



Follow-Up Life Sciences Coffee Break #1



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Life Sciences 2026: Navigating Europe's Next Regulatory Wave

The European Union has embarked on a comprehensive reform of its legal framework for the Life Sciences, anchored by the Life Sciences Strategy 2030. The overarching objective is to make Europe the most attractive and competitive hub for research and innovation by 2030. To achieve this, the EU is introducing a series of interlinked legislative initiatives, including the Pharma Package, the Biotech Act, and amendments to the MDR and IVDR. These initiatives seek to accelerate and harmonise approvals, incentivise innovation, and improve data access, thereby establishing an investment-friendly and competitive environment for Life Sciences and translating research into practical healthcare solutions.

For a more detailed analysis, please refer to our full article [here](#).

1 Pharma Package

The Pharma Package constitutes the most significant reform of EU pharmaceutical legislation in more than two decades. It consists of a new Regulation and a new Directive designed to modernize the regulatory framework, recalibrate incentives and strengthen supply security. On 11 December 2025, the European Parliament and the Council reached political agreement on the package. Following formal endorsement and publication in the Official Journal of the EU, the legislation will enter into force, with application to follow according to transitional provisions.



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Key points of the current proposal:

- Data & Market Exclusivity = 8+1(+1+1): Data exclusivity period shall remain at 8 years, market exclusivity shortened to 1 year, possibility of up to 2 extra years for certain criteria.
- Availability & Supply: Member States may require MAHs to ensure sufficient supply of protected medicinal products.
- Bolar Exemption: Clarified and extended to include submissions for public procurement tenders.
- Antimicrobial Resistance: Introduction of a transferable exclusivity voucher (+1 year protection for another product).
- Orphan Medicines: Exclusivity reduced from 10 to 9 years; but 11 years for “breakthrough medicines for rare diseases”.
- Marketing Authorisation: Approval timelines shall be shortened from 210 to 180 days.

with discussions ongoing in the European Parliament and the Council. Final adoption is not expected before the end of 2026. The initiative is designed to address setbacks in scaling biotech solutions and to drive Europe’s competitiveness. A further legislative initiative (“Biotech Act II”) has already been announced for the third quarter of 2026.

Key points of the current proposal:

- Innovation: Introduction of regulatory sandboxes & support structures to promote innovation and AI-driven solutions.
- SPC: Possibility for a 12-month extension of the supplementary protection certificate for biotechnological inventions.
- Clinical Trials: Introduction of “minimal intervention clinical trials”; simplified procedures for minimal and low-interventional clinical trials; single core dossier for IMPs, single authorization process for combined medicinal product and medical device/IVD trials; reduced timelines for multinational trials from 106 to 75 days (47 if no additional information is required).

2 Biotech Act I

The proposed Biotech Act establishes a broad framework aimed at strengthening the EU’s biotechnology and biomanufacturing sectors. The Commission presented its proposal on 16 December 2025. The Act is currently in the early stages of ordinary legislative procedure,



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3 EUDAMED-Rollout

EUDAMED is entering a decisive operational phase following the Commission's confirmation of full functionality through Commission Decision (EU) 2025/2371. A six-month transitional period began on 27 November 2025.

From 28 May 2026 onwards, the use of Modules 1 (Registration of Economic Operators), 2 (UDI & Product Registration), 3 (Certificates & Notified Bodies) and 5 (Market Surveillance) will become mandatory. However, Modules 4 (Vigilance / Post-Market Surveillance) and 6 (Clinical Investigations / Performance Studies) are not yet fully functional. The mandatory rollout marks a significant milestone in the digitalization and transparency of the EU medical device regulatory framework.

More information on the functionality of EUDAMED can be found [here](#).

4 Notified Bodies

On 12 December 2025, the European Commission released a draft Implementing Regulation aimed at standardizing the quality management and procedural requirements for Notified Bodies operating under the MDR and IVDR. The European Commission anticipates adoption of the Regulations in the first quarter of 2026, following which it will be sent to the European Parliament and Council for further consideration.

Key points of the current proposal:

- Limits information NB may request prior to issuing quotation
- Defines maximum mandatory content of NB quotations
- Sets maximum timelines for conformity assessment
- Re-certification requirements (e.g. specifies documentation NB shall request; max. 60 days to review re-certification documentation; max. 60 days to verify QMS re-certification)

5 MDR / IVDR 2.0

On 16 December 2025, the European Commission proposed targeted amendments to the MDR and IVDR following a broad consultation. The aim is to address structural weaknesses, simplify regulatory requirements, and future-proof the regime for medical devices and IVDs. The proposal is currently in the ordinary legislative process, with the first reading expected in the first half of 2026 and adoption of the amending Regulation anticipated in the second quarter of 2027.



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Key points of the COM-proposal:

- Simplification: Removal of maximum 5-year certificate validity; periodic review by Notified Bodies (NB); facilitations of PRRC requirements for SMEs; adjusted classification rules (in particular for software); alignment with AI Act.
- Reduction of Administrative Burden: Reduced frequency of post-market updates; PSUR review integrated into surveillance; no prior authorization for certain low-risk performance studies; reduced NB involvement for certain IIa/IIb and B/C devices.
- Innovation & Special Devices: New Criteria and priority review for breakthrough/orphan devices; Expanded in-house exemptions (including central laboratories); Removal (IVDR) of “no equivalent device” requirement; Justification for “single-use” claims.
- NB: Limits on pre-quotation information requests; Maximum timelines for conformity assessment and recertification.

Our Next Coffee Break

For a deep dive into the amendments to the MDR / IVDR, join our Life Sciences Coffee Break Session #3 on 18 March 2026 – register [here](#).

Recalibrating EU Medical Device Regulation: Deep Dive into the EU MDR / IVDR COM-Proposal

The EU Commission’s proposal for amending the MDR and IVDR marks a pivotal moment in medical device regulation. This Coffee Break provides a structured overview of the upcoming reform: regulatory simplification, reduced administrative burdens, and more efficient conformity assessments. Join us for practical insights into key changes, including device classifications, “well-established technology” designations, and regulatory sandboxes designed to foster innovation. Discover what these developments mean for manufacturers, notified bodies, and healthcare providers—and prepare for the next phase of compliance in the EU MedTech sector.



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Your Host

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