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Newsletter

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EUROPEAN UNION

The European Health Data Space Board: organisation, functions and regulatory implementation

Commission Implementing Regulation (EU) 2026/771 of 7 April 2026[1] lays down the necessary measures for the establishment and operation of the European Health Data Space Board. This Board was already provided for in Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space ('EHDS'), which set out its functions and established it as a key body responsible for ensuring the consistent application of the European framework for health data use and exchange.

On that basis, it is now envisaged that the Board *a*) may issue written contributions relating to technical specifications and other relevant matters in accordance with the EHDS Regulation, supporting the access to and exchange of electronic health data, particularly in the form of implementation guides; *b*) may issue written contributions, including in the form of non-binding guidelines to support the implementation of Regulation (EU) 2025/327 for example, identifying common implementation challenges and proposing coordinated responses or joint road maps for the Member States, as well as EHDS communication strategies; c) may facilitate thematic exchanges among its members, the Commission, and with relevant bodies, agencies and authorities.

Furthermore, the Regulation establishes the structure and functioning of the Board, which is co-chaired by a representative of the Member States and a representative of the Commission, although the latter is not entitled to vote. It also regulates aspects such as decision-making procedures, transparency, access to documents, the duty of confidentiality and the financing of expenses.

[1] J L, 2026/771, 8.4.2026; see this *link*.

Uniform requirements for notified bodies: Implementing Regulation (EU) 2026/977

Commission Implementing Regulation (EU) 2026/977 of 4 May 2026 lays down uniform quality management and procedural requirements for conformity assessment activities carried out by notified bodies for medical devices or for in vitro diagnostic medical devices in the European Union.

The aim is thus to address the current situation, described in recital 4 of the Regulation, whereby "the individual practices that notified bodies apply as regards quality management and procedural requirements diverge significantly, thus putting manufacturers in unequal positions across the internal market. This is particularly relevant in case of manufacturers that are small and medium-sized enterprises. Such practices have an impact on the predictability and on the timely completion of conformity assessment activities, with significant repercussions and delays for innovation and the health of patients".

This harmonises aspects such as the minimum information that such bodies should request to issue a quotation, to ensure that the related following applications for conformity assessment activities are not rejected because they are incomplete or because the device is outside the scope of the notified body's designation.

The regulation also sets time limits for each stage of the assessment process —including the review of applications, the conduct of audits, product testing and the issuance of certificates — with the aim of enhancing predictability, efficiency and equal treatment among manufacturers. It also regulates the management of changes to products or quality systems, as well as recertification procedures, avoiding duplication and focusing assessments on essential issues such as post-market surveillance and risks. Overall, it aims to strengthen safety, foster innovation and improve the functioning of the internal market through more transparent, streamlined and uniform processes.

European Data Protection Board Guidelines on processing of personal data for scientific research purposes

The European Data Protection Board has drawn up guidelines on personal data processing for scientific research purposes[2]. These are Guidelines 1/2026 of 15 April, which have been submitted for public consultation.

The guidelines address issues such as the definition of scientific research, the compatibility of further processing, the retention of data over extended periods of time, and the various legal bases that may legitimise processing, such as consent (including broad or dynamic consent), public interest or legitimate interest. Similarly, reference is made to the rights of data subjects, as well as to the allocation of responsibility when several entities are involved in the processing of personal data for scientific research purposes, and to the safeguards that data controllers must put in place to protect the rights and freedoms of data subjects when processing personal data for scientific research purposes. In this regard, it is emphasised that, "in line with the principle

[2] See this *link*.

of data minimisation, anonymised - or alternatively pseudonymised data - should be used for scientific research, as long as the purposes of processing can be fulfilled using such data. The processing of personal data that can be used to directly identify a person is only allowed where it is strictly necessary and proportionate to achieve the purposes of the scientific research. Depending on the nature, scope, context and purposes of processing, it may be necessary to also apply other safeguards than anonymisation or pseudonymisation of personal data. Such safeguards can be independent or ethical oversight, secure processing environments, privacy enhancing technologies, protective measures for publication of research results, confidentiality arrangements, conditions for further use, etc".

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Pharmaceutical trade marks and likelihood of confusion

In its Judgment of 6 May 2026, T-480/25, the General Court upheld the decision of the European Union Intellectual Property Office ('EUIPO') refusing registration of the figurative trade mark

on the grounds that there was a likelihood of confusion with the earlier word mark 'ALMA HYBRID'.

The rejected trade mark was applied for to distinguish cosmetic preparations, supplements and medical services (classes 3, 5 and 44), whilst the earlier trade mark is registered for class 10: 'Lasers for medical purposes; lasers for surgical use; medical ultrasound apparatus' and for class 44: 'Medical services; human hygiene and beauty care'. The Opposition Division upheld the opposition and the Board of Appeal affirmed that decision, finding that the goods and services were, in part, identical and, in part, similar to an average degree and that the element 'alma' was the dominant and most distinctive element of those marks, giving rise to relevant visual, phonetic and conceptual similarities.

According to the General Court, when assessing the relevant public, it is appropriate to focus on the Spanish-speaking and Portuguese-speaking public, as it is sufficient that the likelihood of confusion exists in part of the European Union. Furthermore, as regards the relevant public's level of attention, the level displayed is average for cosmetic products and high for health-related products and services. Furthermore, the court also confirms that the trade marks are visually and phonetically very similar and conceptually similar to a high degree, although not identical, and, in relation to the goods and services, there is similarity (and even identity in some cases) between the goods and services covered by

both trade marks, including the complementary nature of pharmaceutical products and medical services. In short, therefore, the General Court finds that there is a likelihood of confusion and dismisses the action brought against the EUIPO decision.

Prohibition on registering descriptive signs as trade marks for medical services

The General Court, in its Judgment of 25 March 2026, T-411/25, has upheld the EUIPO's refusal to register the figurative mark

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on the grounds that it was descriptive and lacked distinctive character in relation to services in Class 41 ("Education; providing of training; entertainment; sporting and cultural activities") and Class 44 ("Medical services; veterinary services; hygienic and beauty care for human beings or animals; agriculture, horticulture and forestry services").

According to the General Court, 'the term Barcelona designates the city of Barcelona in both Spanish and English', so that the Board of Appeal "did not err in its assessment in finding that the use of that term in the sign applied for would inevitably be understood as descriptive information regarding the place where the services are provided or the centre is located".

The Court of Justice interprets the general system of liability for defective products

In its Judgment of 26 March 2026, LF and Sanofi Pasteur S.A., C-338/24, and in relation to a case involving defective vaccines, the Court of Justice has established two interpretative guidelines for 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, guidelines which are equally relevant in relation to the current 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.

Indeed, according to the Court of Justice, the victim of a defective product may seek compensation for his or her injury from the producer under a general system of fault-based liability, relying in particular on the fact that the product has been allowed to remain in circulation, a failure to exercise vigilance with respect to the risks associated with the product or, more generally, a safety defect in that product.

Furthermore, with regard to the three-year limitation period for seeking compensation under the Directive, the Court of Justice states that the starting point of the three-year limitation period "is the date on which the claimant became aware, or should reasonably have become aware: of the damage, which has definitively become apparent, linked to the defective product, irrespective of its subsequent evolution; of the product defect; and of the identity of the producer, and as precluding a situation in which that starting point can only be the date on which the damage stabilised".

Generic medicinal products based on biological medicinal products and judicial review of their correct classification

The Court of Justice, in its recent judgment of 23 April 2016 (Laboratoires Eurogenerics and Theramex France, C-118/24, ECLI:EU:C:2026:330), has held that a biological medicinal product may serve as reference medicinal product for the purpose of obtaining a marketing authorisation ('MA') for a generic medicinal product and that, therefore, the abridged procedure for granting the MA provided for in Article 10 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 may be applied.

Furthermore, "Member States are free to provide that, in an action brought by the holder of an MA for a biosimilar of a biological medicinal product against a decision to grant an MA for a generic medicinal product of that biological medicinal product, adopted following a decentralised MA procedure, a court of a Member State concerned has jurisdiction to review whether the medicinal product the marketing of which has been authorised by that decision may be classified as a 'generic medicinal product".

The standing of associations to challenge Commission decisions on marketing authorisations for medicinal products

In its order in Case T-278/25, the General Court dismissed an action against the European Commission's decision not to renew the conditional marketing authorisation for a Ducheme orphan medicinal product for the treatment of muscle dysphoria, on the grounds that the applicant association lacked standing.

In this regard, the order is interesting because it summarises the case law of the Court of Justice on the matter, and highlights that actions brought by associations are only admissible in three cases: where a rule expressly grants associations procedural powers; when the association represents the interests of its members who, in turn, have standing to act; or when the association's own interests are affected as such, in particular where its negotiating position has been prejudiced by the act whose annulment is sought.

In the present case, the General Court considers that none of those circumstances applies. With regard to the second scenario, it states that "it is true that the appellant is an association composed of mothers who legally represent their children affected by Duchenne muscular dystrophy, whose purpose under its articles includes taking action aimed at supporting and promoting the inclusion of such children. However, not only does the appellant fail to provide any evidence in its pleadings to show that its members themselves have standing to bring proceedings against the contested decision, but it also expressly states, in its observations on the plea of inadmissibility, that its standing to bring proceedings is distinct from that of its members and that it is the collective nature of the interests it represents, as an association, which justifies that standing".

And, as regards the third scenario, it states that, although the role played by an association in proceedings leading to the adoption of a measure may justify the admissibility of an action brought by that association, even where

its members are not directly and individually affected by that measure, in particular where that act has affected its negotiating position, the appellant did not play any role in the procedure leading to the adoption of the contested decision.

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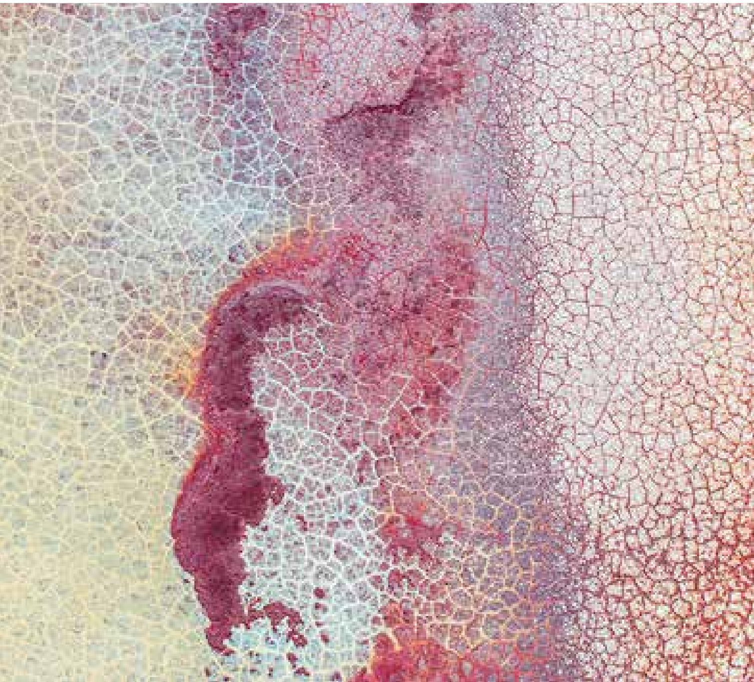

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