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Regulation of the European Parliament and of the Council on the European Health Data Space

The Regulation of the European Parliament and of the Council on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 has been approved by the Council of the European Union on 21 January 2025, after last year (on 15 March 2024) the European Parliament and the Council reached a provisional agreement on the Proposal presented by the Commission on 3 May 2022 [Document COM (2022) 197 final], together with a Communication to the European Parliament and the Council of the same date entitled "A European Health Data Space: harnessing the power of health data for people, patients and innovation" [COM(2022) 196 final].

Following the adoption of the regulation by the Council, the regulation still needs to be formally signed by both the Council and the European Parliament and subsequently published in the *Official Journal of the European Union*.

The new regulation - and the European Health Data Space - is primarily intended to facilitate patients' access to their health data, as well as to enable and facilitate the transfer of health data, including across borders. As stated in the explanatory notes to the regulation (point 6), "[m]ore and more individuals living in the Union cross national borders to work, study, visit relatives, or for other reasons". And to "facilitate the exchange of health data, and in line with the need to empower citizens, they should be able to access their health data in an electronic format that can be recognised and accepted throughout the Union".

Secondly, the regulation also aims to facilitate the use of health data for purposes other than the medical treatment of the person to whom they pertain, such as research, public health, etc. These types of uses of data are called *secondary uses* in the regulation, as opposed to the former ones, which are called *primary uses*.

New directive on liability for defective products

In November 2024, the new Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October on liability for defective products and repealing Council Directive 85/374/EEC was published in the *Official Journal of the European Union*[1]. This new directive also applies to the field of medicines and medical devices.

[1] OJ L, 2024/2853 of 18 November 2024. See this ***link***.

In the almost forty years since the adoption of Directive 85/374/EEC, there have been important developments in the case law of the Court of Justice. Moreover, the application of the system set out in the Directive has revealed the need to review certain provisions, a need which has increased in recent years as a result of digitisation and the emergence of highly technological products, which pose new risks and make it appropriate to extend the special liability system laid down in Directive 85/374/EEC.

The new directive aims to establish common rules on the liability of economic operators for damage suffered by natural persons caused by defective products and on compensation for such damage. Against this background, the general principle is that Member States shall ensure that any natural person who suffers damage caused by a defective product is entitled to compensation in accordance with the directive, which establishes a strict liability system.

However, on this premise, the new directive extends the scope of application of the special product liability system, for example, to interconnected goods and related services, software and digital manufacturing files.

Compensable damage is also extended to include damage to property in certain products dedicated to professional uses, by abolishing the deductible for damage to property established in the 1985 directive, as well as the possibility - established in Article 16 of Directive 85/374/EEC and which has been adopted by the Spanish legislator (Article 141*b* of the Consumer and User Protection Act) - to limit the maximum amount of the producer's global liability for death or bodily injury caused by identical articles with the same defect.

It is also very important that the new directive establishes mechanisms to facilitate proof, as well as a series of rebuttable presumptions of the defective nature of the product and of the causal link between the defect and the damage, which undoubtedly reinforces the protection afforded to injured parties, resolving the difficulties they sometimes encounter in proving the defect or the causal link with the damage (for example, when a defective product that has caused the damage has disappeared or almost nothing remains of it, because it has exploded, etc.).

On the other hand, the new directive maintains the so-called 'development risk defence', so that operators will not be liable if they prove "that the objective state of scientific and technical knowledge at the time the product was placed on the market or put into service or during the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered". And the new directive (art. 18) also maintains flexibility in relation to this defence, insofar as it allows Member States to maintain or introduce measures whereby economic operators are liable even if they prove the above points (which is why the Kingdom of Spain may continue to exclude this defence by way of derogation in relation to medicinal products, foodstuffs and food products intended for human consumption). But, in addition, States may introduce new exclusions, referring to specific categories of products, which are justified by public interest objectives and are proportionate.

Procedures for joint scientific consultations on medicinal products for human use at Union level

Commission Implementing Regulation (EU) 2024/3169 of 18 December laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council with regard to the procedures for joint scientific

consultations on medicinal products for human use at Union level has been adopted and published in the Official Journal of the European Union[2].

Joint scientific consultations are provided for in Article 16(1) of Regulation (EU) 2021/2282, which requires the Coordination Group to carry out joint scientific consultations in order to exchange information with health technology developers on their development plans for medicinal products for human use. And, as the explanatory notes to the new regulation recalls, "[t]he aim of such consultations is to facilitate the process of preparing joint clinical assessments for medicinal products, as they will allow health technology developers to obtain guidance from the Coordination Group on the information, data, analyses and other evidence that are likely to be required from clinical studies for the joint clinical assessment of those medicinal products".

The new regulation lays down detailed procedural rules for joint scientific consultations as regards submission of requests from health technology developers for joint scientific consultation on medicinal products for human use; the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts in joint scientific consultation on medicinal products and cooperation, in particular by exchange of information, with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried out in parallel with the scientific advice on medicinal products by the European Medicines Agency.

"Killer acquisitions" in the pharma sector: Report commissioned by the European Commission is published

In the field of company takeovers and competition law, killer acquisitions have gained particular prominence in recent years. This is the name given to the phenomenon whereby companies already established in a certain sector may acquire competitors with innovative projects with the ultimate intention of paralysing such projects and preventing future competition.

In 2022, the Commission commissioned a study report on the acquisition of innovative competitors in the pharma sector in order to conduct an ex-post evaluation of the acquisitions to see to what extent they had affected competition. The report - entitled "Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector leading to the discontinuation of overlapping drug research and development projects. Final Report" - was prepared by the Italian consultancy Lear and, although commissioned by the Commission, contains a disclaimer stating that its content reflects only the personal views of its authors and not the official opinion of the Commission. Furthermore, although finalised in May 2024, the report was not published until November 2024[3] in order to reflect the findings of the European Court of Justice in its judgment of 3 September 2024 in the Illumina / GRAIL case (which prevents merger control where the thresholds set by European or national law are not met).

[2] DO L, 2024/3169, 19.12.2024. See this ***link***.

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

The study report is divided into two main parts: the first (fact-finding challenge chapter) examines acquisitions that took place in the pharma sector between 2014 and 2018 to determine whether they may have led to the discontinuation of drug R&D projects in the acquired companies; the second (evaluation challenge chapter) assesses the legal response mechanisms to such acquisitions.

Update to the guidance on confidentiality in marketing authorisation applications in marketing authorisation applications for medicinal products

In December 2024, the European Medicines Agency and the Heads of Medicines Agencies have updated the guidance on confidentiality in marketing authorisation applications for medicinal products ("HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application (MAA) dossier"[4]). Among other new developments, a number of examples of information that may be considered confidential information or protected personal data are now included.

Notification of the start of manufacturing of medical devices in hospitals

Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices, allows, subject to certain obligations, health institutions to manufacture their own medical devices (so-called *"in-house" manufacturing*). In Spain, this EU regulation is implemented in Royal Decree 192/2023, of 21 March, regulating medical devices, which stipulates, among other things, that only in-house manufacture by hospitals is permitted.

The Spanish Medicines and Medical Devices Agency (AEMPS) has created a computer application[5] for hospitals to comply with the obligation to notify the start of the manufacturing of medical devices in hospitals for their exclusive use in the hospital itself.

"Guidelines for undertaking decentralised items in clinical trials"

The Spanish Medicines and Medical Devices Agency (AEMPS) has also published guidance on clinical trials. This is the "Guidelines for undertaking decentralised items in clinical trials", dated November 2024[6], whose objective, as stated in the guidelines, is to "describe the main characteristics to be taken into account when conducting decentralised or hybrid clinical trials with medicinal products at the national level". To this end, it addresses "the processes to be considered for each decentralised item, thereby establishing a uniform way of implementing them, and ensuring the safety of participants and data quality".

It supplements, moreover, the recommendation paper adopted by the European Medicines Agency in 2022 under the title "Recommendation paper on decentralised elements in clinical trials".

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

[5] See this ***link***.

[6] See this ***link***.

Judgments, rulings and decisions

European Union

Pharmacy customer data as data concerning health

The Court of Justice - in its judgment of 4 October 2024, C-21/23, ECLI:EU:C:2024:846 - has held that in a situation where the operator of a pharmacy markets pharmacy-only medicinal products on an online platform, the information which the customers of that operator enter when ordering the medicinal products online, such as their name, the delivery address and the details required for individualising the medicinal products, constitutes data concerning health, within the meaning of General Data Protection Regulation (Regulation (EU) 2016/679) and Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. That is so, according to the Court of Justice, even where the sale of those medicinal products does not require a prescription.

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