respect of "[botanical substances]" in the Community lists referred in Articles 13 and 14 of Regulation No 1924/2006, a product may be promoted with those claims or with a general claim (referring to general benefits for overall good health).

The CJEU confirms that the pending claims may continue to be used in accordance with the transitional measures provided for in the Regulation, stating that the Regulation "must be interpreted as precluding a food business operator from using health claims relating to botanical substances until the Commission has completed its examination of those claims for the purposes of their inclusion in the lists of authorised health claims, unless such use is permitted under the transitional measures laid down in that regulation".

In this specific case, as these are health claims describing or referring to psychological or behavioural functions, they fall within the scope of Article 28(6) of Regulation No 1924/2006, provided that they were used in accordance with the national provisions applicable before the date of entry into force of that regulation. Furthermore, where such claims have not been the subject of an evaluation and authorisation in a Member State, they may continue to be used, provided that an application has been submitted in accordance with that regulation before 19 January 2008. This is not the case here, as one of the two claims at issue in the main proceedings was the subject of a late application, whereas, for the other claim, no application was submitted.

Furthermore, the CJEU recognises that, where the pending claims fulfil the conditions of the transitional regime applicable to them, not only may the specific claim pending evaluation be used, but it may also be accompanied by a general claim referring to general and non-specific benefits of the nutrient or food for overall good health or health-related well-being. This means that the regime of Article 10(3) of the Regulation also applies to pending claims.

Traditional herbal medicinal products and traditional herbal preparations

1. In its judgment of 26 June 2025, C-618/23, ECLI:EU:C:2025:485, the CJEU ruled that

products classified as 'traditional herbal medicinal products' under 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, may not be regarded simultaneously as 'plant-based traditional herbal preparations' within the meaning of Annex I to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products.

2. The CJEU also holds that including on the packaging of a traditional herbal medicinal product labelling elements provided for in Chapter IV of Regulation 2018/848 (such as the official organic production logo of the European Union, the company's own organic production logo, the code number of the control body, the place where the agricultural raw materials were produced, "non-EU agriculture" or "EU agriculture", the term "bio" or the reference "from organic production") "is liable to be promotional in nature in particular where those elements are devoid of any value as regards health, they do not correspond to any of the indications provided for in the summary of the product characteristics, and the medicinal product can be purchased without a prescription. Indeed, in that eventuality, the information is addressed to the patient without the intermediary of a healthcare professional, with the result that it could lead, directly, to a decision to purchase on the part of the patient".

Compulsory vaccination

The CJEU (in its judgment of 12 June 2025, C-219/24, ECLI:EU:C:2025:442) has ruled that Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, and Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work, must be interpreted as not precluding national legislation pursuant to which an employer may require workers with whom it has concluded an employment contract to undergo vaccination if they are exposed to a biological risk.

Extinguishment of liability for damage caused by defective products

1. Advocate General Laila Medina, in her Opinion delivered on 19 June 2025 in Case C-338/24, *LF v Sanofi Pasteur SA*, ECLI:EU:C:2025:467, proposes that the CJEU hold that Article 11 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, under which the rights conferred on an injured person by that directive are extinguished on expiry of a period of 10 years from the date on which the harmful product was put into circulation, is invalid in the light of Article 47 of the Charter of Fundamental Rights of the European Union, in so far as its application has the effect of extinguishing the right to claim compensation of injured persons suffering from a progressive disease who, according to medical evidence, due to the progressive nature of their medical condition, cannot fully evaluate the damage caused to them and have therefore been unable to initiate proceedings against the producer within that period, thereby depriving

those persons of their right of access to a court.

Similarly, the Advocate General is of the opinion that Article 10(1) of Directive 85/374 should be interpreted as meaning that, in the situation of a progressive disease, the three-year limitation period established in that provision starts to run on the date of stabilisation of the damage, defined as the moment from which, according to medical evidence, the condition of the injured person is no longer evolving.

2. It should be recalled that Directive 85/374/EEC has been repealed by Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC. Article 17 of Directive (EU) 2024/2853 retains the 10-year limitation period for liability, although it introduces an exception whereby, where an injured person has been unable to bring an action within ten years due to the latency of a personal injury, the injured person shall no longer be entitled to compensation pursuant to this Directive upon the expiry of a period of 25 years, unless that injured person has, in the meantime, initiated proceedings against an economic operator that can be held liable.

G A _ P
Gómez-Acebo & Pombo

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