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Medical Devices: the EU Parliament approved a new Resolution to call upon the EU Commission to propose delegated and implementing acts to the MDR and the IVDR

On 23 October 2024, the EU Parliament adopted a Resolution to warn the EU Commission of the urgent need to revise EU Regulations 2017/745 ("**MDR**") and 2017/746 ("**IVDR**").

In particular, the EU Parliament recommended the EU Commission to, among others:

- propose delegated and implementing acts to the MDR and the IVDR to address the most important challenges and bottlenecks in the implementation of the legislative framework and to propose the systematic revision of all relevant articles of the MDR and the IVDR by the end of the first quarter in 2025;
- resolve issues of divergent interpretation and of practical application to streamline the regulatory process, improve transparency and eliminate unnecessary administrative tasks, without compromising patients' safety;
- increase support and cooperation to ensure that the notified bodies (*i.e.*, legal entities which are involved in the certification process of medical devices, provided by the MDR and IVDR) have the upmost capabilities and capacities to fully implement the regulatory framework;
- consider prioritising channels for the approval of innovative technologies in areas where medical needs are unmet and for medical devices linked to medical emergencies.

In addition to the above, in its Resolution the EU Parliament – in compliance with European data protection policies – underlined the need to protect health data, collected by e-health applications, by expressly including these applications in the scope of the revised MDR.

The EU Parliament Resolution is an important act to stimulate the elaboration (and then, the adoption) of measures to achieve the full implementation of the MDR and IVDR and prevent shortages of medical devices.

We look forward to monitoring how the EU Commission will implement the recommendations made by the EU Parliament.

Medical Devices and product liability: a new EU Directive concerning product liability and its implications on the medical devices industry

On 18 November 2024 the new EU Directive concerning product liability No. 2024/2853 (the "**Product Liability Directive**") was published in the EU Official Gazette.

The Product Liability Directive repeals and revises the previous EU Directive 374/1985 concerning product liability in order to, on the one hand, address the risks and implications related to the development of new technology – including artificial intelligence – and, on the other hand, ensure coherence and consistency with product safety and market surveillance legislation at EU and national levels. Indeed, the previous regulation and the development of new technology led to inconsistencies and legal uncertainty, in particular with regard to the meaning of the term 'product'.

The Product Liability Directive applies, among others, to products placed on the market or, where relevant, put into service in the course of a commercial activity, whether in return for payment or free of charge (e.g. to products supplied in the context of a sponsoring campaign or products manufactured for the provision of a service financed by public funds, since this type of supply nonetheless has an economic or business character). Taking into account the broad definition of product and the clarification provided by '*Whereas*' no. 51 (which expressly refers to the MDR), the Product Liability Directive also applies to medical devices placed on the market or put into service within the EU.

The main features introduced by the Product Liability Directive are, among others:

- the new definition of 'product', which means "*all movables, even if integrated into, or inter-connected with, another movable or an immovable; it includes electricity, digital manufacturing files, raw materials and software*" (Article 4(1)). The definition of product has been extended to include digital manufacturing files (*i.e.*, a digital version of, or digital template for, a movable which contains the functional information necessary to produce a tangible item by enabling the automated control of machinery or tools) and software;
- the extension of the liability for defective products to the EU-based company importing the product, or the EU-based representative of the foreign producer (Article 8(1)(c));
- the extension of liability to the legal entity (other than the original manufacturer) who made substantial changes to the product, outside the manufacturer's control, and subsequently makes it available on the market or puts it into service (Article 8(2));

- the easing of the burden of proof for the claimant who has been injured. In fact, when the claimant faces excessive difficulties in proving the defectiveness of the product or the causal link between its defectiveness and the injury, the National Court shall presume the defectiveness of the product and/or the causal link between its defectiveness and the injury (without prejudice to the right of the defendant to rebut any of the mentioned presumptions) (Article 10(4));
- the provision of an expiry period after which a person who has been injured is no longer entitled to compensation pursuant to the Product Liability Directive. Pursuant to Article 17, the person who has been injured is no longer entitled to compensation after 10 years, unless, in the meantime, the person who has been injured, has initiated the relevant proceedings. The expiry period starts from the date on which the defective product was placed on the market/put into service or – in the case of a substantially modified product – the date on which that product was made available on the market/put into service following its substantial modification. By way of derogation, the 10-year expiry period is extended to 25 years if a person who has been injured has not been able to initiate proceedings within 10 years due to the latency of a personal injury.

The Product Liability Directive applies to products placed on the market or put into service starting from 9 December 2026 (Article 2(1)); in the meanwhile, EU Directive 374/1985 will continue to apply (Article 21). EU Member States have time until 9 December 2026 to transpose the Product Liability Directive within their legal framework (Article 22) and, in principle, Member States shall not maintain or introduce, in their national law, provisions diverging from those laid down in the Product Liability Directive, including more stringent or less stringent provisions (Article 3).

Italian National Health Service: the Italian State-Region Conference approved the new rates for the reimbursement of healthcare services provided by healthcare facilities under the new LEAs (Essential Levels of healthcare Assistance)

New LEAs (*i.e.*, essential levels of healthcare assistance and services to be provided by the Italian National Health Service) have been introduced within the Italian National Health Service in relation to numerous diseases (including medically assisted reproduction, rare diseases, celiac disease, eating disorders) through Decree of the Prime Minister (D.P.C.M.) dated 12 January 2017 ("**DPCM 2017**").

Ministerial Decree dated 23 June 2023 ("**Ministerial Decree 2023**") provided for the rates of the abovementioned LEAs, so that the new services included within such LEAs would become effective and actually be provided by the National Health Service. Such Ministerial Decree should have come into force on 1 January 2025.

On 14 November 2024, the Italian State-Region Conference (*i.e.*, a public administration composed of the Italian Government and Regions) approved a new Ministerial Decree ("**Ministerial Decree 2024**") to replace the abovementioned Ministerial Decree 2023. Therefore, the rates of the LEAs provided for under Ministerial Decree 2023 have never come into force, having been updated by those provided for under Ministerial Decree 2024.

In light of the above, the new LEAs introduced in 2017 shall come into effect as of the date of entry into force of Ministerial Decree 2024, which is set for 30 December 2024.

Ministerial Decree 2024 also provides for a transitional period of the previous rates (applicable to the LEAs provided before DPCM 2017), that will continue to apply for the services prescribed until 29 December 2024 and provided within one year from the entry into force of Ministerial Decree 2024.

Ministerial Decree 2024 shall now be formally adopted by the Italian Ministry of Health and then published in the Italian Official Gazette.

Medical Assisted Reproduction (MAR): the Italian Parliament approved a new law that will punish Italian citizens who access surrogacy abroad

On 16 October 2024, the Italian Parliament approved Law No. 169/2024 which will punish Italian citizens who access surrogacy, even if the surrogacy takes place outside Italy.

The new law amends Article 12, paragraph 6 of the Italian law that regulates access to medical assisted reproduction (Law No. 40/2004), which stipulates the crime of surrogacy, consisting in the realization, organisation or advertisement of surrogacy committed within the Italian territory. The new law extends the criminal liability to Italian citizens for the conduct described above, even if carried out abroad.

The punishment for the crime mentioned, provided for under Article 12, paragraph 6 of Law No. 40/2004 consists of imprisonment (from three months to two years) and a fine (from 600,000 to 1,000,000 Euros). Law No. 169/2024 was published in the Italian Official Gazette on 18 November 2024 and entered into force on 3 December 2024.

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