Regulatory Round-up

October 2026

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UNITED KINGDOM

Medicines and Healthcare Products Regulatory Agency (MHRA)

UK Government accepts all recommendations on AI regulation in healthcare

The UK Government has accepted all 44 recommendations from the National Commission on the Regulation of AI in Healthcare and outlined a programme of regulatory reform to support the safe, effective and scalable adoption of AI-enabled health technologies.

Key priorities include:

- modernising the regulatory framework for AI-enabled medical devices
- delivering equitable access and outcomes for patients and members of the public, with a special focus on underserved populations
- shifting towards stronger post-market assurance
- enabling safe iteration and earlier patient access
- creating the assurance conditions necessary for safe, real-world deployment, including risk controls
- building system capability and readiness for widespread adoption of AI, including training of the workforce
- strengthening accountability, including through a culture of safety and reporting
- strengthening transparency and public confidence
- improving regulatory clarity and navigability
- strengthening regulatory capability and the evidence base for AI in healthcare

The response also commits to advancing tools such as Predetermined Change Control Plans (PCCPs), AI workforce training, and coordinated governance across healthcare, regulatory and research organisations, with an implementation roadmap due by Spring 2027.

The proposals signal a move towards risk-based, lifecycle-focused regulation, clearer qualification and classification criteria, greater reliance on real-world evidence, and increased alignment between the MHRA, National Institute for Health and Care Excellence (NICE) and other health system partners. Please find further information here.

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MHRA Strategy to 2030: what it means for you

The MHRA has published a series of explainers on its strategy to 2030, outlining what the strategy means in practice for healthcare professionals, innovators and academics, the life sciences industry, MedTech, patients and the public. The strategy focuses on modernising regulation in response to advances in science, technology and healthcare, with priorities including patient-centred regulation, faster access to innovation, safe adoption of new products and technologies, and strengthening the UK's position as a global life sciences leader.

UK Government confirms indefinite recognition of CE-marked medical devices

The UK Government has confirmed that CE-marked medical devices and in vitro diagnostic devices (IVDs) will continue to be recognised in Great Britain on a long-term basis, avoiding the need for an additional approval route for devices already approved for the EU market. The decision follows a public consultation and aims to maintain regulatory predictability, continuity of supply and patient access to medical technologies. The United Kingdom Conformity Assessed marking route will remain the domestic approval pathway, alongside strengthened post-market surveillance and ongoing reforms to modernise the UK medical device regulatory framework, including provisions addressing software and AI-enabled medical devices. Continued recognition of CE-marked devices also reflects the wider ambition of the MHRA Strategy to 2030 which expands reliance and recognition routes with trusted regulators, reducing regulatory burden, strengthening supply resilience and supporting timely patient access.

MHRA sets out new AI and MedTech regulatory agenda

The MHRA has outlined its developing approach to software and AI-enabled medical devices, including more flexible lifecycle regulation, regulatory sandboxes and increased international collaboration. The plans form part of the MHRA Strategy 2030 and include establishing a Centre for AI and Digital Health, improving device data and traceability, expanding recognition routes with trusted regulators, and using the AI Airlock regulatory sandbox to test approaches for AI-enabled medical devices. The MHRA is also strengthening collaboration with the US Food and Drug Administration (FDA) through the MHRA-FDA Pioneer Programme, while progressing wider reforms to medical device regulation and post-market surveillance. Please find more details here.

Health Research Authority (HRA)

UK commercial clinical trial set-up times continue to fall

The HRA has reported further improvements in UK commercial clinical trial set-up times. In January to March 2026, the average set-up time fell to 100 days, compared with 169 days in 2024/25 and 122 days in the first half of 2025/26. All 24 commercially

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sponsored clinical trials set-up during the quarter were completed within the Government's 150-day target. The HRA also reported improvements in Combined Review, with the median time for a Research Ethics Committee to provide a final outcome falling from 29 days in 2025 to 26 days in 2026, against a 60-day target.

Secure Data Environments reach national milestone for trusted research

The HRA has highlighted a major milestone in England's health data research infrastructure, with all regional NHS research Secure Data Environments (SDEs) now established and continuing to mature. SDEs allow approved researchers to access health data within secure, NHS-controlled environments, rather than patient-level datasets being transferred or downloaded. The Confidentiality Advisory Group supports appropriate use of confidential patient information through advice on Section 251 of the NHS Act 2006, alongside Research Ethics Committee review. The regional SDE Network will also provide a foundation for the development of the UK-wide Health Data Research Service, supporting more joined-up, secure and efficient access to health data for research. Please find further information here.

HRA responds to Information Commissioner's Office (ICO) consultation on anonymisation and pseudonymisation

HRA has responded to the ICO's consultation on draft guidance covering the use of anonymisation and pseudonymisation for research. The guidance aims to clarify when information constitutes personal data, how identifiability should be assessed, and how these principles apply in research settings, including Trusted Research Environments (TREs) and SDEs. The HRA has called for greater clarity on controller, processor and joint-controller relationships, the distinction between accessing data within a TRE/SDE and disclosing research outputs, and the role of the research sponsor as controller. It also emphasised the importance of distinguishing data protection requirements from the common law duty of confidentiality and wider research governance requirements.

Human Tissue Authority (HTA)

Consultation on the HTA's Code of Practice and Standards for the Research sector (Code E)

HTA is consulting on proposed changes to its research sector Code of Practice and Licensing Standards (Code E), which provides guidance for compliance with the Human Tissue Act 2004. The proposed revisions aim to improve clarity and usability, strengthen research-specific guidance, clarify regulatory expectations and support a proportionate, risk-based approach. Key changes include clearer guidance on regulated research activities, relevant material, consent and legal duties, the release of diagnostic material for research, and human application in light of developments in the regulation of Substances of Human Origin (SoHO), alongside additional practical

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examples and updated research standards. The consultation is open until 20 November 2026.

EUROPE

European Directorate for the Quality of Medicines (EDQM)

Council of Europe publishes position paper on ex situ manipulation of human organs

The European Committee on Organs, Tissues and Cells (CD-P-TO) has published a position paper proposing a European regulatory approach for human organs undergoing ex situ manipulation prior to transplantation. The paper defines ex situ manipulation as processing or intervention performed outside the human body that goes beyond static or dynamic preservation, such as genetic or enzymatic modifications. Such interventions may involve medicinal products, medical devices or SoHO applied for therapeutic or preventive purposes. The paper recommends that manipulated donated organs remain within the established transplantation legal and ethical framework, with a clear distinction between the organ itself and the technologies used to manipulate it.

EDQM releases 6th edition of the Tissues & Cells Guide

EDQM has released the 6th edition of the Guide to the quality and safety of tissues and cells for human application, providing updated technical and ethical guidance for professionals working with SoHO. The revised edition reflects recent scientific and clinical developments and introduces a new four-level structure covering standards, Good Practice Guidelines, recommendations and supplementary information. It also updates terminology to align with regulation (EU) 2024/1938 on Substances of Human Origin and includes 52 SoHO monographs, 11 of which are new. Please find further information here.

European Medicines Agency (EMA)

EMA launches roadmap initiative to advance women's health in medicines development

EMA has announced plans to develop a regulatory roadmap by the end of 2026 to improve how women's health is considered throughout medicines development and regulation. The initiative follows a multi-stakeholder workshop held in Amsterdam on 28-29 September 2026, which brought together more than 100 representatives from regulatory authorities, patient groups, healthcare professionals, academia, industry and NGOs. Participants identified ten priority actions aimed at addressing persistent gaps in research, evidence generation, diagnosis, treatment and clinical trial representation of women. The roadmap will outline short-, medium- and long-term

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actions to promote more inclusive medicines development and support better health outcomes for women in Europe and beyond. Please find more details here.

ACT EU clinical trial application advice pilot to become permanent

EMA has announced that the Accelerating Clinical Trials in the EU (ACT EU) clinical trial application advice pilot will become a permanent initiative from January 2027. Coordinated by the Heads of Medicines Agencies (HMA) through its Clinical Trials Coordination Group, the service provides sponsors with consolidated technical and regulatory advice before submission of clinical trial applications through the Clinical Trials Information System. Since its launch in 2024, the pilot has helped improve application quality and support more efficient assessment processes across the EU regulatory network. A final report summarising lessons learned from approximately 30 pilot applications is expected by the end of 2026, with updated guidance and templates to follow in January 2027. Please find more details here.

EMA consults on Data Quality Framework for adverse drug reaction reporting

EMA has published for consultation a draft chapter of its Data Quality Framework (DQF) for EU medicines regulation, focusing on the collection, management and submission of adverse drug reaction (ADR) reports. The document addresses data quality challenges across five dimensions: reliability, extensiveness, coherence, timeliness and relevance, and provides recommendations to improve the quality of ADR data used in regulatory decision-making for both human and veterinary medicines. The deadline for comments is on 14th December 2026.

Concept paper on the need for the guideline on the clinical investigation of medicinal products for the treatment of inherited retinal dystrophies - Scientific guideline

EMA has published a concept paper proposing a new guideline on the clinical investigation of medicinal products for inherited retinal dystrophies (IRDs). The guideline would clarify EU regulatory expectations for demonstrating safety and efficacy, addressing areas including trial populations and design, comparators, endpoints, paediatric considerations, minimum efficacy and safety requirements, and, where applicable to advanced therapies and biologicals, immunogenicity and shedding. The concept paper notes ongoing development of gene therapies, gene-agnostic approaches and optogenetic therapies for IRDs. The consultation is open until 31 January 2027, with a draft Committee for Medicinal Products for Human Use (CHMP) guideline planned for consultation by Q4 2027.

USA

Food and Drug Administration (FDA)

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FDA launches Rare Disease Framework Initiative

The FDA has launched the Rare Disease Framework Initiative, a new programme aimed at developing a holistic, fit-for-purpose framework for rare disease drug and biologic development. The initiative seeks to improve clarity, consistency and predictability in regulatory decision-making while recognising the unique challenges of generating evidence in small patient populations. Key priorities include stronger patient engagement, greater use of external expertise, risk-based regulatory approaches, and the adoption of innovative scientific and statistical methods to support rare disease product development. Public feedback will help shape the framework through meetings, roundtables and future consultations.

FDA Updates Biological Product and HCT/P Deviation Reporting Codes

The FDA has updated its resources for Biological Product Deviation (BPD) and Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P) Deviation Reporting. The Deviation Codes resource provides codes used to classify specific reportable events when submitting a BPD report to the FDA, while the separate Non-Blood Product Codes resource provides the corresponding product-code information for non-blood biological products. Both resources identify changes introduced on 1 October 2025.

View the FDA Deviation Codes | View the FDA Non-Blood Product Codes.

FDA launches new programme to advance neuroscience medical product development

The FDA has launched the Neuroscience Advancement and Innovation Nexus (NAIN), a new programme designed to advance the science, tools and regulatory approaches supporting development of medical products for conditions affecting the brain and nervous system. Bringing together expertise across drugs, biologics and medical devices, NAIN will initially focus on the Alzheimer's Prevention Accelerator, exploring innovative approaches to clinical trials for Alzheimer's disease prevention and early-intervention drug development.

Individualised human genome editing products: considerations for biologics license application submission and post approval management

The FDA has issued a draft guidance, *Individualised Human Genome Editing Products: Considerations for Biologics License Application (BLA) Submission and Post approval Management*, providing recommendations on how individualised human genome editing products with multiple product variants may be submitted within a single BLA. The guidance addresses defining the extent of genome editing component variation within a BLA, adding new product variants after licensure,

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manufacturing and control strategies, potency and safety, and product labelling and naming. The deadline for comments is 27 November 2026.

INTERNATIONAL

International Coalition of Medicines Regulatory Authorities (ICMRA)

ICMRA calls for advancement of alternatives to animal testing

The ICMRA has issued a statement supporting the continued transition towards scientifically valid, regulatory-acceptable alternatives to animal testing throughout the medicines lifecycle, from early development and non-clinical testing through to licensing, marketing and batch release. ICMRA calls on developers, manufacturers and regulators to advance non-animal approaches, including in vitro, ex vivo, in silico and human-derived methods, while continuing to apply the 3Rs principles of Replacement, Reduction and Refinement where animal testing remains necessary. The statement particularly encourages validated non-animal methods for batch release testing and greater international harmonisation of regulatory requirements and acceptance criteria.

International Conference on Harmonisation (ICH)

ICH expands Training Library with materials overing 11 Harmonised Guidelines

The ICH has expanded its Training Library with new materials covering 11 harmonised guidelines. Published between July and October 2026, the resources include presentations, videos, transcripts and multi-module training packages designed to support globally harmonised implementation of ICH guidelines.

The new materials cover ICH E6(R3) Good Clinical Practice, E14/S7B, M11 CeSHarP, M13B, M15, and principles and concepts relating to ICH Quality Guidelines Q8–Q12. Notably, new E6(R3) modules address Data Governance and Essential Records, while ten new modules support implementation of the M11 clinical electronic Structured harmonised Protocol. Please find further information here.

Public consultations

Human Tissue Authority (HTA)

	Title	Consultation Period	Category

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1.	*Consultation on the HTA's Code of Practice and Standards for the Research sector (Code E)*	*End Date: 20 November 2026*	*Public Consultation*

EUROPEAN MEDICINES AGENCY (EMA)

	Title	Consultation Period	Category
1.	*Data Quality Framework (DQF) for EU medicines regulation: application to collection, management and submission of Adverse Drug Reaction reports*	*End Date: 14 December 2026*	*Public consultation*
2.	*Guideline on the clinical requirements for medicines intended for the treatment of sickle cell disease*	*End Date: 31st January 2027*	*Draft Guideline*
3.	*Guideline on the clinical requirements for medicines intended for the treatment of thalassaemia*	*End Date: 31st January 2027*	*Draft Guideline*
4	*Concept paper on the need for the guideline on the clinical investigation of medicinal products for the treatment of inherited retinal dystrophies - Scientific guideline*	*End date:31 January 2027*	*Public consultation*

Food and Drug Administration(FDA)

	Title	Consultation Period	Category
1.	*Potency Assessment of Active Immunotherapy Products*	*End date: 18 November 2026*	*Draft guidance*
2.	*Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management*	*End date: 27 November 2026*	*Draft guidance*
3.	*Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosage*	*End date: 1 December 2026*	*Draft guidance*
4.	*Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosage*	*End date: 01 December 2026*	*Draft guidance*

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5.	*Fit-for-Purpose Rare Disease Framework Initiative; Public Meeting; Request for Information and Comments*	*End date: 11 December 2026*	*Request for comment*

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