



Department
of Health &
Social Care

*From the Lord Bethell
Parliamentary Under Secretary of State for Innovation (Lords)*

Vaughan Gething MS
Minister for Health and Social Services

14th September 2020

Dear Vaughan,

MEDICAL DEVICES INFORMATION SYSTEM

Thank you for your letter of 28th August 2020. I am writing further to my letter of the same date, in which I reiterated my commitment to ensuring that we consider the interests of the Devolved Administrations in the design and implementation of the Medical Devices Information System (MDIS).

As you will be aware, the Bill had its Second Reading in the House of Lords on the 2nd September, and I was very pleased that Peers recognised the potential that the MDIS clause (clause 16) offers us to significantly increase our oversight of the safety of medical devices, and to improve outcomes for patients.

There was considerable discussion of the findings of Baroness Cumberlege's Independent Medicines and Medical Devices Safety Review, and the importance of ensuring that we learn from her findings by putting the appropriate mechanisms in place to protect and support the recipients of implanted medical devices. Several Peers spoke passionately about the suffering of women who have experienced adverse outcomes after receiving pelvic mesh implants, and the failures of the system to ensure a prompt response that afforded them the necessary support.

As I outlined in my previous letter, I believe that the MDIS clause is a critical step towards ensuring that we can put in place a system that significantly improves our ability to ensure the safe use and monitoring of these sorts of medical devices. The development of a UK-wide database will allow better detection of the 'signals' where any devices may be causing concern, and the ability to trace any such devices will ensure that individual patients can be offered the appropriate clinical follow-up.

I remain confident that a UK-wide approach will offer the greatest benefit in enhancing patient safety across all four nations and I am grateful to you for beginning the process of securing legislative consent. I am aware that you and Ministerial counterparts from the other Devolved Administrations have raised concerns about ensuring that you are appropriately engaged and consulted on the development of MDIS regulations. As I have indicated previously, I am clear that it is absolutely right that we consider the interests and

arrangements of the Devolved Administrations as discussions on the design of the information system progress, and I recognise that a statutory consultation requirement will provide you with significant reassurance on your involvement on the development of the MDIS operational model. I have therefore secured agreement to table an amendment to the Bill that will require that the Secretary of State consults Welsh Ministers, Scottish Ministers and the Department of Health in Northern Ireland when making regulations under clause 16. I trust that this statutory requirement to consult the Devolved Administrations on MDIS, building on the existing general consultation requirement at clause 41, provides you with additional reassurance as you progress legislative consent.

In your letter of 28th August, you indicated that you hoped to see draft MDIS regulations by this point in time. I can assure you that we are committed to ensuring that any MDIS regulations will implement an operational model which will serve the best interests of patients across the UK and take account of the particular considerations of the Devolved Administrations. It is for that reason that we must take the time to engage with yourselves and other experts and stakeholders as appropriate on the proposed operational model that those regulations will establish. These discussions are in their early stages. And, as you have indicated in your earlier correspondence, it is important that we allow these to develop in order to understand how to best align with the different operational arrangements at the local level. These conversations will be fundamental to ensuring that draft regulations deliver the right outcomes and need to be allowed to progress further to ensure that the regulations have the appropriate buy-in and support.

You also raised concerns about the role of the Devolved Administrations in the governance of MDIS. I note from your most recent correspondence that this is something you are keen to have clarity on, and, as indicated in my letter of 28th August, I have asked my officials to work closely with yours to see what more can be done. Officials are discussing these issues further this week and are in the process of considering different potential options for working arrangements. I trust that these discussions will make valuable progress. I am confident that we can reach satisfactory agreement but consider that governance arrangements are not points of detail which it would be appropriate to reflect on the face of the Bill.

I would like to reiterate my gratitude to you for initiating the consent process with the Senedd. I trust that the proposed amendment to require consultation of the Devolved Administrations on regulations under clause 16, as well as the ongoing discussions on MDIS governance arrangements and other operational details will reassure you of my commitment that the Devolved Administrations are engaged in MDIS policy and operational discussions and the development of draft regulations.

With best wishes,



LORD BETHELL

MINISTER FOR INNOVATION