Regulatory Round-up

August 2026

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UNITED KINGDOM

Medicines and Healthcare products Regulatory Agency (MHRA)

Pioneering AI health innovations regulatory sandbox launched

The launch of the London AI Health Innovations Regulatory Sandbox marks an important milestone in advancing the safe and responsible adoption of AI-enabled medical technologies across the NHS. Designed as a real-world testing environment, the London sandbox will enable regulators, healthcare providers, and innovators to collaborate in evaluating the safety, effectiveness, and clinical benefits of AI medical devices under appropriate regulatory oversight. Please find further information here.

MHRA launches consultation on statutory fees for 2026

The MHRA has launched a public consultation on proposed updates to its statutory fees from 1 April 2027. The proposals are intended to support ongoing cost recovery and fund service improvements, including:

- enhanced service standards
- greater support for eligible SMEs
- improvements to scientific advice services
- updates to medical device post-market surveillance activities.

The consultation seeks stakeholder views on inflation-linked fee increases for most services, as well as targeted changes for selected higher-value services, with responses invited until 25 September 2026.

UK Space Agency (UKSA)

UK Space Agency seeks stakeholder input on in-orbit pharmaceutical manufacturing

The UKSA is working with the MHRA, Civil Aviation Authority and Regulatory Innovation Office to improve regulatory clarity and develop a regulatory roadmap for space-enabled pharmaceutical manufacturing. They have issued a Request for Information (RFI) to gather stakeholder feedback on the development of in-orbit pharmaceutical research, development and manufacturing. The initiative is part of the Government's *Unlocking Space for Business* programme and aims to better

understand the barriers and opportunities facing the emerging space-biopharma sector. The Agency Responses will help inform future support measures and commercialisation activities intended to advance the UK's capabilities in space-based drug discovery and manufacturing. Please find further information here.

EUROPE

European directorate for the quality of medicines (EDQM)

EDQM enhances Certificate of Suitability (CEP) database with new data download feature

EDQM has introduced a new feature to its CEP database, allowing users to download complete CEP datasets. The enhancement is intended to improve access to certification information and increase transparency for stakeholders using CEP data. CEPs confirm that a pharmaceutical substance complies with the relevant European Pharmacopoeia standards and are widely used to support regulatory submissions across Europe and other jurisdictions. Please find further information here.

New control of ethylene glycol and diethylene glycol in Macrogols (1444) published for comment

The EDQM has published for public consultation a proposed revision to the European Pharmacopoeia monograph Macrogols (1444), introducing a new gas chromatography method for the determination of ethylene glycol (EG) and diethylene glycol (DEG). The revision aims to strengthen the detection and control of these toxic contaminants in macrogol (polyethylene glycol) excipients, addressing ongoing global concerns regarding contamination and adulteration risks. The proposal includes separate acceptance limits for EG (620 ppm) and DEG (0.10%), replacing the current combined limit approach. Stakeholders should assess the impact on raw material specifications, supplier qualification programs, analytical methods, and quality control testing to ensure readiness for potential implementation following the consultation period.

The consultation period is open until 30 September 2026, and EDQM has encouraged submission of comments supported by analytical data. Please find further information here.

European medicines agency (EMA)

EMA and Heads of Medicines Agencies (HMA) launch consultation on draft European Medicines Regulatory Network (EMRN) data standards framework

The EMA and the HMA have launched a public consultation on the draft EMRN Data Standards Framework. The framework aims to establish a structured approach for

the adoption, development, update, and implementation of data standards across the EMRN, supporting greater interoperability, data quality, and data exchange in medicines regulation. It introduces a streamlined governance process with defined roles and responsibilities to accelerate standards implementation and reduce the fragmented, ad hoc approaches used previously. The consultation is open until 18 September 2026.

EMA updates pre-authorisation procedural advice for centralised marketing authorisation applications

Please find EMA's updated Questions & Answers (Q&A) document providing pre-authorisation procedural advice for centralised marketing authorisation applications including revised guidance on eligibility requests and procedural requirements for marketing authorisation applications. The update also supports ongoing implementation of EMA digital submission initiatives, including use of the Product Lifecycle Management portal and electronic application forms (eAFs). Applicants are encouraged to review the revised guidance to ensure compliance with current submission requirements and timelines.

USA

Food and drug administration (FDA)

FDA accelerated approval: Tudriqev

FDA has granted accelerated approval for Tudriqev (vusolimogene oderparepvec-wtpg), a genetically modified oncolytic viral immunotherapy, which is based on a modified herpes simplex virus type 1 (HSV-1) that is engineered to selectively target and destroy cancer cells. Tudriqev is administered in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma that has progressed following PD-1 inhibitor therapy.

FDA accelerated approval: Genglycos

The FDA has granted accelerated approval for Genglycos (pariglasgene brecaparvovec-opnr), the first approved treatment for glycogen storage disease type Ia (GSDIa) in adults and children aged 8 years and older. Glycogen storage disease type Ia (GSDIa), also known as von Gierke disease, is a rare inherited metabolic disorder caused by deficiency of the enzyme glucose-6-phosphatase due to pathogenic variants in the G6PC gene. The one-time AAV8-based gene therapy is designed to address the underlying cause of the disease by delivering a functional copy of the G6PC gene, helping to reduce patients' reliance on daily cornstarch supplementation as part of nutritional management.

FDA issues draft guidance on potency assessment for active immunotherapy products

The FDA has published a draft guidance, *Potency Assessment of Active Immunotherapy Products*, providing recommendations for the design, validation and evaluation of potency assays as part of a potency assurance strategy for active immunotherapy products (ACTIMPs). The guidance outlines approaches for identifying potency-related critical quality attributes and developing appropriate assays to demonstrate biological activity and product consistency throughout development and manufacture.

Active immunotherapy products are intended to treat existing diseases by inducing, stimulating or modulating immune responses through the introduction of disease-associated antigens. The draft guidance includes considerations for peptide-, protein-, vector- and cell-based ACTIMPs, and is intended to supplement the FDA's broader draft guidance on *Potency Assurance for Cellular and Gene Therapy Products*. The FDA notes that potency assessment for ACTIMPs can be particularly challenging due to their dependence on host immune responses and encourages sponsors to develop robust, quantitative potency assays linked to the product's mechanism of action. Comments on the draft guidance are invited until 18 November 2026**.**

FDA finalises guidance addressing frequently asked questions (FAQ) on cell and gene therapy development

The FDA has issued a final guidance, *Frequently Asked Questions: Developing Potential Cellular and Gene Therapy Products*, providing answers to common regulatory, chemistry, manufacturing and controls (CMC), nonclinical, clinical, and clinical pharmacology questions encountered during the development of cell and gene therapy products. The guidance is intended to support more efficient product development and regulatory interactions, helping sponsors navigate key aspects of the cell and gene therapy (CGT) development pathway. The guidance consolidates FDA responses to FAQ across the CGT lifecycle, including Investigational New Drug (IND) submissions, regulatory interactions, meeting for advanced therapies.

FDA issues draft guidance on container closure systems for drugs and biologics

The FDA has published a draft guidance, "Container Closure Systems for Human Drugs and Biological Products," providing updated recommendations on the pharmaceutical quality, CMC considerations for container closure systems used with human drugs and biological products. The guidance outlines both, general principles and product-specific considerations for the development, assessment and lifecycle

management of packaging systems, including those used in combination products. When finalised, it will replace FDA's previous container closure guidance issued in 1999 and 2002, reflecting advances in science, technology and regulatory expectations. The deadline for comments is on 13th October 2026.

FDA outlines plan to strengthen early clinical development in the US

The FDA has identified challenges within the current pre-IND process, including increasing development complexity, unclear Phase 1 data requirements and limited opportunities for iterative regulatory engagement. To address these issues, the FDA announced plans to modernise the IND pathway through clearer expectations for sponsors and the launch of an Expedited IND Pilot aimed at improving the speed, predictability and efficiency of early-stage clinical development. Please find further information here.

FDA finalises guidance on formal meetings between sponsors and the Agency for Prescription Drug User Fee Act (PDUFA) products

The FDA has finalised its guidance, *Formal Meetings Between the FDA and Sponsors or Applicants of Prescription Drug User Fee Act Products*, providing updated recommendations on formal interactions between sponsors and the Agency during the development and review of new drug and biological products regulated by Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). The guidance outlines meeting types, formats, request procedures, and timelines intended to support efficient regulatory engagement throughout product development.

INTERNATIONAL

International conference on harmonisation (ICH)

Updated support package published for ICH M8: Electronic Common Technical Document (eCTD)

On 30 July 2026, the ICH announced updates to the support materials for ICH M8: Electronic Common Technical Document (eCTD) v4.0. The updated package includes revisions to the Implementation Guide Package, Controlled Vocabulary Package, and Q&A document. The eCTD v4.0 information and update packages can be accessed here.

Therapeutic goods administration (TGA)

TGA seeks feedback on planned adoption of international scientific guidelines

Australia's TGA has launched a consultation on the adoption of 11 additional international scientific guidelines as part of its ongoing strategy to align with global regulatory standards. Among the documents under consideration is the EMA *Guideline on the Immunogenicity Assessment of Therapeutic Proteins*. Although primarily intended for biological medicinal products, the guideline is also relevant to Advanced Therapy Medicinal Products (ATMPs). Gene therapies and genetically modified cell therapies often involve the *in vivo* expression of engineered or foreign proteins—such as the chimeric antigen receptor constructs found in Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), and Breyanzi (lisocabtagene maraleucel). Because host immune responses against these synthetic domains can alter product clearance, safety, efficacy, and overall treatment durability, these established protein risk-assessment and assay validation frameworks serve as a relevant reference point for evaluating immunogenicity across such modern advanced therapies.
Please find further information on TGA's planned adoption of scientific guidelines here.

Public consultations

Medicines and Healthcare products Regulatory Agency (MHRA)

	Title	Consultation Period	Category
1.	*MHRA consultation on statutory fees (2026)*	*End Date: 25 September 2026*	*Public Consultation*

UK Space Agency (UKSA)

	Title	Consultation Period	Category
1.	*Unlocking Space for Business: In-orbit R&D and manufacturing of pharmaceuticals RFI*	*End Date: 7 September 2026*	*Reguest for Information*

European Medicines Agency (EMA)

	Title	Consultation Period	Category
1.	*Draft - EMRN Data Standards Framework*	*End date: 18 September 2026*	*Public Consultation*

Food and Drug Administration (FDA)

	Title	Consultation Period	Category
1.	*Drug Establishment Registration and Drug Listing Requirements for Establishments Engaged in Distributed Manufacturing and Certain Foreign Establishments*	*End date: 11 September 2026*	*Public consultation*
2.	*Container Closure Systems for Human Drugs and Biological Products Guidance for Industry*	*End date: 13 October 2026*	*Draft guidance*
3.	*Potency Assessment of Active Immunotherapy Products*	*End date: 18 November 2026*	*Draft guidance*