Department of Health & Social Care

Baroness Merron
Parliamentary Under-Secretary of State for Patient Safety

39 Victoria Street
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Dear Noble Lords,

I thank you for the constructive discussion during the debate on The Medical Devices (Amendment) (Great Britain) Regulations 2025 on 6th May 2025. I am pleased to follow up on the points raised relating to the international context in which these Regulations will operate.

Northern Ireland

As you will be aware, under the terms of the Windsor Framework, Northern Ireland continues to apply the EU regulatory framework for medical devices in order to facilitate its dual access to both the UK Internal Market and EU Single Market.

Lord Kamall asked about the competitiveness of businesses in Northern Ireland should the EU impose additional regulatory burden. I would like to provide assurance that the UK Government engages directly with businesses in Northern Ireland to understand their concerns, as well as working closely with Northern Ireland officials. As we engage with the EU on future regulatory changes and, as we develop updated regulations for Great Britain, the UK Government will continue to take into consideration any impacts on patients and businesses in Northern Ireland and work through any concerns using our channels with the EU under the Windsor Framework.

United States

Baroness Finlay of Llandaff questioned compatibility with the medical devices regulations in the United States (US). I mentioned briefly in the debate that the Medicines and Healthcare products Regulatory Agency is currently developing new policy that will introduce an international reliance scheme for medical devices, and I am pleased to say that this will include a new, quicker, route to the Great Britain market for qualifying devices that have already been approved by the US regulator. The proposed International Reliance routes will also apply to devices approved in Canada, Australia and the EU. We are in early discussions with other comparable regulators with a view to expanding this list in the future. I would like to provide some reassurance that the approach to International Reliance does not involve us aligning our domestic regulations with those of the US or other comparable regulators on this list; rather, we will take decisions made by these regulators into account when assessing whether a medical device meets our own regulatory requirements for access to the Great Britain market.

The planned regulations for Great Britain demonstrate pragmatism and, where appropriate, align with global best practice, aiming to ensure patient safety while supporting and encouraging innovation.

Finally, Lord Kamall asked about the impact of US tariffs on medical devices. You will all be aware that the US announced several changes to their tariff rates in the past months. Through steady negotiations, we secured an economic prosperity deal with the US on 8 May 2025, which has begun the process of reducing the barriers to trade between our two countries. As part of this agreement, the US has removed a 25% tariff on steel and aluminium and has committed to further negotiations to lower tariffs across the economy. Currently, the UK remains subject to a 10% tariff, which we know is affecting the medical devices industry.

The Department is working closely with our life sciences stakeholders and other government departments to assess the impacts these tariffs may have on the sector and on global supply chains. We are also ascertaining potential repercussions for Northern Ireland resulting from the Windsor Framework's customs requirements. These assessments are ongoing, and we will continue to review our response as more information becomes available.

I hope this letter provides further clarification on the points raised. I am copying this letter to the Peers who spoke during the debate and I will deposit this letter in the libraries of both Houses.

All good wishes,

BARONESS MERRON