NEW SERVICE!
Regulatory support in the transition from trusted pathways to new recognition pathways

International Recognition Procedure (IRP)

A new regulatory recognition procedure for the registration of medicinal products in UK is available using approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States

Entry into force

This recognition procedure that is in place from 1 January, 2024, marks the start of a new international recognition framework for medicines.

Recognition/Decentralised Reliance Procedure (MRDCRP) will be incorporated under the umbrella of IRP.

IRP will be open to applicants that have already received an authorisation for the same product from one of MHRA's specified Reference Regulators.

Work is underway to establish similar pathways for medical devices.

Applicability

IRP can be used for the following types of marketing authorisation applications (MAAs):

- Chemical and biological new active substances and known active substances.
- Generic applications.
- Hybrid applications.
- Biosimilar applications.
- New fixed combination product applications.
- Post-Authorisation procedures, including line extensions, variations and renewals.

Advantages

- Efficient and harmonized approach to the recognition of medicinal products: benefiting patients in the UK by providing quicker access to medicines that have been approved by other trusted regulatory authorities.
- Streamlined process: By incorporating both ECDRP and MRDCRP under the IRP umbrella, process is simplified, complexity reduced and timelines potentially accelerated.

Also note that...

Until the Windsor Framework is implemented in Northern Ireland on 1 January, 2025, products falling within the scope of the EU Centralised Procedure can only be authorised in Great Britain.

There are two recognition timetables for initial MAAs:

- Recognition A: 60-day timetable
- Recognition B: 110-day timetable

Suitability for Recognition A or B will be determined according to eligibility criteria.

IRP can also be used during product lifecycle (line extensions, variations Type IB and Type II and renewal applications).

Contact Asphalion to learn how to enhance your registration through IRP!

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Knowledge from experience

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