



Ein cyf/Our ref MA/VG/0003/21

Dr Dai Lloyd MS
Chair, Health, Social Care and Sports Committee

5 January 2021

Dear Dai,

I wrote to you in August and in October replying to your requests for information about the rationale for laying a Legislative Consent Memorandum before the Senedd for the Medicines and Medical Devices Bill and the on-going discussions between the Welsh Government and Department of Health and Social Care (DHSC) on the proposal for a medical device information system (MDIS). On 2 December, I laid a Supplementary Legislative Consent Memorandum on the Bill concerning a Government amendment passed by the House of Lords that the Devolved Administrations (DAs) should be consulted before any regulations under Clause 16 (new Clause 18) are made, irrespective of whether the proposed regulations are seen as relating primarily to supporting specific device safety elements or supporting the wider healthcare system.

As you know a debate on the legislative consent motion on the Bill has been scheduled for 12 January. I am writing to update you on recent developments and my intentions in relation to the motion.

Since the summer there has been much discussion between officials of the Welsh Government, the other DAs and DHSC about the design, functions and governance of the medical device information system. I also corresponded with and met Lord Bethell to progress matters. This has resulted in a draft memorandum of understanding (MOU) that includes a number of assurances relating to the operation of the information system. For example it emphasises the importance of four nation consultation and reporting on the operation of the MDIS, the establishment of joint officials' working groups to discuss and draft the regulations, escalation arrangements in the event of disagreement and technical operational matters. There are also safeguards on issues such as the use and sale of data. A copy of Lord Bethell's recent letter and draft MOU, which has to be agreed by Devolved Administrations, is attached.

Although the arrangements have not gone as far as I would have wished towards joint Ministerial governance of the MDIS an MOU is a positive compromise approach to the information system. This is now envisaged as a partnership involving other agencies,

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

manufacturers, clinicians, individuals and the four governments. The proposed frequent Ministerial meetings on the MDIS as the preparation of the regulations progresses provides a real level of Ministerial oversight.

In terms of the regulations and the principles proposed by the DAs Lord Bethell has given an assurance 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 DAs”.

Scotland and Northern Ireland had already given legislative consent to the proposals before agreement was reached with the Welsh Government to progress to an MOU. In the light of the assurances, the cross over with a significant reserved matters, the likely significant benefits of the information system to patient safety and medical device improvement and innovation, which I have previously outlined, I intend to recommend that the Senedd approves the legislative consent motion to the Medicines and Medical Devices Bill. This will ensure that Wales fully participates in the MDIS.

I have written in similar terms to the Chair of the Legislation, Justice and Constitution Committee, Mick Antoniw MS and I am also copying this letter to all Members of the Senedd.

Yours sincerely,

A handwritten signature in black ink that reads "Vaughan Gething". The signature is written in a cursive, flowing style.

Vaughan Gething AS/MS

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services