A Review of the UK's International Recognition Procedure and Its Role in Expediting Access to Innovative Treatments

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Summary

- The UK's International Recognition Procedure (IRP), aims to accelerate access to medicines by allowing companies to leverage regulatory decisions from trusted international authorities. This study provides an early evaluation of the IRP's performance, focusing on applications for new active substances submitted via Route B, which offers broader eligibility for innovative therapies.
- During its first 16 months, most IRP applications relied on EMA as the reference authority. Notably, three cases supported by the FDA and Health Canada, gained UK approval before EU authorisation, highlighting the IRP's capacity to accelerate patient access to new medicines.
- While early examples are promising, a longer evaluation period is needed to determine whether the IRP can consistently deliver faster access to innovative treatments for UK patients.

Background

- Following Brexit, the UK introduced several regulatory schemes to address challenges in medicine access after leaving the EU's Centralised Procedure[1].
- The IRP is intended for applicants who have already obtained a Marketing Authorisation (MA) from one of the MHRA's designated Reference Regulators (RRs)[2].
- It offers two routes:

  Route A (60 days): For recent (≤2 years) RR approvals; continuous review with no pauses.

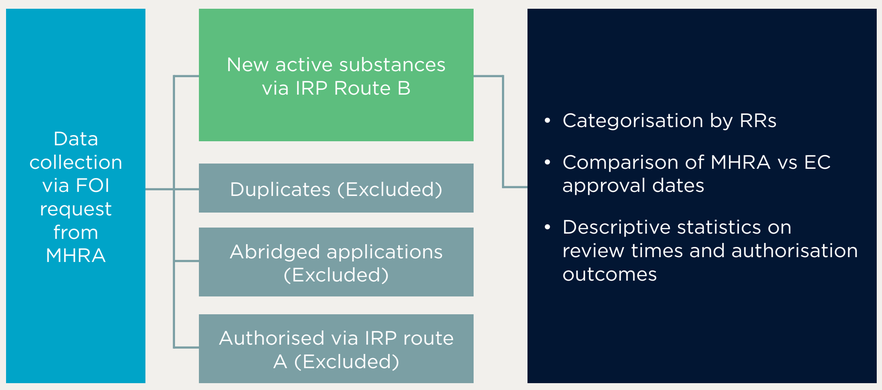
  Route B (110 days): For older (≤10 years) or more complex cases; includes a pause at Day 70 for applicant response.
- Both routes are significantly faster than the traditional 210-day timeline, improving timely access to innovative medicines in the UK.
- By enabling quicker assessments and decisions, the IRP enhances the availability of new medicines in the UK. Notably, the 110-day IRP timeline allows innovative drugs to reach the UK market faster than the typical review time differences between the EMA and FDA[3-4].

Objectives

- To review the implementation of the UK's IRP since its launch on 1 January 2024.
- To compare IRP applications supported by different RRs.
- To evaluate whether the IRP has accelerated access to innovative medicines in the UK compared with the EU, with a focus on Route B, which is frequently used for complex or novel therapies.

Methods

- We conducted a retrospective analysis of IRP applications submitted to the MHRA between 1 January 2024 and 1 May 2025. Application-level data were obtained via a Freedom of Information (FoI) request, including product names, IRP routes, RRs, submission types, and authorisation status.
- To focus on innovative therapies, the analysis was restricted to new active substances submitted via IRP Route B, which permits broader eligibility and is more relevant for complex or novel products. Duplicate entries for different doses or formulations of the same active substance were excluded to avoid overcounting.
- Applications were categorised by RR, and MHRA approval dates were compared with European Commission (EC) authorisation dates to evaluate whether the IRP accelerated UK access. Descriptive statistics were used to summarise review times and approval patterns.



Results

Most of the applications used RRs from outside of EU

- As of 1 May 2025, 456 IRP applications had received decisions, of which 238 represented unique (non-duplicate) authorisations.
- The 238 unique IRP applications originated from 19 different RRs. Of these, 96% came from EU regulators and 4% from outside the EU (Figure 1). Within the EU, the MRDC (42%) and EMA (40%) accounted for the majority, while the remaining 18% were spread across 17 other EU RRs—most commonly Portugal, Sweden, and Iceland (Figure 2). Only 4% of applications came from non-EU regulators, including the US, Canada, and Australia.

Figure 1. Distribution of Reference Regulators for Unique IRP Applications (EU vs. Non-EU)

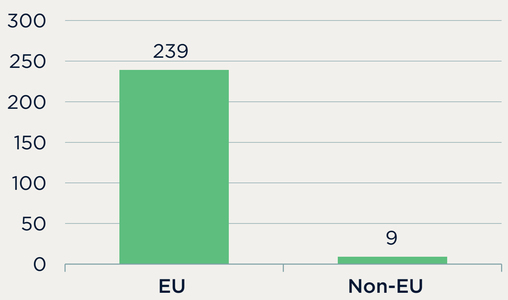
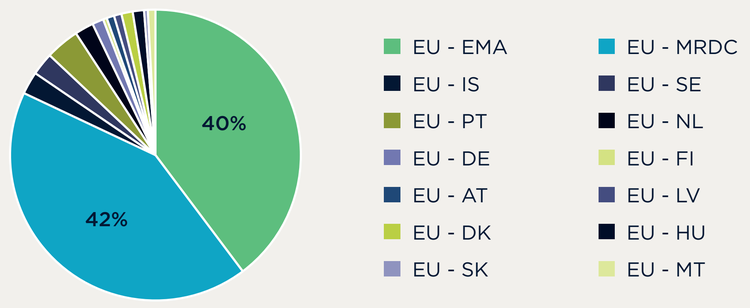
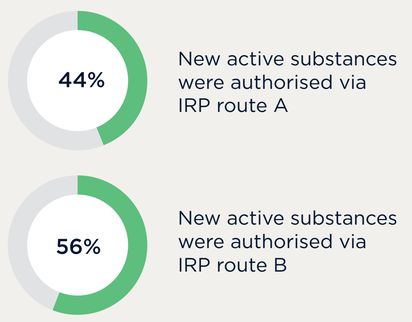


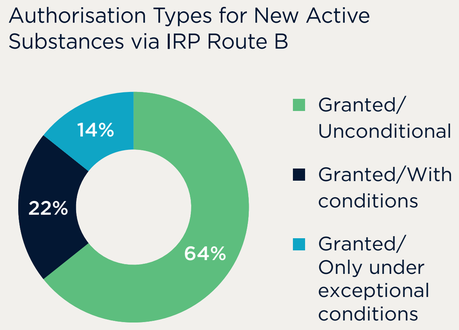
Figure 2. Breakdown of EU Reference Regulators Supporting IRP Applications



More than half of the new active substances were authorised via IRP route B

- These 238 applications covered 25 distinct active substances. Among them, 25 were new active substances, with the majority (14 out of 25; 56%) authorised via IRP Route B and the remainder via Route A. Within the Route B group, 9 out of 14 (64%) received unconditional approval, with the rest granted with conditions or under exceptional circumstances.





IRP Route B enabled faster UK approvals in some cases

- Route B applications were primarily supported by EMA decisions (11), with additional contributions from the US FDA (2) and Health Canada (1) (Figure 3). The average review time for new active substances under Route B was 184 days (range: 73–335 days).
- The 3 applications supported by the US FDA and Health Canada were authorised in the UK before European Commission approval. In contrast, the 11 EMA-supported substances reached the EU market first before becoming available in the UK.

Figure 3. Rapporteur Country Distribution for IRP-route B Licensed new active substance Products

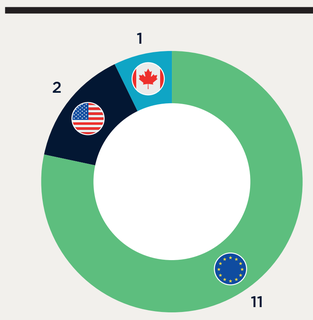


Table 1. Timeline of IRP Route B approvals for new active substances supported by non-EU RRs, compared with FDA and EC decisions

Licensed Product Name	Authorisation Holder Company Name	Rapporteur Country	Effective Date of Granting	FDA Approval date	EC Opinion adopted date*
JOENJA FILM-COATED TABLETS	PHARMING TECHNOLOGIES BV	US	25/09/2024	03/24/2023	N/A (Under review)
DUVYZAT ORAL SUSPENSION	ITALFARMACO SPA	US	20/12/2024	03/21/2024	25/04/2025
WINLEVI CREAM	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CA	30/01/2025	08/26/2020	N/A (Under review)

*Data current as of August 2025; subsequent changes not reflected.

Conclusions

- The majority of IRP applications assessed over our analysis timeframe (between 1 January 2024 and 1 May 2025) have relied on EMA as the Reference Regulator. This likely reflects a transitional phase, where many applications were originally submitted to EMA prior to Brexit and only received authorisation after the IRP was introduced.
- Notably, three IRP Route B applications supported by FDA and Health Canada, achieved UK authorisation ahead of EC approval, demonstrating the IRP's potential to accelerate access to innovative treatments.
- These early examples highlight the strategic value of the IRP, particularly when leveraging decisions from non-EU regulators. However, a longer evaluation period is needed to fully assess its impact on regulatory efficiency and patient access in the UK.

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Abbreviations
AT, Austria; DE, Germany; DK, Denmark; EC, European Commission; EMA, European Medicines Agency; EU, European Union; FDA, U.S. Food and Drug Administration; FI, Finland; HC, Health Canada; HTA, health technology assessment; IRP, International Recognition Procedure; IS, Iceland; LV, Latvia; MAA, Marketing Authorisation Application; MHRA, Medicines and Healthcare products Regulatory Agency; MRDC, The Mutual Recognition/Decentralised Reliance Procedure; MT, Malta; NICE, National Institute for Health and Care Excellence; NL, Netherlands; PT, Portugal; RR, Reference Regulators; SE, Sweden; SK, Slovakia; UK, United Kingdom.

Disclosures
The authors declare no conflicts of interest related to this work.