

Understanding the UK’s International Recognition Procedure

Since the United Kingdom’s exit from the European Union in 2020, there have been numerous changes in the procedures implemented to ensure that there is access to medicines for UK patients. One area of interest and a growing topic of discussion in the pharmaceutical industry is the International Recognition Procedure (IRP) which was introduced by the Medicines and Healthcare products Regulatory Agency (MHRA) on 1 January 2024, replacing and expanding on the EC Decision Reliance Procedure (ECDRP).¹

The introduction of the IRP has brought opportunities for faster market access for manufacturers by enabling the MHRA to conduct more targeted assessments by taking into account the expertise and decision-making of trusted regulatory partners.

The IRP also allows the MHRA to perform product lifecycle activities utilised for post-approval submissions including line extensions, variations (Type IB and Type II) and renewals for a medicinal product with an existing Marketing Authorisation (MA) provided by one of MHRA’s acceptable Reference Regulatory (RR) which include:

The IRP may also be used for Access Consortium approvals that did not include MHRA as part of the work-sharing procedure.¹

IRP Process

New IRP Marketing Authorisation Application (MAA)

A new MA may be achieved via one of two possible recognition pathways:

- **Recognition A** – Is applicable if the reference regulator MA has been granted within the previous 2 years (60-day procedure, no clock stop)¹
- **Recognition B** – Is applicable if the reference regulator MA has been granted within the previous 10 years and fulfils at least 1 of the 24 listed criteria (110-day procedure with no more than 1 clock stop. If there are outstanding Major Objections at Day 110, formal advice on approvability will be sought from CHM and the timetable will revert to the national 210-day timetable.¹

Post-authorisation IRP Applications: Variations and Renewals

The IRP can be used during the lifecycle of products that have been initially authorised or

subsequently varied via standalone national, MRDCRP or ECDRP routes. Conversely, where a product has been authorised via IRP, it is acceptable to submit standalone national post-authorisation procedures including variations.¹

Who Can Apply?

To ensure that the applicant/Marketing Authorisation Holder (MAH) can fulfil the submission requirements as well as all their legal obligations as holder of an MA, such as the obligations stated in Regulations 74 and 75 of the Human Medicines Regulations 2012, the applicant/MAH must be established in the UK (Great Britain or Northern Ireland) or in the EU/EEA and it is anticipated that the applicant for an IRP application is the same company or belongs to the same (legal) group of companies as the MAH of the RR procedure.¹

In some situations, it may be possible to accept applications from third parties if the applicant can demonstrate and provide written assurance that all the legal obligations can be met at submission, during the assessment process and throughout the life of the MA.¹

Key Advantages of Using the IRP?

Expansion of International Collaborations

The IRP allows the MHRA to consider the decisions of trusted regulatory partners both from the EU and globally; expanding international collaborations and reducing repetition of work for the health authorities and MAHs alike.¹

Fast Market Access

Navigating the regulatory processes in the lead-up to the submission can be challenging and submitting a marketing application is a significant undertaking process, involving multiple stakeholders over a period of up to 2 years (if all goes to plan).

Expedited approval with review times of 60 days (Route A) and 110 days (Route B) are significantly shorter than the MHRA national route for MAA which has a 210-day timetable.² This will allow quicker market access for medicines authorised outside of the EU and reduce assessment pressure and time burden on the MHRA.

Country or jurisdiction	Regulatory authority
Australia	Therapeutic Goods Administration
Canada	Health Canada
Switzerland	SwissMedic
Singapore	Health Science Authority Singapore
Japan	Pharmaceuticals and Medical Devices Agency
United States	Food and Drug Administration
European Union/European Economic Area	European Medicines Agency and Member State Competent Authorities of the EU, Norway, Iceland and Lichtenstein. (This includes approvals through the centralised, MRP/DCP and individual member state national routes)

MHRA Support

For MAAs, the MHRA require an online eligibility form which determines the suitability for recognition pathway A or B. Applicants intending to submit via the IRP have the option of requesting pre-submission advice through a form and returning this to presubmission@mhra.gov.uk.³

The IRP has been operational since 1 January 2024. In May 2025, for all Medicine licence applications through the IRP, 100% were approved within the statutory timeframe.

MHRA Metrics for May 2025⁴

Work type	Average time to determination in days*	Target time to determination in days	% granted within statutory time
Medicines licence applications via the national route			
Licensing applications: National (Established)	176	210	100%*
Licensing applications: National (new active substance; NAS)	N/A in May	210	
Licensing applications: International Recognition Procedure (IRP)			
Route A	53	60	100%**
Route B	99	110	

*MHRA will determine 95% of medicines licence applications within 210 days via the national route.

***MHRA will determine 95% of medicines licence applications within 60 days via recognition Route A and within 110 days via Route B through the International Recognition Procedure (IRP)

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OTHER CONSIDERATIONS

Eligibility Constraints

IRP is only applicable to:

- Chemical and biological new active substances and known active substances
- Generic applications
- Hybrid applications
- Biosimilar applications
- New fixed combination product applications

It is not applicable to:

- Bibliographic applications
- Traditional herbal registrations
- Homoeopathic registrations

Best use of IRP

What is your understanding of the IRP and have you used it for marketing applications? We are interested in hearing about your experiences around this topic and are happy to offer guidance on managing IRP submissions in the UK.

REFERENCES

1. International Recognition Procedure - GOV.UK Updated 29 Jan 2024
2. The International Recognition Procedure – The United Kingdom’s new route for accelerated marketing authorization – Voisin Consulting 6 February 2024
3. <https://www.gov.uk/guidance/pre-submission-advice-support> 13 August 2024
4. MHRA Performance Data - GOV.UK Updated 16 June 2025
5. <https://www.abpi.org.uk/media/blogs/2023/september/mhra-s-new-international-recognition-procedure-irp-how-does-it-shape-up/> 20 September 2023

Full details of the IRP submission process and requirements are provided on the MHRA website:

<https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure>

<https://www.gov.uk/government/publications/international-recognition-procedure/ectd-guidance-for-irp-mas-and-lifecycle>



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