Medicines & Healthcare products Regulatory Agency

Overview of Future Regulation of Medical Devices



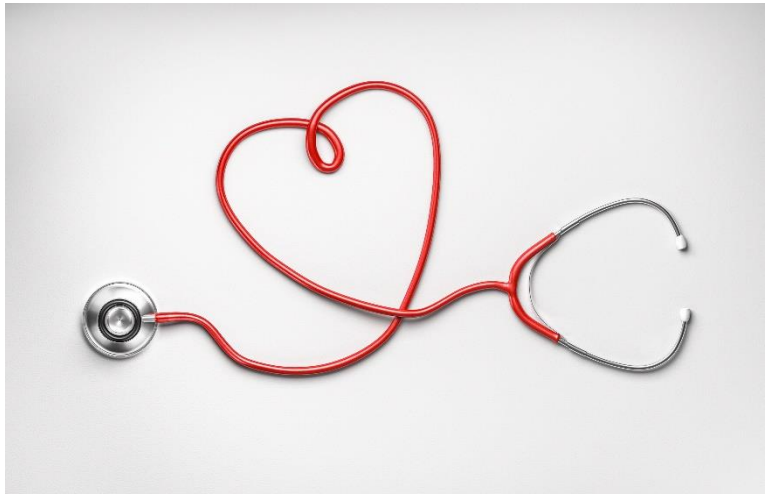
CPRD NIBSC MHRA

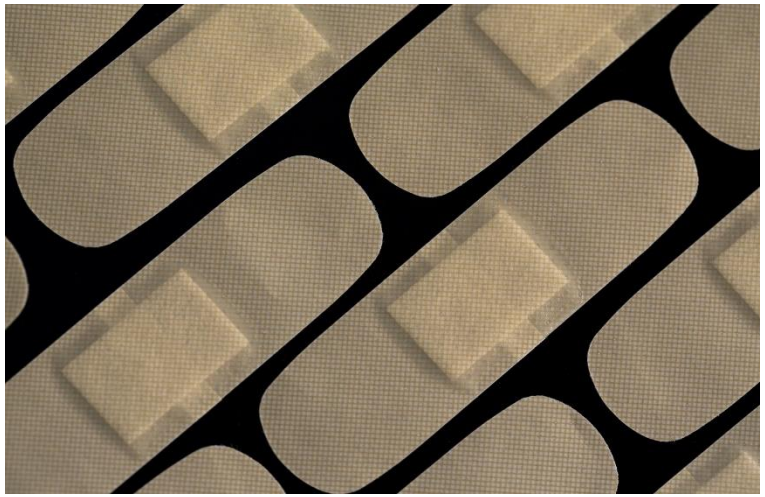
Our aim

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

A system that….

1. Prioritises patient safety
2. Enables access to innovative medical devices
3. Has enhanced trade and international collaboration
4. Swiftly detects and responds to problems with devices effectively and proportionately
5. Is agile - adaptive to a fast changing market



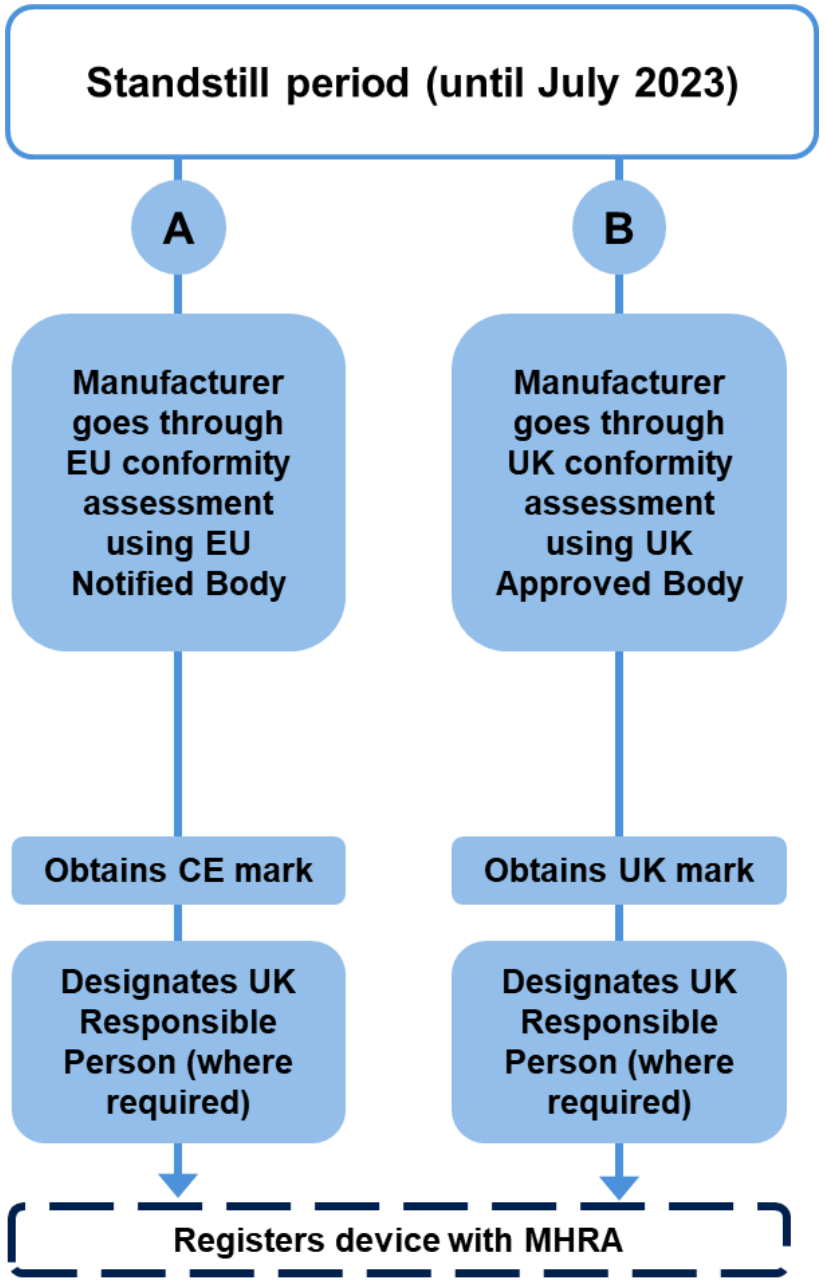


Standstill Position

- The transition period between the UK and the EU ended on 1 January 2021
- 2.5 year ‘standstill period’
- Different regulation in Great Britain (England, Wales, Scotland) and Northern Ireland due to the Northern Ireland Protocol
- Northern Ireland will have access to the EU Single Market and it will continue to align with EU rules for medical devices

Current state of play

- Unilateral recognition of the CE mark will end on 30 June 2023. The new UKCA requirements come in to force 1st July 2023, and there will be a considered transition to the new framework.
- Current UKCA marking requirements are based on EU Directives.
- The new EU MDR now fully applies in Northern Ireland (came into effect from 26 May 2021).



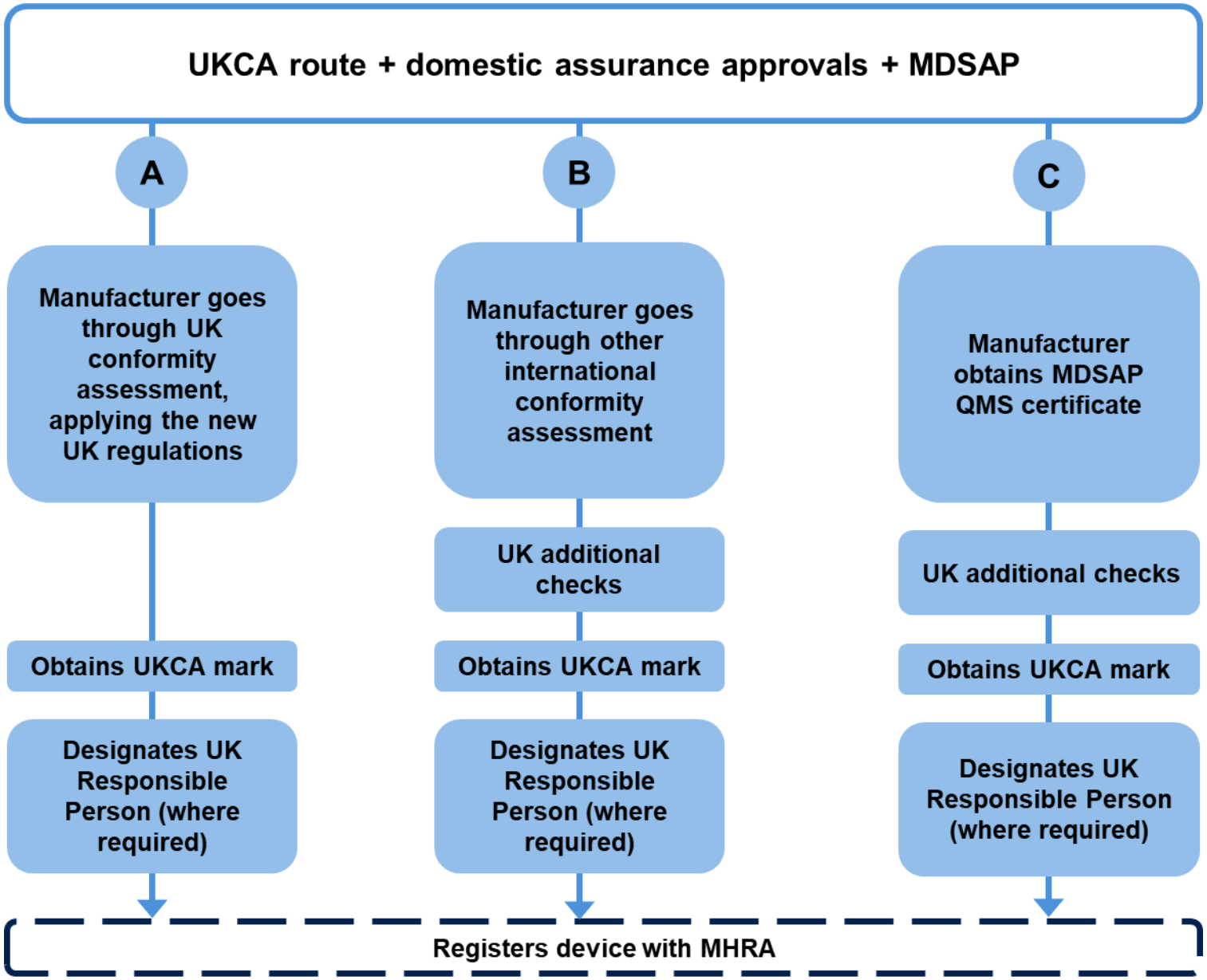
Foundational work

The foundational work for developing our market access regime **by 1 July 2023** will involve:

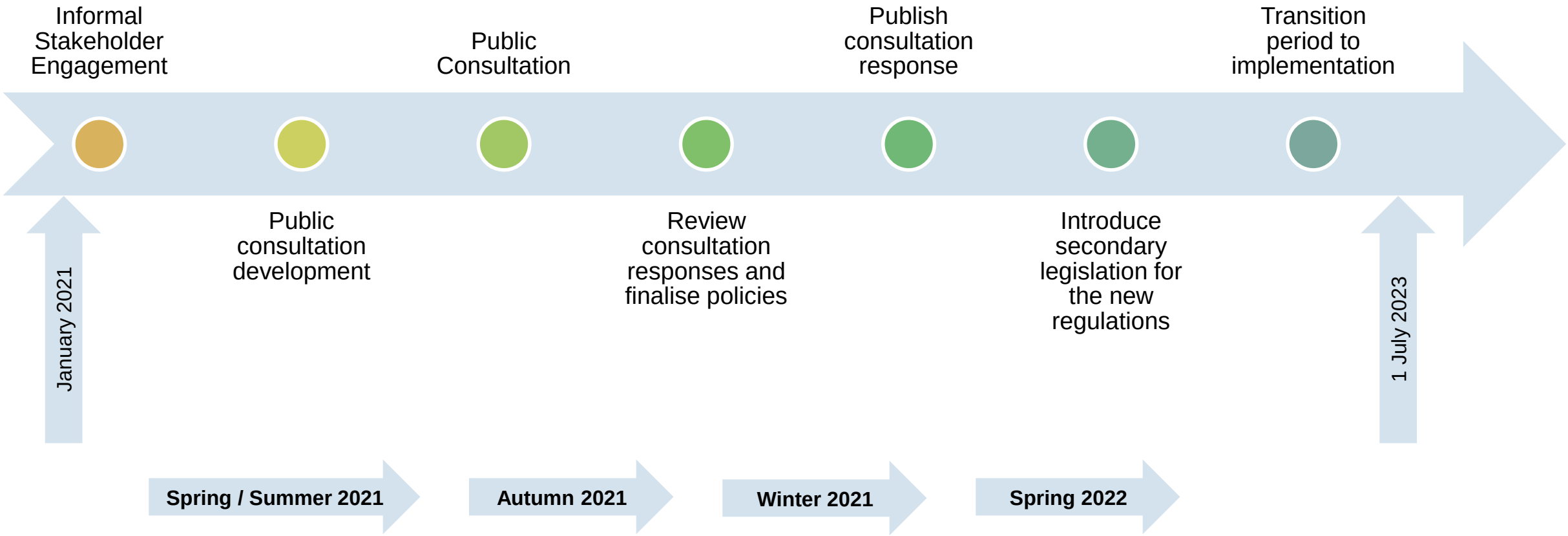
A. building on the existing statutory framework;

B. considering how the Medical Device Single Audit Program (MDSAP) route to market could fit into the framework;

C. developing the domestic assurance approval route to market.



Indicative Timeline and Key Milestones



Public Consultation Update

- Public consultation is being finalised for publication this Autumn.
- No confirmed publication date yet but will run for 10 weeks throughout the Autumn.

The below is a non-exhaustive list of provisions that we are intending to seek views on :

- *Scope and definition of a medical device, including how a device combined with a medicinal element should be regulated*
- *Revision of the classification rules and an assessment of whether certain products require up-classifying (such as surgical mesh and software)*
- *Economic operator obligations, including liability and advertising issues*
- *Whether the MHRA should regulate importers and distributors, including online sellers (such as Amazon and the Apple Store)*
- *How devices that are manufactured or modified within health institutions should be regulated*
- *Data and traceability considerations, such as Unique Device Identifiers and implant cards*
- *Conformity assessment requirements, including scrutiny placed on UK Approved Bodies*
- *Clinical evidence and performance evaluations (including clinical evidence requirements and post-market clinical follow-ups)*
- *Post-market surveillance requirements*
- *Vigilance and reporting requirements*