Medicines & Healthcare products Regulatory Agency

UK Regulatory Update

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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

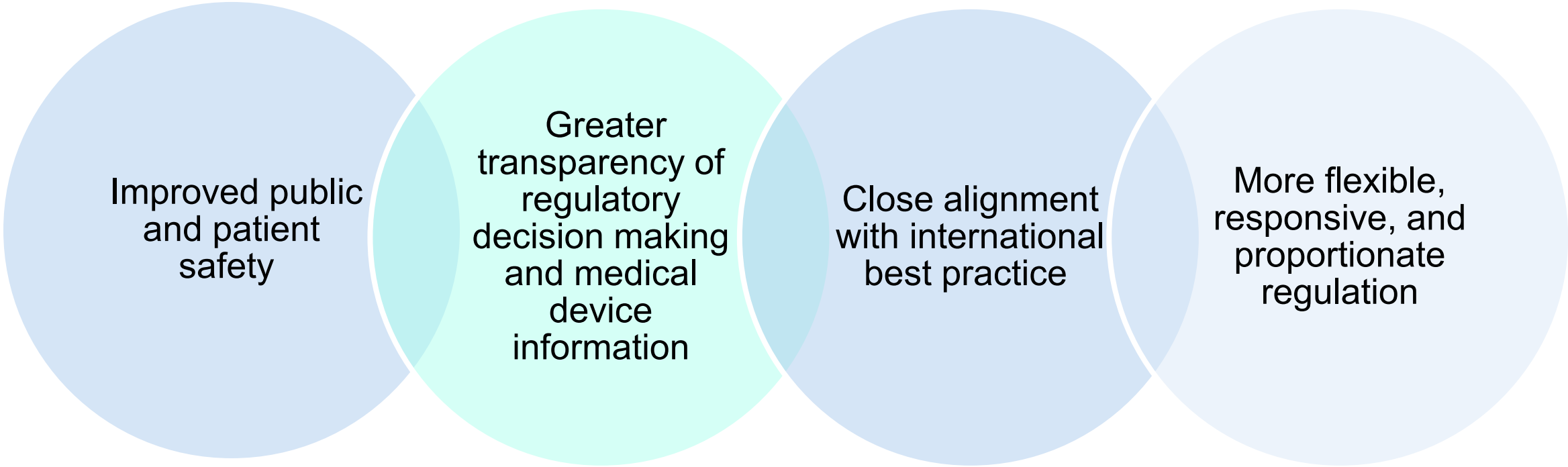
Medical devices are regulated in the UK under the **UK Medical Devices Regulations 2002**

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.….



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

Consultation response

Examples of planned changes:

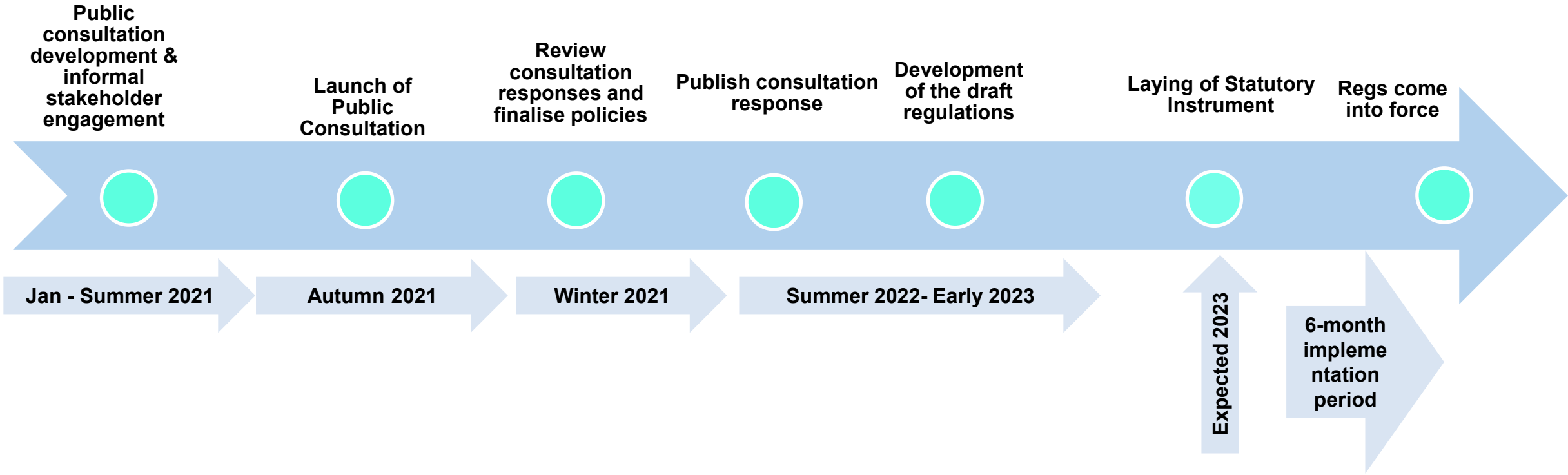
- Strengthening **classification** of medical devices to be more commensurate with risk
- Introducing **alternative routes** to market
- **Increased post-market requirements** including increased requirements to monitor and report on adverse events after a device is placed on the market
- Introducing 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:

UKCA marked under 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

Future regime timeline



Questions

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

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