PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Third Delegated Legislation Committee

DRAFT MEDICAL DEVICES (AMENDMENT) (GREAT BRITAIN) REGULATIONS 2025

Wednesday 23 April 2025

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Sunday 27 April 2025

The Committee consisted of the following Members:

Chair: Sir Edward Leigh

† Bennett, Alison *(Mid Sussex)* (LD)
† Brown-Fuller, Jess *(Chichester)* (LD)
Craft, Jen *(Thurrock)* (Lab)
† Dalton, Ashley *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Dewhirst, Charlie *(Bridlington and The Wolds)* (Con)
† Fortune, Peter *(Bromley and Biggin Hill)* (Con)
† Hatton, Lloyd *(South Dorset)* (Lab)
† Johnson, Dr Caroline *(Sleaford and North Hykeham)* (Con)
† Macdonald, Alice *(Norwich North)* (Lab/Co-op)
† McAllister, Douglas *(West Dunbartonshire)* (Lab)
† Mayer, Alex *(Dunstable and Leighton Buzzard)* (Lab)
† Morris, Joe *(Hexham)* (Lab)
† Owatemi, Taiwo *(Lord Commissioner of His Majesty's Treasury)*
† Smith, Nick *(Blaenau Gwent and Rhymney)* (Lab)
† Stafford, Gregory *(Farnham and Bordon)* (Con)
† Sullivan, Kirsteen *(Bathgate and Linlithgow)* (Lab/Co-op)
† Yasin, Mohammad *(Bedford)* (Lab)

George James, *Committee Clerk*

† **attended the Committee**

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[Sir Edward Leigh *in the Chair*]

Draft Medical Devices (Amendment) (Great Britain) Regulations 2025

2.30 pm

The Parliamentary Under-Secretary of State for Health and Social Care (Ashley Dalton): I beg to move,

That the Committee has considered the draft Medical Devices (Amendment) (Great Britain) Regulations 2025.

It is a pleasure to serve under your chairmanship, Sir Edward. I am grateful to be debating these short but important regulations. I will start by setting out some background. The Medical Devices Regulations 2002 provide for the safe and effective regulation of medical devices and in vitro diagnostic, or IVD, devices in Great Britain. Those regulations promote the safety and availability of such devices for British patients and ensure that the UK remains a great place to research, develop, manufacture and supply medical devices. We have a thriving life sciences sector, and this Government are determined to harness that power for growth.

The 2002 regulations originally transposed three EU directives into UK law, and they reference other pieces of EU law that form part of the regulatory framework for Great Britain. We are working to reform the regulations to improve patient safety and access to the latest innovations, but I will say more on that shortly. The statutory instrument we are discussing today prevents four of those pieces of assimilated EU law from expiring by revoking their sunset dates. Without it, they would expire on 25 and 26 May this year.

Those four pieces of assimilated EU law are: first, the decision on common specifications for IVD devices, which sets out the technical specifications—for example, around performance testing—that ensure that these devices are safe and accurate; secondly, the regulation on electronic instructions for the use of medical devices, which sets out when instructions may be provided electronically instead of on paper; thirdly, the regulation on devices manufactured using animal tissue, which sets out what must happen before these devices are placed on the market; and fourthly, the regulation on the designation and supervision of approved bodies—approved bodies are the organisations that assess whether certain medical devices meet the regulations, and this piece of EU law allows them to be properly monitored by the Medicines and Healthcare products Regulatory Agency.

These laws may seem technical, but they are also necessary, and they have been working as intended since they were introduced in the 2002 regulations. Without them, the resulting changes to well-established regulatory requirements would create industry disruption, and we would be unable to effectively regulate the medical devices industry and ensure that devices are safe and effective for patients. However, I want to be clear that this statutory instrument is a temporary measure to maintain the status quo, pending wider reforms. In time, the Government intend to fully replace these pieces of assimilated EU law as part of a broad programme of medtech regulatory reform.

Medtech has transformed the quality of care for patients since the 2002 regulations were introduced. We need only look at digital health products involving software, advanced diagnostics and AI. Diagnostic accuracy for cancers and other conditions has vastly improved, alongside tools that can identify previously undiagnosed spinal fractures. However, that is not the only reason we need updated regulations. In 2020, Baroness Cumberlege published the recommendations of her independent medicines and medical devices safety review, including those relating to device regulations. We must also keep up with the regulations of both our friends and competitors internationally.

For all those reasons, we have published plans to introduce several SIs to amend the regulatory framework for medical devices, which will improve patient safety, drive access to devices and support innovation. Some members of the Committee may recall the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024, which were debated in the House in November. Those will come into force in June this year and will strengthen the legal requirements for manufacturers to monitor and report on their devices once they are being used in the real world. That will mean that safety issues can be identified, investigated and resolved faster, saving the NHS time and money. It will amplify patients' voices by requiring manufacturers to engage with patients and the public during their post-market surveillance, where appropriate.

That SI will go hand in hand with the pre-market regulations, which we are currently developing. As the name suggests, those regulations will bring further improvements to patient safety, with additional measures that must be taken before a product goes to market. Those will include measures for unique device identifiers and implant cards, which improve the traceability of devices; new rules to ensure that claims that manufacturers make about their devices are consistent with the device's intended purpose, so that patients are not misled; and changes to the classification of some medical devices, so that the level of regulatory burden is proportionate to the risk of the device.

That pre-market SI will also include an international reliance scheme for medical devices. That will be a huge step forward in reducing unnecessary and duplicative red tape for the medtech industry, where appropriate regulatory approval has been granted in a comparable country. That will mean that a patient waiting for a device that has already been approved by our friends in Australia, for example, does not need to wait for it to go through the same lengthy process in Great Britain. Those measures address some of the key recommendations of the Cumberlege review, while providing alternatives to the assimilated EU law in question.

That pre-market legislation is being developed with the intention of it coming into force in 2026. As well as the measures I have described, it will remove the need for two of the pieces of assimilated EU law: those relating to IVD devices and to electronic instructions for use. The reference to the EU decision on IVD devices will be replaced with a reference to the updated EU common specifications, which reflect the latest scientific and technical progress in that area. The EU regulation on

electronic instructions for use will be replaced with the latest version of those rules, with some modifications for the GB market. That regulation allows manufacturers to take a more flexible and proportionate approach to providing electronic instructions for use instead of paper copies. The remaining two pieces of assimilated EU law will also be replaced in due course, as part of our ongoing efforts to improve the regulations. Indeed, the pre-market SI is not the end point of our work to ensure that the regulatory framework is up to date, safe and proportionate.

The Government will continue to work to improve the regulatory framework for devices. Technology does not stand still, and neither should our regulations. In conclusion, I hope I have demonstrated that the draft regulations are necessary for continuity and innovation, for safety and smart regulation, and for growth and the people's priorities. I commend them to the Committee.

2.37 pm

Dr Caroline Johnson (Sleaford and North Hykeham) (Con): It is a pleasure to serve under your chairmanship, Sir Edward. We can all agree that we want safety. We want the equipment that doctors such as me use to be safe, reliable and regulated to the highest standards. We also want strong support for the science and technology sector, and patients in the UK to have early access to the best and most innovative medical devices. The instrument removes the revocation dates currently attached to four pieces of assimilated EU law, currently enshrined in the Medical Devices Regulations 2002. By doing so, it keeps those EU regulations in force until new, bespoke UK regulations are introduced.

There was significant concern that allowing that assimilated EU law to expire under the sunset clause would disrupt the UK medical devices regulatory framework and could negatively impact patient safety. In response, the MHRA conducted a public consultation involving device manufacturers, healthcare professionals, patient groups and businesses. Based on the results of that consultation, the MHRA proposed removing the revocation date for those four pieces of EU law. That proposal was welcomed, with 83% of respondents favouring maintaining the status quo.

Opposition Members support these pragmatic measures, and we welcome any legislation that protects patient safety. However, it is essential that the new UK regulatory framework is delivered in a timely manner to provide clarity for industry stakeholders. In that spirit, I would be grateful if the Minister could provide clarity on a few points.

First, the retention of these laws is intended as a temporary transitional measure, with the first phase of the new UK regime—the pre-market regulations—expected in 2026. Is that information up to date, and when can we expect further details on the timeline, publications and upcoming consultations?

Looking ahead to the new UK regulations, particularly those on post-market surveillance of medical devices, are the new UK replacements for assimilated EU regulations expected to diverge significantly from the current EU frameworks when they take effect, or will they remain broadly aligned with them?

Although the amendment regulations extend across the UK, in practice they apply only to England, Wales and Scotland. Northern Ireland remains subject to the 2017 EU medical device regulation and the 2017 in vitro diagnostic medical device regulation. If these frameworks impose additional regulatory or administrative burdens on manufacturers and distributors in Northern Ireland, what steps will the Government take to support those businesses and help protect their competitiveness?

Finally, will the Minister comment on how she expects US tariffs to affect medical devices, including their manufacturers and their availability, in the UK?

2.40 pm

Ashley Dalton: I thank the shadow Minister for her input, and I will try to respond to the points she raised. The MHRA has published the road map for this process, and I can let her have a copy of it after the debate; it sets out the timeframe for the various steps that need to be taken. Specifically on further SIs, there will be a further SI dealing with two of these issues by the end of the year, and two further SIs in 2026 and 2027.

On Northern Ireland, we are obviously aware that there are concerns and issues that have to be dealt with differently. Once the provisions have been updated, the GB framework will still refer to EU law, but certain domestic requirements may differ from those in other jurisdictions. However, we recognise the benefit of international harmonisation of medical device regulations. Of course, we will ensure that any future legislation meets our obligations under the Windsor framework.

On US tariffs, the Committee will appreciate that there is an ongoing discussion, and decisions have not yet been made by the US. I would not want to pre-empt or second-guess any decisions made by colleagues. Obviously, those tariffs will be taken into account once we have a final view of what they might look like.

Dr Johnson: My understanding is that the US Government are reviewing whether the tariffs will affect medical pharmaceutical products. However, some manufactures of medical devices, as per this SI, are concerned that the tariffs that have already been announced affect medical devices. Can the Minister please give more clarity on that?

Ashley Dalton: I am not able to give further clarity on that today, but I am more than happy to write to the shadow Minister when we have some more clarity.

I hope I have set out why these regulations, while only a small part of the wider reform programme, are nevertheless important to ensuring a smoothly functioning regulatory environment. They will give manufacturers certainty and ensure that patients can continue to access safe and effective devices. They are just a small part of the reforms that are under way, and I am grateful to members of the Committee for playing their part in bringing them into force.

Question put and agreed to.

2.43 pm

Committee rose.