Medicines & Healthcare products Regulatory Agency

Recent Developments – MHRA

EFSPI, Basel, 2026

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Contents

The MHRA remit and responsibilities

- We are the Medicines and Healthcare products Regulatory Agency (MHRA).
- We are the UK regulator of medicines, medical devices and blood components for transfusion.
- We are responsible for making sure these products meet set standards for safety, quality and efficacy.
- The MHRA left the EMA regulatory eco-system in January 2021.
- The Windsor Framework that came into place from 1 January 2025 means MHRA makes decisions for the whole of the UK, and not for GB only.
- The MHRA is an independent regulator and makes national decisions for all medicines.

Types of UK marketing authorisation procedures and pathways; focussing on new medicines

Licensing Pathways Update

National application	150 day 210 day Rolling review (modular submission)
Collaboration	ACCESS Consortium Project Orbis
International Recognition	Recognition A Recognition B

Improved Timelines for New Medicines

The innovative medicines timetable allows for a positive decision within 150 clock-on days if all issues are resolved following one round of questions.

National assessment procedure for medicines - GOV.UK

MHRA-NICE alignment is a UK initiative within the 10-Year Health Plan to accelerate patient access to new medicines by enabling parallel decision-making on safety/licensing and clinical/cost-effectiveness… aiming to provide parallel approvals and recommend new treatments for NHS use 3-6 months faster than before.

Medicines 3-6 months faster under 10-Year Health Plan

Guidance

National assessment procedure for medicines

Guidance on the MHRA's national assessment procedure for marketing authorisation applications.

Press release

Patients will receive medicines 3-6 months faster under 10-Year Health Plan, as regulators set out plans

Under a joint information sharing agreement, pharmaceutical companies will be invited to register early with the MHRA and NICE to allow parallel decision making over licencing and value.

The Access Consortium

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

- brings together medicines regulators in Australia, Canada, Singapore, Switzerland and the UK to grow and advance regulatory cooperation and alignment
- coordinated medicine application review process gives potential access to a combined population of 150 million people
- consolidated list of questions from trusted regulators simplifies submission process
- predictable timelines, comparable to other leading regulatory procedures
- Access continues to mature as a practical, multi-market pathway:
  - 73% increase in submissions through New Active Substance work-sharing initiative in 2025 compared to 2024
  - more 4 and 5 country submissions
- exploring ways to align regulatory standards across the life cycle of medicines – industry engagement is key.

Project Orbis

Project Orbis is a programme to review and approve promising cancer drugs helping patients access treatments faster.

The programme provides a framework for concurrent submission and review of oncology products among international partners. It aims to deliver faster patient access to innovative cancer treatments with potential benefits over existing therapies.

Project Orbis is coordinated by the US Food and Drug Administration (FDA). Alongside the MHRA, it involves the regulatory authorities of:

TGA, Health Canada, HSA, Swissmedic, ANVISA, and Ministry of Health - Israel

UK Aim is to be involved in as many Type A and B applications as possible for the benefit of UK patients.

Reliance Route: International Recognition Procedure (IRP) (1 of 2)

- Open where applicants that have already received an authorisation for the same product from one of MHRA's specified reference regulators (RRs).
- Allows the MHRA to take into account the expertise and decision-making of trusted regulatory partners for the benefit of UK patients.
- The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust.

Reliance Route: International Recognition Procedure (IRP) (2 of 2)

Summary of IRP

- Two different timetables and fees for initial marketing authorisation applications only.
- Recognition A is 60 calendar days with no clock-stop.
- Recognition B is 110 calendar days with clock-stop at day 70 if required.

- The pre-submission eligibility form will determine suitability for Recognition A or B.
- Applicant to complete 6 weeks before submission.
- In a few cases MHRA triage needed to determine if A or B.

Innovative Licensing and Access Pathway (ILAP) – 2.0

- **Relaunched** 30 January 2025
- The ILAP scheme aims to accelerate the time to market for innovative and transformative medicines and drug-device combinations.
  - **Criterion 1**: the intended indication of the product is life-threatening and/or seriously debilitating and there is a significant unmet clinical need.
  - **Criterion 2**: the product must be innovative; it is novel, or it is an approved medicine being developed in a clinically significant new indication.

Innovative Licensing and Access Pathway (ILAP) - GOV.UK

The new ILAP ambition

The Innovative Licensing and Access Pathway (ILAP) is a unique initiative focused on getting the **most transformative new medicines to patients** in the **National Health Service (NHS)** more quickly.

The ILAP is the only **end-to-end access pathway** in the world which aims to accelerate the time to patient care for transformative medicines and drug-device combinations, facilitating patient access by providing a **single integrated platform** for sustained **collaborative working** between the developer and the ILAP partners.

Accelerating innovation

Launched the **Aligned Pathway and Integrated Scientific Advice service** between the MHRA and NICE, accelerating medicines access by 3–6 months.

Health System Alignment

MHRA-NICE alignment is a UK initiative within the 10-Year Health Plan to accelerate patient access to new medicines by enabling parallel decision-making on safety/licensing and clinical/cost-effectiveness… aiming to provide parallel approvals and recommend new treatments for NHS use 3-6 months faster than before.

Medicines 3-6 months faster under 10-Year Health Plan

MHRA-NICE Approval Pathway NICE launched and includes an Integrated Scientific Advice service that offers drugmakers a single-entry point, meeting and report, and one payment, while aligning data and scientific expectations where possible

Press release

Patients will receive medicines 3-6 months faster under 10-Year Health Plan, as regulators set out plans

Under a joint information sharing agreement, pharmaceutical companies will be invited to register early with the MHRA and NICE to allow parallel decision making over licencing and value.

Individualised Medicines

Introduction

- The MHRA is working to provide a clear and comprehensive regulatory framework to support the development, evaluation, and approval of highly personalised and individualised medicines.
- By streamlining development and regulatory review, we hope to facilitate and speed up patient access, especially in areas of high unmet need.
- Initially, we are focusing on regulatory guidance for **individualised mRNA cancer immunotherapies** (also known as personalised cancer vaccines) as these are in late clinical development.

New Guidance

Human medicines Modular Manufacture and Point of Care regulations 2025: Overview - GOV.UK

- Allows personalised medicines to be prepared in small or individual batches
- May only have a shelf life of seconds or minutes or need to be highly personalised, so must be manufactured on demand when the patient is present
- Provides guidance on the new regulatory framework that will support the manufacture and supply of these innovative products.

Rare Diseases Consortium Initiative and regulatory framework

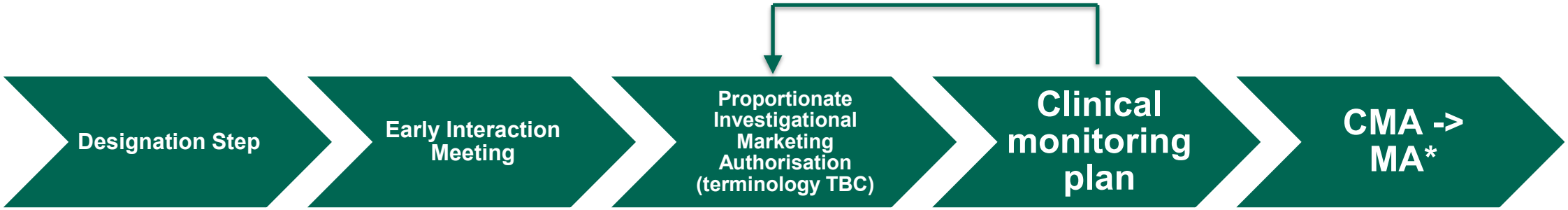
Rare Diseases Consortium Initiative

Scope:

- Risk-appropriate evidence generation for clinical and pre-clinical studies
- Licensing and regulatory assessment, including ongoing patient access
- Risk-proportionate CMC data generation and appropriate GMP compliance
- Post-market data collection and surveillance

Underpinning the development of a new pathway is the principle of a sliding scale of evidence and compliance requirements which enable the levels of evidence and methods of control to be appropriate to the disease outcome, patient population and balanced to patient interests.

High-Level Licence Structure Being Developed



- Eligibility criteria to be defined – based on rarity & unmet need
- IVD discussion*

- **For example:**

-knowledge package

-Methodologies and Endpoints

-trial design, numbers, comparator data, etc

- data quality for comparator

-economic evaluation data collection

- Part 1: core / fixed part
- Part 2: variable part
- Data package as discussed at Early Interaction Meeting
- Checkpoints and additional meetings with MHRA and HTAs to assess safety and efficacy data

- Generation of RWE
- Post-Marketing Surveillance as required

- *May go straight to full MA or MA under Exc. Circumstances
- Timelines for delivery of data

Concepts being considered:

- '**Source files**' to leverage prior knowledge for internal use, sharing, and licensing
- **Platform-based technologies** and individualised medicines.
- Review frequency/requirements
- **manufacturing and supply considerations**; Investigational Manufacturing Licence **'accredited' centres**.
- **patient engagement**
- ***Adaptive Risk Management Plans***

Timeline target

Phase	Activity	Timing
Framework Development	Draft regulatory model and internal consultation	Q1 2026
Public Consultation	Open consultation on rare therapies framework	Q2 2026

Rare Disease Therapy Regulatory Framework

Challenges with Current Regulations

Current regulatory approaches often do not suit rare diseases, necessitating a tailored, lifecycle-based framework.

Future Framework Goals

Goal is to support patient access while maintaining strong regulatory standards through flexible and proportionate pathways.

System Leadership and Collaboration

The MHRA and partners fostering innovation and cross-system collaboration in rare disease space.

New Licensing and Manufacturing Strategy

A proportionate, flexible approach for rare disease therapies

- MHRA intends a **flexible investigative pathway** (CT / IMA) designed for rare diseases
- IMA applications are assessed using **national Marketing Authorisation principles**
- **Initial 90-day review**, with targeted requests for clarification where needed

Proportionate clinical regulation

GCP applied proportionately, reflecting rarity and feasibility of conventional trials

Patient consent addresses **uncertainty, long-term follow-up, and post-IMA data collection**

Scientific advice expected where **unvalidated surrogate endpoints** are proposed

Risk-based manufacturing

GMP applied proportionately, recognising small batch sizes, short shelf-life and clinical urgency

Focus on **process understanding, control strategies, and real-time quality assurance**

GMP requirements **scale over the lifecycle** as experience, exposure and distribution increase

Consultation

Press release: Landmark new plans bring treatments for rare diseases a step closer - GOV.UK

https://assets.publishing.service.gov.uk/media/6a0c189dc75cc34a8ff8f48e/draft_rare_disease_therapies_regulatory_framework.pdf

Press release

Landmark new plans bring treatments for rare diseases a step closer

The MHRA launches public consultation on new framework that could lead to earlier licensing for therapies for up to 3.5 million people in the UK.

Opportunities and challenges

Opportunities

- AI and digital health technologies
- Advanced therapies and precision medicine
- New regulatory models
- Global regulatory leadership
- New Approach Methodologies
- Strengthened horizon-scanning and regulatory science capability
- Supportive environment for reclassification

Challenges

- Technology outpacing regulatory frameworks
- Capacity and capability constraints
- Global competition for innovation and influence
- Supply-chain and geopolitical instability
- Public trust, misinformation
- Emerging health security risks

Summary

- The MHRA has several initiatives ongoing to establish ourselves and be a leader in the regulatory eco-system.

- The MHRA is welcoming engagement from stakeholders, for the benefit of patients.

Medicines & Healthcare products
Regulatory Agency

Thank you

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