Medicines & Healthcare products Regulatory Agency

Government response to the consultation on Medical Devices Regulations: Assimilated EU Law

Published 26 February 2025

Contents

Ministerial Foreword

The *Medical Devices Regulations: Routes to market and in vitro diagnostic devices* consultation was an important step in our reform of the medical devices regulations, focusing on some key proposals for legislative change. The consultation also set out in high-level terms the broader plans that the Medicines and Healthcare products Regulatory Agency (MHRA) is driving forwards to ensure that the MedTech ecosystem continues to support access to innovative medical devices while keeping patient safety at the forefront.

Making and implementing new legislation is not quick or simple. I am pleased with the progress being made and am grateful to so many of you for engaging with the consultation and sharing your views. The responses we received from a diverse range of partners, including medical device manufacturers, healthcare professionals, patients and the public, have been extremely valuable and our legislative plans are informed by the insights provided by that feedback.

This government response relates only to the final proposal in the consultation, relating to a small number of important pieces of assimilated EU law. It is clear from the results of the consultation that these pieces of law should not be sunsetted on 26 May 2025, and should therefore be retained until such time as they are replaced. I can confirm that our intention is to replace them – and update the regulatory framework more widely – as soon as is practical, and I know that many people and organisations are keen to be involved in that process.

I am just as interested in ensuring that our partners are involved and commit to keeping up regular communication. More information about the outcome of the other proposals in the consultation will follow in the coming weeks.

Baroness Merron

Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health

Executive Summary

This document sets out the responses to the public consultation on the proposed amendments to the Medical Devices Regulations 2002 regarding four specific pieces of assimilated EU law only. The consultation ran from 14 November 2024 to 5 January 2025 and received 287 responses in total from various stakeholders, such as medical device suppliers and producers, healthcare professionals, trade associations, and individuals.

The majority of the respondents agreed with the government's proposals to remove the revocation date of the four pieces of assimilated law so that they continue to apply in Great Britain, until such time as they are replaced with updated UK law. Doing so will avoid disruption to the regulatory framework and ensure continuity for manufacturers and all who use medical devices.

The proposed approach applies to the regulatory framework for Great Britain. For guidance on the regulation of devices in Northern Ireland, see Regulation of devices in Northern Ireland.

The other consultation proposals are not as time-sensitive and require more in-depth analysis. The government response to those parts of the consultation will be published separately in due course.

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for the regulation of medical devices.

Medical devices are products or equipment that are used for medical purposes, such as diagnosis, prevention, monitoring or treatment of diseases or injuries. They include a wide range of products, such as pacemakers, artificial hips, blood glucose meters, pregnancy tests, medical decision support software, syringes, surgical instruments and wheelchairs.

At the MHRA, we put patients first in everything we do, right across the lifecycle of the products we regulate, and we ensure that medicines and healthcare products available in the UK are effective and acceptably safe. We want to develop a future regime for medical devices that enables:

- strengthened patient and public safety;
- innovation;
- close alignment with international best practice;
- earliest possible access to medical devices; and
- risk proportionate regulation of medical devices.

As set out in the consultation document, the MHRA intends to update the regulatory framework to improve the scrutiny and oversight of medical devices. An important role of the MHRA is to ensure that there is continuity of a legislative framework, and legal certainty for those who must follow the regulations. It should be noted that the MHRA does not intend to keep the four pieces of assimilated EU law in place indefinitely. Rather, this is a temporary measure to maintain the status quo until more permanent measures are in place; the first of those is expected to come into force in 2026 with the ‘Pre-Market’ regulations that are currently being developed.

The responses to the majority of the proposals set out in the consultation are still under consideration. In light of the responses received, this document sets out the government’s approach to the last of the proposals, regarding assimilated EU law only. This proposal has been separated from the others given the deadline of the current ‘sunset date’ for those pieces of law.

Respondents

The consultation received 287 responses, from those either responding on behalf of an organisation or as an individual sharing professional or personal views. Table 1 below shows the breakdown of respondents.

Table 1. Type of respondent

Type of individual	Number of responses	Percentage of total responses
Organisation	180	63%
Individual sharing professional views	88	31%
Individual sharing personal views	19	7%

The organisations that responded to the consultation represented a variety of sectors and interests, such as device manufacturers, healthcare professionals, trade associations, academic institutions, and patient groups; most responses were submitted by businesses. Table 2 below shows the breakdown of the type of organisations that responded to the consultation, although it should be noted that not all respondents provided this demographic information.

Table 2. Type of organisation and number of responses

Types of organisation	Number of responses	Percentage of responses provided
Business	162	56%
Trade association	20	7%
Professional regulator	15	5%
Research organisation	9	3%
Professional representative group	10	3%
NHS	2	1%
Patient group	2	1%
All other responses	48	17%

No response	19	7%

Those who responded as an organisation or as an individual sharing their professional views were asked where their organisation operates. The majority of those respondents operate in England, followed by locations outside of the UK, Wales, Scotland and Northern Ireland. It should be noted that the proposal only applies to Great Britain. Table 3 below shows the breakdown of these locations; respondents were able to select more than one location, or none at all.

Table 3. Location of organisation

Location of organisation	Number of responses	Percentage of responses provided
England	212	80%
Outside the UK	160	60%
Wales	120	45%
Scotland	115	43%
Northern Ireland	106	40%

The majority of the individuals sharing personal views were also based in England, followed by Wales, locations outside the UK, and Scotland. Table 4 below shows the breakdown of the locations of the respondents.

Table 4. Location of individuals

Location of individuals	Number of responses	Percentage of responses provided
England	14	74%
Wales	2	11%
Outside the UK	2	11%
Scotland	1	5%

Assimilated EU Law

Background

'Retained EU Law' was a type of domestic law created by the EU (Withdrawal) Act 2018 and came into effect at the end of the UK's EU Exit transition period, to provide legal continuity and certainty. Any retained EU law that had not been revoked by the end of 2023 became 'assimilated law.' Further information on this subject can be found at GOV.UK.

Medical devices and *in vitro* diagnostic devices on the Great Britain market are regulated under the Medical Devices Regulations 2002 (as amended). Those Regulations transpose three EU Directives (the Medical Devices Directive (93/42/EEC), Active Implantable Medical Devices Directive (90/385/EEC) and in vitro Diagnostic Medical Devices Directive (98/79/EC)) into national law. As such, the Regulations contain references to a number of other pieces of assimilated EU law, which also form part of the regulatory framework for Great Britain.

The government is committed to ensuring that the regulations for medical devices continue to prioritise patient safety and give patients access to the medical devices they need. As mentioned above, the government intends to introduce new legislation in order to achieve this aim; subject to Parliamentary time, that legislation to update the broader regulatory framework is expected to be introduced in 2025 and to come into force in 2026.

Four of the pieces of assimilated law that form part of Great Britain's current regulatory framework are due to be sunsetted – i.e. they are due to expire – on 26 May 2025 (before any new Regulations are in force). They are referred to at regulations 4H, 4J, 4K and 4L of The Medical Devices Regulations 2002, and can be summarised as follows:

- **Commission Decision 2002/364 on the common technical specifications for *in vitro* diagnostic medical devices** sets out technical requirements that certain *in vitro* diagnostic medical devices must meet to demonstrate compliance with essential requirements when they are placed on the market or put into service.
- **Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices** establishes the conditions under which the instructions for use of medical devices may be provided in electronic form instead of in paper form and sets out certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form.
- **Regulation (EU) No 722/2012 concerning particular requirements for medical devices manufactured utilising tissues of animal origin** lays down requirements in relation to the placing on the market and putting into service of

medical devices, including active implantable medical devices, manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue. The Regulation applies to animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats.

- **Regulation (EU) No 920/2013 on the designation and the supervision of approved bodies** sets out further requirements on the designation of approved bodies and a list of elements to be included in the interpretation of the relevant annexes of the Medical Devices Directive and Active Implantable Medical Device Directive on minimum criteria to be met for the designation of bodies.

Proposal

The MHRA proposed to remove the revocation date of these four pieces of assimilated law so that they continue to apply in Great Britain until such time as they are replaced with updated UK law.

The objective is to maintain the regulatory status quo, facilitating a smooth transition to a future regulatory framework. Allowing these regulations to be sunsetted on 26 May 2025 would cause significant disruption and, consequently, negative impacts on patient safety.

Feedback

Of the 287 respondents to the proposal to remove the revocation date of this assimilated EU law:

- 238 agreed with the proposal (83%)
- 35 had no opinion (12%)
- 14 disagreed with the proposal (5%)

Table 5 shows the breakdown of responses from organisations and individuals sharing their professional and personal views.

Table 5. Answer by type of respondent

Respondent	Yes	No	No opinion
Organisations	157	6	17

Individuals sharing professional views	71	4	13
Individuals sharing personal views	10	4	5

Many respondents supplemented their answers with written commentary. The vast majority of those comments expressed general agreement with the proposal, with a significant number of respondents citing the importance of continuity in regulation for patient safety. Some respondents believed that, longer-term, the four EU regulations should be updated, but that maintaining them in the short term was the most sensible approach.

A small number of respondents noted that guidance would be beneficial, and also requested clarification or provided comments on the government's policy on electronic instructions for use of medical devices (related to Commission Regulation (EU) No 207/2012) and common specifications for *in vitro* diagnostic devices (Commission Decision 2002/364).

Where respondents disagreed with the proposal, most comments expressed insufficient understanding to be able to agree. There was also a technical concern that the four pieces of assimilated EU law are not currently specific enough to be fully effective in the UK. Of those respondents who answered the question in disagreement, a small number of their written comments expressed general agreement with the proposal; many did not provide written comments.

Government response

The overwhelmingly positive response to this proposal is indicative of the importance of preserving the status quo in this area to avoid creating a gap in regulation that could have serious patient safety implications. Having considered the views of all respondents, taking into account their concerns and suggestions, the government intends to amend the Medical Devices Regulations 2002 to revoke the sunset date of the following pieces of assimilated EU law: Commission Decision 2002/364; Commission Regulation (EU) No 207/2012; Regulation (EU) No 722/2012; and Regulation (EU) No 920/2013, which the MHRA considers to form an effective and vital part of the UK's regulatory framework for medical devices. It should be noted that references to these pieces of EU law are 'non-ambulatory,' meaning that they do not automatically update when the EU updates its regulations.

In response to comments received about electronic instructions for use and common technical specifications, as mentioned in the introduction to this document, the MHRA is currently developing 'Pre-Market' legislation that will make a series of updates to the Medical Devices Regulations 2002 to improve patient safety. That legislation will not make any changes to Regulation (EU) No 722/2012 or 920/2013, however it will replace the reference in domestic law to Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices with the more up to date Implementing Regulation (EU) 2021/2226.

The Pre-Market legislation will also address common technical specifications. Between 21 May and 14 June 2024, the MHRA ran a short public consultation that proposed the inclusion in the Medical Devices Regulations 2002 of Common Specification requirements for manufacturers of high-risk *in vitro* diagnostic devices, and the removal of current Coronavirus Test Device Approvals requirements. The government intends to publish its response to that consultation in the coming weeks.

The MHRA is actively considering what new and updated guidance is required to ensure that the current and future regulations are fully understood and complied with by all those who need to use them. The topics covered in this consultation will be considered as part of that work.

Next steps

We are grateful for respondents' time in considering and providing views on all of our proposals. Following careful analysis of the responses to the proposal relating to assimilated EU law in particular, the government will draft and make the necessary secondary legislation as soon as Parliamentary time allows.

The government will publish a response to the other proposals in the consultation in due course.