IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

11:05 – 11:20

United Kingdom

Harriet Teare

Deputy Director of Partnerships, Medicines and Healthcare products Regulatory Agency (MHRA)

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Regulatory Update: MHRA, UK

Harriet Teare, Deputy Director for Partnerships

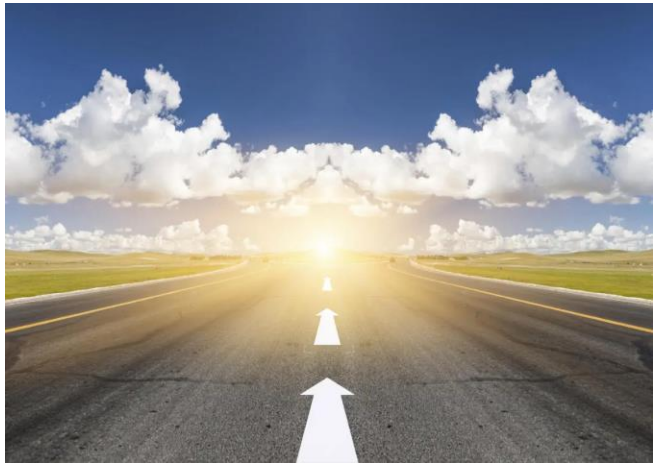
28 March 2023

Overview

- A recap of where we are now
- Overview of the statutory instruments we expect to lay
- Transitional arrangements
- Post-market surveillance
- International Recognition Framework

Where are we now?

- Twelve month extension to the implementation of the future UK Medical Device Regulations
- We are updating the UK Medical Device Regulations 2002 (UK MDR 2002)- to reflect the areas covered within the government response to the public consultation
- We expect to lay statutory instruments in 2023, which will amend the standstill date in the current UK MDR 2002, lay the transitional arrangements and the new post-market surveillance requirements.



Overview of Statutory Instruments (SIs)

Statutory Instrument	Purpose
Transitional Arrangements (*Expected to be laid Spring 2023*)	Intended to amend the end of the standstill date (30 Jun 2023) in the current UK Medical Device Regulations 2002 (UK MDR 2002) and introduce the transitional arrangements for CE marked devices
Post-market Surveillance (*Expected to be laid Autumn 2023)*	Bring into force the new post-market surveillance requirements for CE marked and UCKA devices as laid out in the government response to the public consultation
Future Medical Device Regulations (*Expected to be laid 2024*)	The SI relating to the future regime will bring into force the wider medical device regulations as laid out in the government response to the public consultation

Transitional Arrangements

UKCA marked under current UK regulations	Sooner of: • 3 years for general medical devices • 5 years for IVDs, or • when certifications expire
CE marked under EU directives	As above for UKCA marked devices
CE marked under EU regulations (EU MDR and EU IVDR)	Up to 5 years

Post-Market Surveillance

More stringent PMS requirements

Tighter timelines for reporting adverse incidents

Detail on what should be covered in a PMS plan/PMS systems

Requirements for health institutions

Requirements for custom-made devices

Details on what should be covered in trend reports/FSCA/PSURs etc

International Recognition Framework

UK Life Sciences Council Priority Areas:

1. International recognition
2. Routes for innovation
3. System capacity

International recognition proposals:

- Building on current product recognition routes from the EU, rapidly explore building a UK product regulation equivalence route for the approvals of medical devices to include other trusted jurisdictions.
- Explore greater flexibility over the requirements for physical UKCA markings on parts, instructions and labels before products can be marketed in the UK. Make greater use of registration and traceability mechanisms to ensure patient safety.
- The MHRA has already announced its intention to expand recognition for medicines, and create a new recognition framework by the end of 2023. Aim to align changes to the Medical Devices Legislation to the Medicines legislative timeline if possible.

IMDRF International Medical Device Regulators Forum

Thank you