# Regulatory Round-up

## July 2026

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**United Kingdom**

**Medicines and Healthcare products Regulatory Agency (MHRA)**

### MHRA delivers record performance as 2025-26 Annual Report and Accounts confirms growing global influence

The MHRA has published its 2025–26 Annual Report highlighting a year of strong regulatory performance.

The key regulatory highlights of the report are:

- Approving 921 medicinal products for use, including 39 new medicines, while assessing 100% of clinical trial applications and 97% of national medicines licence applications within target timelines.
- Launch of the Aligned Pathway and Integrated Scientific Advice service between the MHRA and National Institute for Health and Care Excellence (NICE), accelerating medicines access by 3–6 months.
- Proposing a new Rare Disease Therapies Regulatory Framework to support earlier, more frequent, and iterative engagement with developers, providing structured regulatory flexibility where conventional approaches are not feasible.
- Development of the new clinical trials regulations to make it easier and faster to run safe high-quality trials in the UK.
- Playing a leading role in shaping the future regulation of AI in healthcare, with the launch of the National Commission into the Regulation of AI in Healthcare bringing together global AI leaders, clinicians, and regulators to advise the MHRA on the development of a new regulatory framework.
- Securing £7.5 million in new research grant funding to advance regulatory science and support innovation in medicines and medical devices.
- Supporting public health research and regulatory decision-making through the Clinical Practice Research Datalink, using anonymised UK primary care data to generate real-world evidence.

- The Department of Health and Social Care has agreed a set of economic growth goals with the MHRA to ensure regulation supports innovation, investment, and patient access while maintaining high safety standards. The aim is to make the UK a faster, more predictable, and innovation-friendly environment for medicines development and clinical research, while continuing to protect patient safety.

Please find the MHRA economic growth goals policy paper here.

## MHRA data requirements to support regulatory decision-making

The MHRA has set out its requirements for a future UK Health Data Research Service (HDRS), highlighting the need for timely access to high-quality, linked real-world health data to support regulatory decision-making, strengthen post-market surveillance, and enhance patient safety while enabling innovation across the life sciences sector. Some of the data types to be featured in the HDRS currently under development are post-market surveillance data, medical device data, and secondary prescribing data. Please find further information here.

## Parallel Review applications for an investigational medicinal product study and an investigational medical device study

In July 2026, the MHRA published updated guidance on Parallel Review applications for studies involving both an investigational medicinal product and an investigational medical device. The guidance applies when a clinical study meets the definitions of both a Clinical Trial of an Investigational Medicinal Product and a Clinical Investigation of a Medical Device (previously known as a combined trial), requiring coordinated review by MHRA medicines and devices teams.

The updated Parallel Review process is intended to bridge differences between medicinal product and medical device regulatory frameworks, timelines, and submission systems, providing applicants with a more streamlined and coordinated regulatory pathway. The MHRA notes that the process has historically been complex and that the revised guidance has been developed to improve the applicant experience and facilitate more efficient assessment of combined medicine-device studies.

While the new research management systems and wider regulatory and digital integration initiatives are being developed, applicants must continue to submit information through both the standard Integrated Research Application System (IRAS) processes and the new sections of IRAS. The MHRA's longer-term objective is to align regulations and processes further in collaboration with the Health Research Authority, supporting a unified submission and review experience for complex clinical research

involving both medicinal products and medical devices. Please find further information here.

## International Recognition Procedure update

The MHRA has updated the International Recognition Procedure to improve efficiency and predictability for marketing authorisation applications that rely on approvals from trusted international reference regulators.

Key updates effective from 13 July 2026:

- Single opportunity to respond to Validation Correction Requests.
- 8-week advance notice required for submissions involving new active substances.
- Route B eligibility window reduced from 10 years to 5 years from the reference regulator's approval date.
- Route A eligibility window remains unchanged at 2 years.
- Transition period allows applicants to use the previous process until 31 August 2026.

Please find further information here.

**Department of Health & Social Care (DHSC)**

## HMG commitments following the Joint Taskforce

A joint taskforce of government and the pharmaceutical industry recently concluded a 10-week sprint process to consider the future of the voluntary scheme, and novel solutions to improve the commercial environment for medicines. As of 2nd July 2026, HM Government has published four new pilots which will work to improve access to innovative medicines, strengthen the UK's life sciences sector, and enhance the medicines commercial environment:

1. Ring-fenced Regional Medicines Budgets
    - Regional budgets to have separate funds for provision of “priority medicines.”
2. Reformed Managed Access Pathways
    - A full cost-effectives analysis not required prior to entry to a managed access agreement (MAA), instead made on MAA exit.
    - Enabling some kind of reimbursement for drugs which do not achieve a NICE recommendation at the end of a MAA.

3. Productivity in NICE HTA Assessments
    - Broadening of the assessment perspective from NHS and Personal Social Services (PSS) costs to also include broader productivity impacts.
4. New Commercial Option for the Budget-Impact Test
    - Broadening of commercial mitigation strategies available to manufacturers if their NICE approved technology breaches the budget-impact threshold.

## EUROPE

### European Directorate for the Quality of Medicines (EDQM)

#### Publication of revised Ph. Eur. general chapter 5.1.6 on alternative microbiological methods

EDQM has announced the publication of the revised European Pharmacopoeia (Ph. Eur.) General Chapter 5.1.6 "Alternative Methods for Control of Microbiological Quality", reflecting the latest developments in rapid and alternative microbiological methods. The revision is intended to facilitate the implementation of modern microbiological testing approaches while maintaining the required level of quality assurance and regulatory compliance. The updated chapter provides clearer guidance on validation strategies based on product-specific risk assessments and better defines the responsibilities of suppliers and users. A training session on the revised chapter will be held for stakeholders during the EDQM Microbiology symposium (13-15 October 2026). Please find further information here.

#### Council of Europe publishes a follow-up position paper on the implementation of the EU's Medical Devices Regulation in the substances of human origin sector

On 8 July 2026, the EDQM, through the European Committee on Organs, Tissues and Cells (CD-P-TO), published a follow-up position paper examining the impact of the EU Medical Devices Regulation (MDR) (Regulation (EU) 2017/745) on the substances of human origin (SoHO) sector. The paper highlights ongoing concerns regarding the practical application of MDR requirements to SoHO organisations

The position paper builds on previous CD-P-TO work that identified risks arising from shortages of essential CE-marked medical devices used in SoHO activities. While acknowledging that the EC's proposed MDR revisions address some previously raised concerns, the committee notes that significant uncertainties remain regarding the interpretation and implementation of Article 5(5) of the MDR in the SoHO context.

Particular attention is given to two common scenarios encountered by SoHO establishments: the use of research-use-only (RUO) products for medical purposes by health institutions, and the use of CE-marked medical devices beyond the manufacturer's originally intended purpose. The committee calls on the EC and the Medical Device Coordination Group to provide further clarification and revisions to the existing guidance. The objective is to ensure that Article 5(5) is applied appropriately to genuine in-house manufacturing activities and does not unintentionally restrict the use of RUO products or repurposed CE-marked devices.

## European Medicines Agency (EMA)

### EMA and European Innovation Council and SMEs Executive Agency (EISMEA) boost cooperation to accelerate health innovations

On 15 July 2026, the EMA and the EISMEA signed a Letter of Intent to strengthen their cooperation aimed at supporting health innovation across the European Union. The initiative is designed to help innovators better understand regulatory requirements and accelerate the development of innovative medicines and healthcare technologies for patients.

Key objectives of the enhanced collaboration include:

- Supporting innovative SMEs, start-ups, spin-offs, universities, and research organisations through training, awareness activities, outreach, and provision of support.
- Improving regulatory readiness for emerging and disruptive health technologies and supporting with horizon scanning and stakeholder engagement.
- Providing innovators with training and education.
- Implementing a 2026–2027 rolling work programme that converts shared goals into concrete actions.

Please find further information here.

### EMA steps up efforts on medicines for women's health

2 July 2026, the EMA announced a series of initiatives to strengthen the integration of women's health considerations into medicines development, evaluation, and regulation across the European Union. The goal is to address persistent gaps in disease prevention, diagnosis, treatment, and research that disproportionately affect women.

EMA's ongoing and planned activities focus on four main areas:

1. Representation in Clinical Trials – EMA will further analyse data from the Clinical Trials Information System to ensure women are appropriately represented in clinical studies and that trial populations reflect the patients likely to use the medicines being developed.
2. Assessment and Labelling of Medicines – The Agency will continue to evaluate and communicate potential sex-specific differences in medicine efficacy, safety, and dosing through product labelling.
3. Medicines During Pregnancy and Breastfeeding – The main actions include funding post-authorisation studies of medicines in pregnancy, improving methods for detecting pregnancy-specific safety signals, advancing methodological guidance, strengthening pharmacovigilance practices, and contributing to international guidance such as the International Conference on Harmonisation (ICH) E21 guideline on the inclusion of pregnant and breastfeeding individuals in clinical trials.
4. Real-World Evidence (RWE) – Through the DARWIN EU® network, EMA is conducting and expanding studies on medicine use and disease epidemiology relevant to women's health, generating evidence from real-world clinical practice to complement clinical trial data.

Please find further information here.

## USA

### Food and Drug Administration (FDA)

### FDA approval: Tregzi

On 30 June 2026, the FDA approved Tregzi, the first regulatory T-cell (Treg)-based immunotherapy indicated to improve chronic graft-versus-host disease (GVHD)-free survival in adult patients with blood cancers undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT).

Tregzi is a donor-derived cellular therapy composed of purified hematopoietic stem and progenitor cells, regulatory T cells (Tregs), and conventional T cells obtained from an HLA-matched donor. The therapy is designed to support immune reconstitution while reducing the risk of chronic GVHD, a serious post-transplant complication in which donor immune cells attack the recipient's tissues.

According to the FDA, this approval addresses an important unmet need by providing a novel cellular therapy approach that not only supports cancer treatment through transplantation but also helps reduce the long-term burden of chronic GVHD, potentially improving overall patient outcomes and quality of life.

## FDA approval of an expanded indication: Casgevy

On July 1, 2026, the FDA announced the approval of an expanded indication for Casgevy (exagamglogene autotemcel), now approved for children aged 2 years and older with sickle cell disease with recurrent vaso-occlusive crises or transfusion-dependent β-thalassemia (TDT). Previously, Casgevy was approved only for patients aged 12 years and older.

Casgevy is a gene therapy consisting of autologous hematopoietic stem cells, administered as a one-time single dose for intravenous infusion. The cells are edited using CRISPR/Cas9 and engrafted in the bone marrow, increasing levels of foetal haemoglobin (HbF), addressing the underlying cause of the diseases. Please find further information here.

## FDA proposes rule to modernise drug manufacturing registration

The FDA has issued a proposed rule to modernise drug establishment registration and drug listing requirements, aiming to support advanced manufacturing technologies, strengthen supply chain transparency, and improve regulatory oversight. If finalised, the rule would introduce a streamlined registration pathway for decentralised manufacturing establishments operating under a "hub-and-spoke" model, allowing multiple manufacturing units overseen by a central quality system to register as a single establishment rather than maintaining separate registrations for each site.

The proposed rule would also clarify registration and drug listing obligations for certain foreign drug manufacturing establishments, including facilities producing active pharmaceutical ingredients (APIs) that indirectly enter the U.S. drug supply chain. FDA states that the changes would improve visibility into upstream manufacturing activities and enhance the agency's ability to identify, trace, and respond to potential quality and safety concerns.

Please find further information here.

## FDA guidance documents on cancer clinical trial eligibility

FDA has issued a series of guidance documents on cancer clinical trial eligibility criteria that encourage sponsors to adopt a more inclusive, scientifically justified, and patient-centric approach to trial design. Specifically, the agency recommends that laboratory value thresholds, performance status requirements, washout periods, and concomitant medication restrictions should be based on the safety profile and mechanism of action of the investigational product rather than on overly conservative or historically established criteria. By minimising unnecessary exclusions, sponsors

can improve trial enrolment, increase the diversity and representativeness of study populations, and generate clinical evidence that is more applicable to real-world patients who may ultimately receive the therapy in routine clinical practice.

The guidance documents are available below:

Cancer Clinical Trial Eligibility Criteria: Laboratory Values | FDA

Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications | FDA

Cancer Clinical Trial Eligibility Criteria: Performance Status | FDA

**INTERNATIONAL**

**International Conference on Harmonisation (ICH)**

### ICH E6(R3): Good clinical practice annex 2 adopted and published

The ICH has announced the adoption and publication of ICH E6(R3) Good Clinical Practice (GCP) Annex 2 on 3 June 2026, completing the revision of the ICH E6(R3) Guideline. The revised guideline has been consolidated into a single document comprising the GCP Principles, Annex 1, and Annex 2, reflecting a modern, flexible, and risk-proportionate approach to the design and conduct of clinical trials.

Annex 2 provides additional GCP considerations for emerging and innovative trial methodologies, including decentralised clinical trial elements, pragmatic clinical trials, and the use of real-world data. The guidance aims to ensure that participant rights, safety and well-being remain protected while supporting advances in technology, alternative trial designs, and evolving data sources.

Please find further information here.

## Public consultations

**Food and Drug Administration (FDA)**

| | Title | Consultation Period | Category |
|---|---|---|---|
| **1.** | *Master Protocols for Drug and Biological Product Development* | *End date: 24 August 2026* | *Draft guidance* |
| **2.** | *Leveraging Prior Knowledge in the Development of Human Gene* | *End date: 1 September 2026* | *Draft guidance* |

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| | *Therapy Products Incorporating Genome Editing* | | |
| **3.** | *Drug Establishment Registration and Drug Listing Requirements for Establishments Engaged in Distributed Manufacturing and Certain Foreign Establishments* | *End date: 11 September 2026* | *Public consultation* |