EU Policy and Regulatory updates

The European healthcare regulatory landscape continued to evolve rapidly throughout March and April 2026, with major developments across pharmaceuticals, medical devices, digital health, artificial intelligence, and health data governance. During this period, EU institutions and agencies focused on implementing the new pharmaceutical reform package, advancing the European Health Data Space (EHDS), strengthening the Medical Devices Regulation (MDR) framework, and preparing stakeholders for the growing impact of the AI Act on healthcare technologies. At the same time, the European Medicines Agency (EMA) continued to support innovation through new initiatives for breakthrough medical devices and advanced therapies, while policymakers increasingly emphasized regulatory convergence, resilience of healthcare systems, and faster patient access to innovative solutions.

EU Public Consultations of Interest to Our Community

Two significant European public consultations are currently open for contributions. These initiatives provide valuable opportunities for stakeholders to contribute to the future development of EU policies and regulatory frameworks affecting healthcare, innovation, and research.

1. **Medical Devices and In Vitro Diagnostics – Targeted Update of EU Legislation**
   New feedback deadline: 06 July 2026
   (previously 19 June 2026)
   This initiative focuses on streamlining and improving the EU regulatory framework for medical devices and in vitro diagnostic devices. The objective is to support the continued availability of safe, effective, and innovative technologies while ensuring a high level of patient safety and public health protection.
   Based on the assessment of the existing legislation, the revision aims to:
   - strengthen the competitiveness of the EU medical device sector both within Europe and internationally;
   - foster innovation and reduce strategic dependencies;
   - ensure that safety and compliance requirements remain proportionate and more cost-effective.

   Feedback rules
   Give your Feedback

2. **Biotech Act**
   New feedback deadline: 06 July 2026
   (previously 19 June 2026)
   Biotechnology is a strategic and rapidly evolving sector that contributes significantly to multiple areas of the European economy. As a highly research-intensive field, it depends on strong public and private investment to support growth and innovation.
   The forthcoming Biotech Act is expected to introduce measures designed to create a more supportive environment for biotechnology development, helping innovative products move more efficiently from research laboratories to industrial production and market deployment, while continuing to uphold the highest standards for public and environmental safety.

   Feedback rules
   Give your Feedback

EMA Adopts ICH M15 Guideline (Step 5)
27 April 2026

The European Medicines Agency (EMA) has formally adopted the ICH M15 Guideline (Step 5), introducing a globally harmonized framework for the planning, assessment, and communication of Model-Informed Drug Development (MIDD) evidence.

This important milestone represents further progress in the integration of modelling and simulation approaches within regulatory decision-making processes. The guideline is intended to promote greater consistency across international regulatory authorities in the evaluation and reporting of quantitative evidence supporting drug development.

The ICH M15 Guideline on General Principles for Model-Informed Drug Development will become legally effective in Europe on 23 July 2026. It establishes structured recommendations for the application of modelling and simulation methodologies in regulatory submissions, including guidance on evidence generation, model evaluation, and standardized MIDD reporting practices.

Alongside the adoption of the guideline, the ICH M15 Expert Working Group is also preparing a series of training resources to facilitate implementation. These materials are expected to cover:

- the overall objectives, scope, and principles of ICH M15;
- frameworks for evaluating MIDD evidence;
- approaches to model assessment and validation;
- best practices for structured reporting and regulatory submissions.

Practical examples and additional supporting documentation are also planned to support stakeholders during implementation.

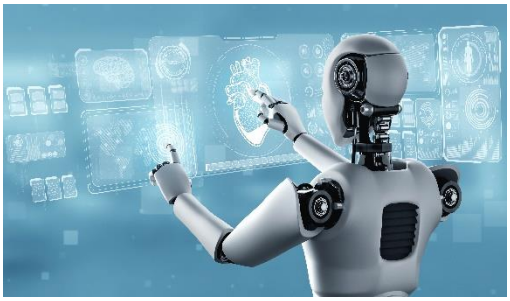
Key Resources

- EMA final adopted guideline: **LINK – ICH M15 Guideline on General Principles for Model-Informed Drug Development (Step 5)**
- ICH M15 Guideline and documents: **LINK**
- ICH M15 Step 4 presentation: **LINK**

Growing focus on AI regulation in healthcare

Healthcare organisations increasingly prepared for the operational impact of the EU AI Act, especially for:

- AI-enabled medical devices,
- clinical decision-support systems,
- governance and documentation obligations,
- interaction between AI Act, MDR/IVDR and EHDS requirements.



Several industry analyses highlighted uncertainty around classification guidance and implementation timelines.

Sources:

- Linklaters – EU Healthcare Update 2026: Key Regulatory Trends
- European Commission – Artificial Intelligence in Healthcare

EMA launches breakthrough medical device pilot

The European Medicines Agency launched a pilot programme supporting “breakthrough” medical devices, initially focused on:

- high-risk Class III devices,
- active Class IIb devices,
- earlier scientific and regulatory interaction for innovators.

The initiative aims to accelerate patient access to transformative technologies while maintaining safety standards.

📎 Source:

- EMA – Breakthrough Medical Devices Pilot

Continued advancement of advanced therapies and rare disease medicines

At the April 2026 CHMP meeting, EMA recommended several innovative products, including:

- a gene therapy for spinal muscular atrophy,
- a treatment for secondary progressive multiple sclerosis,
- a therapy for familial chylomicronaemia syndrome.

This reinforced the EU's strategic emphasis on advanced medicinal products and precision medicine.

📎 Source:

- EMA CHMP April 2026 Meeting Highlights

Strategic healthcare regulatory convergence becomes a major theme

Throughout April 2026, policymakers and industry increasingly focused on the interaction between:

- the Pharma Package,
- EHDS,
- MDR/IVDR,
- the AI Act,
- the proposed Biotech Act,
- critical medicines and supply-chain resilience initiatives.

This convergence is shaping a more integrated EU healthcare regulatory environment for pharma, medtech, biotech and digital health sectors.

📎 Source:

- Linklaters – EU Healthcare Update 2026: Key Regulatory Trends

EMA Publishes NDSG Workplan 2026–2028 on Data and Artificial Intelligence in Medicines Regulation
9 March 2026

The European Medicines Agency (EMA) has released the Network Data Steering Group (NDSG) Workplan 2026–2028, setting out a strategic vision to expand the integration of data and artificial intelligence within the European medicines regulatory system.

The new workplan represents an important milestone in the ongoing modernisation of regulatory science across the EU network. Among the key elements highlighted is the growing role of modelling and simulation (M&S), which is specifically identified as an important emerging methodology for evidence generation and regulatory assessment. The document underlines the increasing reliance on data-driven and AI-supported approaches to enhance regulatory evaluation and decision-making processes.

One of the major priorities outlined in the strategy is the preparation of dedicated guidance on the use of AI in both clinical development and pharmacovigilance activities. This work will be supported by a dedicated implementation roadmap linked to the upcoming EU Biotech Act and is intended to provide regulators and scientific experts with the tools, competencies, and assessment frameworks needed to evaluate AI-enabled technologies and methodologies effectively.

Access the full workplan

Learn more about the Network Data Steering Group (NDSG)

Digital Europe Programme Expands Support for AI, Health Data, and Modelling Capabilities Across Europe

The European Commission has adopted a further amendment to the Digital Europe Work Programme 2025–2027, reaffirming the EU's ambition to strengthen strategic digital capacities and address rapidly evolving technological priorities.

This represents the second revision of the current work programme and is intended to ensure continued alignment between EU funding instruments and the Commission's objectives for the development, deployment, and uptake of critical digital technologies throughout Europe.

The updated programme introduces additional actions and investment priorities designed to accelerate the adoption of advanced technologies, particularly in the areas of artificial intelligence (AI), digital infrastructure, and cybersecurity. It also maintains strong support for strategic domains such as high-performance computing, digital skills development, and the wider integration of digital technologies across multiple sectors.

Increased attention to digital health and health data infrastructures

Of particular importance to our community, the revised programme further strengthens support for the European Electronic Health Record Exchange Format (EEHRxF) and the rollout of digital health services across EU Member States.

This initiative represents a major step toward enabling interoperable and cross-border health data exchange throughout Europe. Such infrastructures are increasingly essential for biomedical research, personalised medicine, and population-level health analysis. Enhanced access to harmonised health datasets will also support the development, calibration, and validation of computational and predictive models related to disease progression, therapeutic outcomes, and healthcare system performance.

Expansion of AI testing and experimentation infrastructures

The amendment also reinforces the deployment of Testing and Experimentation Facilities (TEFs) dedicated to AI applications, including those in healthcare settings.

These facilities are intended to provide researchers, SMEs, healthcare organisations, and public authorities with access to advanced environments where AI technologies can be tested and validated under real-world conditions. In the context of healthcare and modelling, this will further support the development and assessment of:

AI-based diagnostic technologies;
predictive models for disease prevention and management;
simulation and modelling tools for clinical decision support.

Such infrastructures play a critical role in facilitating the transition from research to clinical and regulatory implementation, helping ensure that AI-enabled and model-based solutions are robust, trustworthy, and responsibly deployed.

Further Information
European Commission – Digital Europe Programme and its work programmes.

Pharmaceutical legislation reform moves into implementation phase
The EU's major pharmaceutical reform package continued to advance following the political agreement reached in late 2025. In March 2026, the Council and Parliament published additional agreed texts clarifying implementation details for the future EU pharmaceutical framework, including:

- measures to improve access to medicines,
- stronger shortage prevention rules,
- incentives for innovation,
- simplification of regulatory procedures,
- updates for orphan and paediatric medicines.

📎 Sources:

- Council of the EU – Pharma Package Agreement
- European Medicines Agency – Reform of EU Pharmaceutical Legislation

Medical Devices Regulation (MDR) implementation intensifies
The European Commission increased operational preparations for MDR/IVDR implementation:

- confirmation that EUDAMED will become mandatory from 28 May 2026,
- publication of new implementing rules for conformity assessment and notified bodies,
- high-level discussions on improving the medical device regulatory system.

📎 Source:

- European Commission – Getting Ready for the New Regulations (MDR/IVDR)

European Health Data Space (EHDS) enters operational transition phase
The European Commission marked the first anniversary of the EHDS initiative and published updated FAQs and implementation materials. Main priorities included:

- cross-border electronic health record interoperability,
- secondary use of health data for research,
- governance for secure health data access,
- preparation for EHDS compliance by healthcare institutions and digital health companies.

📎 Sources:

- European Commission – European Health Data Space
- European Commission – Digital Health and Care

EMA focuses on clinical trial modernisation and resilience
The European Medicines Agency Management Board discussed:

- resilience of medicine supply chains,
- improvements to the Clinical Trials Information System (CTIS),
- alignment with the proposed EU Biotech Act,
- new clinical trial performance indicators.

📎 Source:

- EMA Management Board – March 2026 Highlights

CHMP recommends several innovative medicines
At its March 2026 meeting, the EMA's CHMP recommended approval of several important therapies, including:

- Adstiladrin for bladder cancer,

- Imdylltra for small-cell lung cancer,
- Joenja for activated PI3K delta syndrome.

This reflected the EU's continued focus on rare diseases and advanced therapies.

📎 Source:
- EMA CHMP March 2026 Meeting Highlights