



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



Department  
of Health &  
Social Care

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

*39 Victoria Street  
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11 December 2020

Dear Vaughan,

### **MEDICAL DEVICES INFORMATION SYSTEM (MDIS)**

Thank you for the extremely helpful meeting yesterday. I hugely welcomed your agreement on the opportunities that the MDIS can offer and am delighted that you believe that Wales should be part of a UK-wide medical devices information system. As I indicated, this is something which I am committed that all four nations work closely together on as work progresses, and I am confident that in doing so we can make a significant difference for the safety of patients using medical devices.

I explained yesterday that in light of the critical need to make swift progress on the MMD Bill after the end of the Transition Period, and the risk that amending the Bill at Third Reading would introduce delays in securing Royal Assent, that I would be unable to amend the Bill after Lords Report stage, should the Senedd not agree legislative consent for clause 18.

You explained that, in order to provide the necessary assurances to the Senedd, you would welcome a Memorandum of Understanding (MOU) summarising the key commitments and outlined in my previous correspondence of 4<sup>th</sup> December. In light of our discussion, this now includes a further commitment to ongoing Ministerial engagement on MDIS, as well as outlining my intention to amend the Bill to extend the reporting requirement at clause 44 of the Bill to apply to regulations made under clause 18. Given the interest that legislatures in the Devolved Administrations will have in the operation of the MDIS, I have made clear that reports prepared on clause 18 regulations will be shared with Ministers in all four nations. The MOU is attached at Annex A. I will also ask that Ministers from Scotland and Northern Ireland endorse the enclosed MOU.

As discussed yesterday I would therefore be grateful for your confirmation by Monday 14<sup>th</sup> December that you do not wish me to table an amendment to the Bill to remove Wales from the territorial scope of clause 18, and that in light of the assurances I have given, that you intend to recommend that the Senedd give legislative consent. I recognise, of course, that no guarantee can be given on consent until the Senedd debate has taken place on 12<sup>th</sup> January.

Yours,

**LORD BETHELL**

## **ANNEX A – MEMORANDUM OF UNDERSTANDING**

### **Memorandum of Understanding**

**Between:**

**Department of Health and Social Care  
And**

**The Welsh Government, The Scottish Government and The Northern Ireland Assembly**

**Concerning:**

**Participation in United Kingdom  
Medical Device Information System (MDIS) established under clause 18 of the Medicines and  
Medical Devices Bill**

**11th December 2020**

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#### **Introduction**

1. The Medical Device Information System (MDIS), or more than one such system, can be established by regulations made under clause 18 of the Medicines and Medical Devices (MMD) Bill following consultation with Welsh Government Ministers, Scottish Government Ministers and the Northern Ireland Department of Health and public consultation.
2. Establishing MDIS will facilitate the tracking of medical devices by their unique identifiers to individual patient records, ensuring that safety concerns can be identified and followed up promptly. Equally, information collected under the MDIS has the potential to inform future regulation of medical devices, by building our understanding of how particular devices interact with different cohorts of patients. It will support improved post-market surveillance of medical devices on the market, as well as minimising harm to patients in the future by informing when, how and for what purpose products are authorised for use.
3. The primary function of MDIS made under the power will concern the safety and performance of medical devices, and therefore relates to reserved matters. It also has significant potential to support devolved responsibilities to improve patient safety and clinical outcomes. Assessment of the data collected in the MDIS could also improve understanding of patient outcomes for different devices, informing clinical practice and procedures in the future.
4. MDIS work is in its early stages. Close-working between the nations from the outset will support effective dialogue on the MDIS proposals, plans for public consultation across the UK, and the development of operational details and arrangements to deliver the system. It is right that we take this early opportunity to build effective cross-UK working from the start, whilst allowing for the natural evolution of that close-working between the four nations as we progress from early policy development towards implementation and operation of the system.
5. This memorandum of understanding (MOU) sets out principles that will underpin engagement between the UK Government and Ministers in the Devolved Administrations on the development of the UK-wide MDIS, the proposed information system to be established by clause 18 of the MMD Bill. It covers consultation requirements, reporting requirements, official-level working arrangements, how Ministers from all four nations will work together, and other related issues. The points set out in this MOU will be kept under review as development and implementation of the regulations for the MDIS progresses. This MOU is not legally binding and the arrangements it sets out do not extend the statutory duties to consult and report in the MMD Bill.

## **A. Consultation Requirements**

6. Clause 43 of the MMD Bill introduces a legal requirement for the Secretary of State of Health and Social Care, to carry out a public consultation before making regulations under clause 18 of the MMD Bill. In addition, the Secretary of State must specifically consult Welsh Ministers, Scottish Ministers and the Department of Health in Northern Ireland before regulations under clause 18 are made.
7. Further details on how all parties to this MOU will participate in the development of these consultation and engagement exercises are set out in Section C below.

## **B. Reporting Requirements**

8. An amendment to the MMD Bill at Lords Report Stage will require that the Secretary of State provides the UK Parliament with a report every two years on how regulations made under clause 18 have operated during that time. The report must contain a summary of any concerns and proposals raised during consultation in preparing a report, and the Secretary of State's response to those concerns or proposals. This includes providing advance notice of further regulatory change that the Secretary of State is proposing to make.
9. The Secretary of State would be required to consult such persons as the Secretary of State considers appropriate before developing this report. Given the duty to consult the Devolved Administrations before making regulations under clause 18 of the MMD Bill, it would of course be appropriate to consult the Devolved Administrations when preparing the report under clause 44. This would mean that any issues or proposals raised by the Devolved Administrations during consultation on preparation of the report will need to be summarised and responded to within the report.
10. It is recognised that Ministers in the Devolved Administrations may also wish to provide similar reports to their respective legislatures. Copies of the report prepared by the Secretary of State will be shared with Ministerial counterparts in the Devolved Administrations.

## **C. Official Working Level Arrangements**

### Four UK Nations Working Group for the MDIS Regulations

11. All four UK nations will participate in an officials' working group, which will meet regularly and provide a forum to discuss all aspects of the proposed framework to establish regulations that work for the four nations. It is proposed that this group will:
  - Work together to develop plans for early and meaningful engagement with patients and the public, clinicians, providers, and industry in all four nations on the proposed operation of any MDIS recognising that the experts in identifying and talking to the appropriate organisations in each of the nations are those who work in the individual nations.
  - Discuss the provision and development of briefing, communication and consultation materials to support wider engagement.
  - Discuss emerging timescales and plans for public consultation on the MDIS, seeking feedback on plans to help in the development of public consultation and regulations in the longer term.
  - Consider emerging policy options that will inform areas of the regulations such as the establishment of the MDIS, information collection, use and sharing, and enforcement.
  - Discuss issues that may fall outside of regulations but where it may be appropriate to develop agreed standard operating procedures, ensuring there is flexibility in the operating system that is backed by agreed processes.

- Contribute to, and ensure, robust underpinning policy development and analysis reflecting available evidence and data.
12. Should any decisions agreed by this forum need further sign off or, in the event the working group cannot agree, it is proposed that discussions will be escalated through official channels to a more senior level.

#### Technical Working Groups for the MDIS

13. NHS Digital, (working with the Department of Health and Social Care and NHSX) as the organisation responsible for establishing and operating a future MDIS, will hold detailed, technical discussions under three working groups that will be coordinated by a project group, reporting into the Medical Device Safety Programme (MDSP) Steering Group. Officials from the devolved administrations can join all working groups and project meetings relating to the operational development of the MDIS. It is proposed that these groups will:
- Support the design and implementation of any proposed UK-wide MDIS;
  - Support the information governance and legal processes required to develop and implement the MDIS; and
  - Work with the Medicines and Healthcare Products Regulatory Agency (MHRA), device manufacturers and relevant system partners across the four nations to implement a Product Information Master (PIM) database for all relevant products in the UK supply chain.

#### Medical Device Safety Programme (MDSP) Steering Group

14. Officials are establishing a cross system-programme of work for England under a Medical Device Safety Programme (MDSP) that builds upon previous initiatives and will work alongside the UK-wide MDIS and focus on improved clinical specialty level outcome registries, device tracking and patient/clinician decision support.
15. We consider it important that all four nations are given the opportunity to see how the wider MDSP elements operate together, even where they are for England only, to give space to share ideas and experiences.
16. The MDSP will have an over-arching Steering Group, with senior officials from the Devolved Administrations having representatives in attendance. The operation of this group will:
- recognise the benefits of the MDIS being considered alongside the other (England-only) elements of the MDSP under the Steering Group,
  - consider with Devolved Administration colleagues the terms of reference, frequency and appropriate attendance for their engagement with this group; and
  - provide a senior official level governance and escalation mechanism for the operational aspects of MDIS whilst ensuring that this reflects the unique position of MDIS as a UK-wide endeavour relative to the wider MDSP.

#### **D. Ministerial Engagement**

17. Given the interest that Ministers in the Devolved Administrations have in the development and operation of the MDIS, Ministers in Wales, Scotland and Northern Ireland are assured that discussions on the MDIS will be included on the agenda for the weekly four nations Ministerial meetings, as necessary and helpful. This will provide a regular, ongoing opportunity through which Ministers from all four nations can consider progress or issues on the MDIS established under clause 18 of the MMD Bill.

## **E. Related Issues**

### Consideration of local data collection arrangements:

18. Consideration will be given to the mechanisms for collection of information from providers and how this can best work alongside existing local arrangements in the four nations. It is right that such decisions are part of a wider conversation to make sure that all aspects associated with different approaches are fully considered in the context of the objectives for the MDIS.

### Use of data by other bodies for research

19. On the provision of data from the MDIS to commercial organisations, such as for research purposes, as the operators of the MDIS, NHS Digital will work solely on a cost-recovery basis, with data only being shared when it is safe, ethical, and legal to do so, and where the purpose directly benefits the health and care of patients. This can include, for instance, sharing data under appropriate safeguards with researchers, but would exclude sharing for insurance or marketing purposes for example. For the MDIS, the regulations setting out the legitimate purposes for which data could be shared will be subject to both public consultation and consultation with the Devolved Administrations and will remain subject to the data safeguards referenced above.

### Workshops

20. There is a commitment to deliver bi-monthly workshops to develop options for the MDIS design and UK-wide interoperability. These workshops, which will run in parallel with the planned consultation process for the development of the MMD Bill regulations, will include the Devolved Administrations, patients, clinicians and will focus on the technical design and interoperability of the MDIS. They will recognise that the four nations will each have varying local system capabilities and priorities for optimising the approach which will be captured and explored through this planned collaboration.

### Nation-specific pilots

21. There is a commitment to offer nation-specific pilots, at each stage of the phased implementation, to ensure the MDIS meets local requirements of key stakeholders.

## **Conclusion**

22. We are committed to the UK-wide MDIS delivering the greatest possible benefit for patients in all four nations. It offers us all a significant opportunity to ensure the safe use of medical devices. This MOU reflects our collective agreement and commitment to working effectively as this work evolves.

## **Signatures**

## **Date**