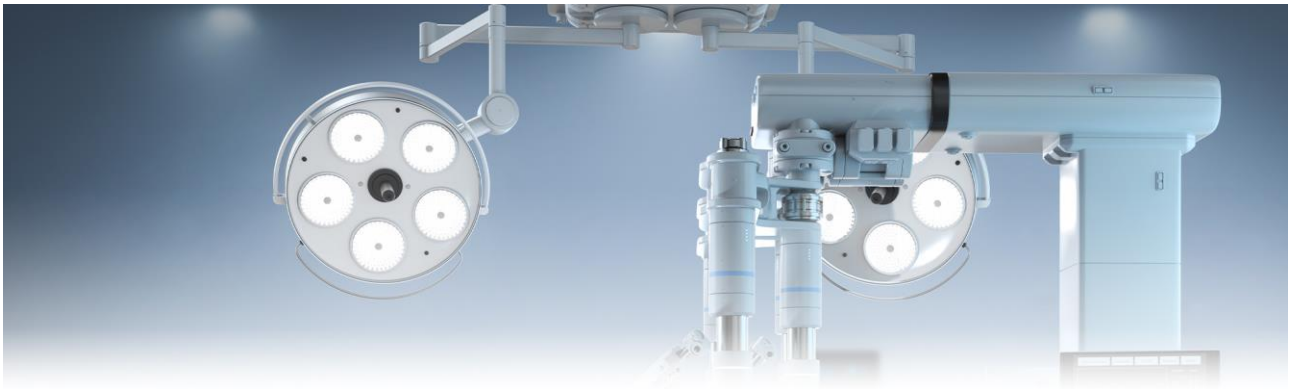

Proposal to amend the In Vitro Diagnostics Regulation and the Medical Devices Regulation

In vitro diagnostics (IVDs) are products used on biological samples to determine the status of a person's health, such as HIV tests, pregnancy tests or COVID-19 tests. The IVDR, applicable since May 2022, aims to modernise and upgrade the EU framework for these products to ensure their safety for patients. However, the available data shows that today a considerable number of in vitro diagnostics currently on the market do not yet comply with the new rules nor have they been replaced by new devices.

The situation is especially critical for high-risk IVDs, which are products used, for example, to test for blood infections. To improve the availability of such essential devices, the European Commission published on 23 January 2024, a proposal for a Regulation to amend the In Vitro Diagnostics Regulation (IVDR) and the Medical Devices Regulation (MDR). The proposal provides for a gradual roll-out of EUDAMED, an information obligation in case of interruption of supply and an extension of the transitional period for certain in vitro diagnostic medical devices. The additional time granted to companies depends on the type of device:

- high individual and public health risk devices such as HIV or hepatitis tests (class D) would have a transition period until December 2027;
- high individual and/or moderate public health risk devices such as cancer tests (class C), would have a transition period until December 2028;
- lower risk devices (class B such as pregnancy tests and class A sterile devices such as blood collection tubes), have a transition period until December 2029.

The proposal also requires manufacturers to give prior notice if they foresee any interruption in the supply of IVDs or medical devices, so that Member States

have more time to take action to ensure patient care.

With this revision, the Commission aims to ensure patient care by improving the availability of these essential healthcare products, without compromising safety requirements. This is very important, also taking into account the fact that many manufacturers producing IVDs are small and medium size enterprises

More transparency on medical devices

The use of EUDAMED, the European database on medical devices, is key for the effective and efficient implementation of the MDR and IVDR. It will increase transparency in the EU, providing an overview of all medical devices available on the European market. The new proposal aims to speed up the launch of the parts of EUDAMED that are already finalised, so that it is mandatory earlier (as from late 2025).

Next steps

The Proposal will now be put forward to the European Parliament and the Council for adoption.

The Commission will already start in 2024 its preparatory work for a targeted evaluation of the legislation on medical devices. The evaluation will assess how the availability of devices is affected, in particular for devices with specific characteristics (e.g. paediatrics, orphan, innovative devices). In the assessment, special attention shall be given to costs and administrative burdens stemming from the implementation of legislation, especially for SMEs.

Other Legislative developments to watch out for in 2024 in the Life Sciences sector

Reform of the EU pharmaceutical legislation: In 2023, the Commission adopted a proposal for a new Directive and a new Regulation, which shall revise and replace the existing general pharmaceutical legislation. Both texts have received a lot of criticism and it remains to be seen whether these shall be adopted 'as is' or amended pursuant to the pressure put by various stakeholders.

Proposal for an EHDS Regulation: In December 2023, the European Parliament adopted a Proposal on a Regulation on the European Health Data Space. Negotiations regarding the final text are ongoing. This Proposal could provide a framework to access patient files or records for research purposes, butMedTech Europe published a plea for refinement of the Proposal.

Proposal for an AI Regulation: The presumably final text was made available on 22 January 2024. If the European Parliament and the Council votes are positive, then, the AI Regulation will be adopted. This Proposal will have an impact on AI used in the lifecycle of medicinal products, as well as, on manufacturers of medical devices incorporating an AI as a safety component. Manufacturers of such medical devices would have about 5 years to comply with the Regulation followings its adoption. However, this may not be ample time to implement the new conformity assessment procedure considering the bottlenecks witnessed with the MDR and the IVDR.

Proposal for a new Product Liability Directive: The European Parliament and the Council have reached a provisional

agreement regarding the Proposal mid-December 2023. If the Proposal is adopted, then the Proposal will be published and enter into force. The adoption of the related Proposal for a Directive to adopt non-contractual civil liability rules governing AI, will be accelerated, once the Proposal for an AI Regulation is adopted.

Proposal for a Regulation on Critical Raw Materials: This Proposal is intended to ensure that the EU has access to a secure and sustainable supply of critical raw materials which are deemed crucial for a transition to clean energy. The Proposal provides for a list of critical raw materials. If adopted, the Proposal may have an impact on the supply chains of Life Sciences companies in the future.

Proposal for a Cyber Resilience Regulation: On 30 November 2023, the Council and the European Parliament's negotiators reached a provisional agreement on the Cyber Resilience Act. The Proposal covers a broad range of devices, namely, all products that are connected either directly or indirectly to another device or network, including hardware, software and ancillary services. Medical devices would, however, be excluded from the scope of the Regulation.

Proposal for a CLP (Chemicals) Regulation: The European Parliament and the Council reached a provisional agreement on the revision of the regulation on the classification, labelling and packaging of chemicals (CLP) in December 2023. If the agreement is ratified, then, the Proposal will be adopted. This Proposal puts an emphasis on the implementation of new hazard classes and may have an impact on cosmetics, food contact material and medicinal product manufacturers.

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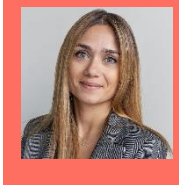

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