

Chapter 15: Transitional Arrangements

Section 74 - Transitional Arrangements

Background

- 74.1 We are exploring what arrangements the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) could set out to enable a smooth transition to any requirements introduced in a future medical devices system in the UK.
- 74.2 New requirements for medical devices could be phased in at different times depending on, for example, device type or the level of risk it presents (its classification). This will allow us to ensure that there is a proportionate approach to implementation of new requirements, recognising that industry requires time to make the necessary changes.
- 74.3 This could also include arrangements for devices holding a previously issued declaration of conformity or certificates of conformity issued by Approved Bodies. Dependent on the transitional arrangements we pursue, there may be caveats included in the Regulations, e.g. devices that are subject to significant changes in design or intended purpose falling out of scope of the transitional arrangements and the potential application of post-market requirements under the new system to transitionally protected devices.
- 74.4 In addition, transitional arrangements could include clinical investigations that commence before 1 July 2023, allowing them to continue to be conducted. However, such clinical investigations may be subject to additional reporting requirements - for example in relation to serious adverse events or identification of device deficiencies after 1 July 2023.

Possible Changes and Questions

- 74.5 We are considering the following transitional arrangement possibilities, to work alone or in combination:

Option 1: for certification/declarations of conformity for medical devices certified before the future regime applies: medical devices and *in vitro* diagnostic medical devices lawfully placed on the market with a valid UKCA certificate/declaration of conformity before 1 July 2023 can remain on the market until the expiry date of that UKCA certificate/declaration of conformity or until a specified date (please see the question below on what this date should be), whichever is the earliest. After the expiry of the certificate/declaration or after the specified date, devices that were placed on the market in accordance

with those certificates/declarations, could continue to be supplied for a further period, for example 1 additional year beyond the specified date.

Option 2: for certification/declarations of conformity for medical devices certified before the future regime applies: medical devices and *in vitro* diagnostic medical devices lawfully placed on the market with a valid CE certificate/declaration of conformity before 1 July 2023 can remain on the market until the expiry date of that CE certificate/declaration of conformity or until a specified date (please see the question below on what this date should be), subject to a light touch assessment that those devices meet the necessary regulatory standard. After the expiry of the certificate/declaration or after the specified date, devices that were placed on the market in accordance with those certificates/declarations, could continue to be supplied for a further period, for example 1 additional year beyond the specified date.

Option 3: device registration requirements could be phased in according to the risk classification of a device and UDI requirements could be introduced over time, including for devices already on the market (see the Registration and UDI Chapter 4 for more detail and an opportunity to comment on transition arrangements for registration requirements introduced in a future regime).

Option 4: Approved Body designations as expanded on in Chapter 5, the MHRA considers that the UK medical devices regulations could set out that Medical Device and Active Implantable Medical Device Approved Body designations issued prior to July 2023 could be 'rolled over' until expiry of the designation. Please see Chapter 5 Approved Bodies to comment on this possibility.

Option 5: Clinical Investigations which commence under the existing regulations before 1 July 2023 could continue to be conducted from 1 July 2023 providing any additional reporting requirements laid out in the new regulations for clinical investigations that commence on or after 1 July 2023 are met, such as around serious adverse events or device deficiencies. Please see Chapter 7 for additional information about clinical investigations and performance studies.

Q74.1 Do you think that we should introduce the transitional arrangements proposed above in Option 1? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q74.2 Do you think that we should introduce the transitional arrangements suggested above in Option 2? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q74.3 Please give your reasoning for your answer to questions 74.1-74.2. If you have answered 'yes' to either question, please include what you consider the required arrangement(s) and any expected impacts of these on you or other stakeholder groups.

Q74.4 Do you agree with the transitional arrangements suggested in Option 5 above? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q74.5 Please give you reasoning for your answer to question 74.4.

Q74.6 Please set out any other transitional arrangements or considerations you believe are required for putting in place a future regime for medical devices in the UK, why, and the expected impacts on you and other stakeholder groups.

Q74.7 How many years after 1 July 2023 should the MHRA accept UKCA certificates / declarations of conformity issued before 1 July 2023? That is, what would be a suitable 'specified date' for Option 1 above?

(30 June 2025, 30 June 2026 or Other – please specify).

Q74.8 How many years after 1 July 2023 the date of implementation of the Regulations should the MHRA accept CE certificates issued before 1 July 2023? That is, what would be a suitable 'specified date' for Option 2 above?

(30 June 2027, 30 June 2028 or Other – please specify).

Q74.9 For how long after expiry of the certificate/declaration of conformity or after the 'specified date' should devices covered by the transitional options 1 and 2 be permitted to be supplied to the UK market?

(They should not be permitted to be supplied after expiry or cut-off date; 6 months; 12 months)

Q74.10 What additional checks, if any, would you consider to be necessary to allow CE marked products to remain on the Great Britain market after 1 July 2023?

Q74.11 Please provide your reasoning for your proposed dates above.