UK Regulatory Update

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September 2022
Overview

Today we will cover:

• MHRA Transformation
• Background on UK medical device regulation
• Recent consultation on future regulation of medical devices in the UK
• Future regime timeline
• Questions
Background - MHRA transformation

MHRA has embarked upon an ambitious Transformation Programme to create the progressive, responsive and sovereign regulator of medical products.

This includes:

- a new organisational structure
- shifting to a life-cycle approach
Background - UK medical devices legislation

Medical devices are regulated in the UK under the **UK Medical Devices Regulations 2002**

EU Medical Devices Regulation (EU MDR) and the EU *in vitro* Diagnostic Medical Devices Regulation (EU IVDR) apply in Northern Ireland and not Great Britain.

**The Medicines and Medical Devices Act 2021**
Consultation aims and scope

To deliver a robust, world-leading regulatory system for medical devices in UK that prioritises patient safety....

- Improved public and patient safety
- Greater transparency of regulatory decision making and medical device information
- Close alignment with international best practice
- More flexible, responsive, and proportionate regulation
Consultation response

Pillars of a future regime:

• Strengthening power to act to keep patients safe
• Making the UK a focus for innovation
• Addressing health inequalities
• Proportionate regulation which supports businesses through access routes that build on synergies with the EU and wider global standards
• Setting world leading standards – building the UKCA mark as a global exemplar
Examples of planned changes:

- Strengthening **classification** of medical devices to be more commensurate with risk
- Introducing **alternative routes** to market
- **Increased post-market requirements** including increased requirements to monitor and report on adverse events after a device is placed on the market
- Introducing requirements **for informed consent** for participants in a clinical trial
- Expanding **device registration** and UDI requirements
Consultation response

Intended transition arrangements for medical devices in the consultation response include:

<table>
<thead>
<tr>
<th>UKCA marked under UK regulations</th>
<th>Sooner of:</th>
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<tr>
<td></td>
<td>• 3 years for general medical devices</td>
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<td>• 5 years for IVDs, or</td>
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<td>• when certifications expire</td>
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<table>
<thead>
<tr>
<th>CE marked under EU directives</th>
<th>As above for UKCA marked devices</th>
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<tbody>
<tr>
<td>CE marked under EU regulations (EU MDR and EU IVDR)</td>
<td>Up to 5 years</td>
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Future regime timeline

- **Jan - Summer 2021**: Public consultation development & informal stakeholder engagement.
- **Autumn 2021**: Launch of Public Consultation.
- **Winter 2021**: Review consultation responses and finalise policies.
- **Summer 2022 - Early 2023**: Publish consultation response.
- **Development of the draft regulations**.
- **Laying of Statutory Instrument**.
- **Regs come into force**.

- **Expected 2023**: 6-month implementation period.
Questions

Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)

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