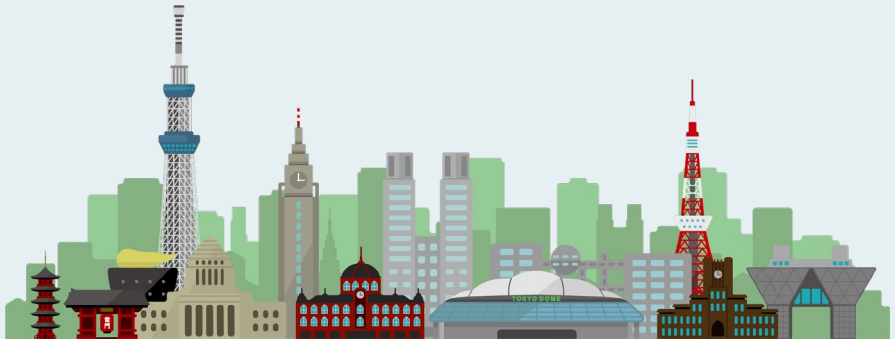
IMDRF International Medical Device Regulators Forum



MHRA Update: International Reliance

Dr Rob Reid
Deputy Director Innovative Devices

Overview

- MHRA are proposing four new access routes for the GB market, based on device classification and type of prior approval.
- Certain devices would be eligible to undergo a streamlined review process due to reliance on assessments already performed in Australia, Canada, the EU or the USA.

How was this developed?

- Criteria for which systems are ‘comparable’ included similarity of population, market size and pre-market regulatory requirements
- Held regular meetings with regulators and approved bodies to gain feedback on draft policy
- Reviewed example case studies under NDA with volunteer companies

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Trusted Advisor Principles:

- All meetings will be **confidential,** and any information shared will be **kept in confidence** by all members.
- Confidential dissemination of the information discussed by the Group outside of the meeting is permitted to **officers, employees, advisers, subcontractors and contractors of host organisations** and for Trade Associations, representatives from their wider membership organisations.
- Members will **not** use the Groups to lobby on behalf of their host organisation.

Public consultation and next steps

Consultation: Nov 2024 – Jan 2025

Publish response: May 2025

WTO notification: May - July 2025

Introduction of SI into parliament and debates: end of 2025

SI in force: 2026
12-month transition for IR

Further work

- Developing guidance to support the new SI
- Working with PMDA and MHLW to explore the reliance of medical device approvals from Japan
- Planning to monitor and evaluate:
  - the effectiveness of the policy in achieving its intended outcome
  - the efficiency of its implementation
  - its broader impact on the medical device sector

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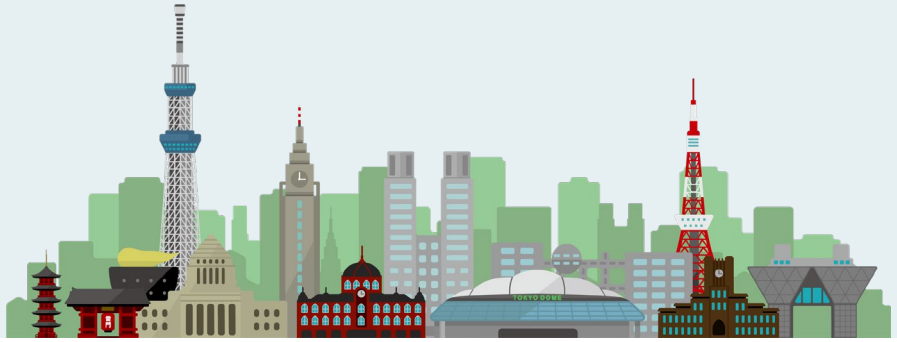

Thank you/Questions

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