Vaughan Gething AS/MS
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Llywodraeth Cymru
Welsh Government

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

Dr Dai Lloyd AS
Cadeirydd y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon

5 Ionawr 2021

Annwyl Dai,

Ysgrifennais atoch ym mis Awst ac ym mis Hydref yn ateb eich ceisiadau am wybodaeth am y rhesymeg dros osod Memorandwm Cydsyniad Deddfwriaethol gerbron y Senedd ar y Bil Meddyginiaethau a Dyfeisiau Meddygol a'r trafodaethau sy'n parhau rhwng Llywodraeth Cymru a'r Adran Iechyd a Gofal Cymdeithasol (DHSC) ar y cynnig ar gyfer system wybodaeth am ddyfeisiau meddygol (MDIS). Ar 2 Rhagfyr, gosodais Femorandwm Cydsyniad Deddfwriaethol Atodol ar y Bil ynghylch gwelliant gan Lywodraeth y DU a basiwyd gan Dŷ'r Arglwyddi y dylid ymgynghori â'r Gweinyddiaethau Datganoledig cyn i unrhyw reoliadau o dan Gymal 16 (Cymal 18 newydd) gael eu gwneud, ni waeth a fernir bod y rheoliadau arfaethedig yn ymwneud yn bennaf â chefnogi elfennau diogelwch dyfeisiau penodol neu gefnogi'r system gofal iechyd ehangach.

Fel y gwyddoch mae dadl ar y cynnig cydsyniad deddfwriaethol ar y Bil wedi'i hamserlennu ar gyfer 12 Ionawr. Rwyf yn ysgrifennu i roi'r wybodaeth ddiweddaraf ichi am y datblygiadau diweddaraf a'm bwriadau innau mewn perthynas â'r cynnig.

Ers yr haf cafwyd llawer o drafodaeth rhwng swyddogion Llywodraeth Cymru, y Gweinyddiaethau Datganoledig eraill a DHSC am ddyluniad, swyddogaethau a llywodraethiant y system wybodaeth am ddyfeisiau meddygol. Gohebais hefyd â'r Arglwydd Bethell a chyfarfod ag ef i fwrw ymlaen â materion. Mae hyn wedi arwain at Femorandwm Cyd-ddealltwriaeth drafft sy'n cynnwys sicrwydd yn ymwneud â gweithredu'r system wybodaeth. Er enghraifft, mae'n tanlinellu pwysigrwydd ymgynghori â'r pedair gwlad ac adrodd ar weithrediad MDIS, sefydlu cyd-weithgorau swyddogion i drafod a llunio'r rheoliadau, uwchgyfeirio trefniadau os bydd diffyg cytundeb a materion gweithredol technegol. Mae mesurau diogelwch hefyd ar faterion megis defnyddio a gwerthu data. Amgaeir copi o lythyr diweddar yr Arglwydd Bethell a'r Memorandwm Cyd-ddealltwriaeth drafft, y mae'r Gweinyddiaethau Datganoledig yn gorfod cytuno iddo.

Er nad yw'r trefniadau wedi mynd mor bell ag y byddwn wedi dymuno tuag at llywodraethiant cyd-weinidogol ar MDIS mae Memorandwm Cyd-ddealltwriaeth yn gyfaddawd cadarnhaol o ran y system wybodaeth. Rhagwelir bellach bod hyn yn

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:
0300 0604400
Gohebiaeth.Vaughan.Gething@llyw.cymru
Correspondence.Vaughan.Gething@gov.wales

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1SN

bartneriaeth sy'n cynnwys asiantaethau, gweithgynhyrchwyr, clinigwyr ac unigolion eraill a'r pedair llywodraeth. Mae'r cyfarfodydd Gweinidogol aml arfaethedig ar MDIS wrth i'r rheoliadau gael eu paratoi yn darparu lefel wirioneddol o oruchwyliaeth weinidogol.

O safbwynt y rheoliadau a'r egwyddorion a gynigiwyd gan y Gweinyddiaethau Datganoledig mae'r Arglwydd Bethell wedi rhoi sicrwydd “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”.

Roedd yr Alban a Gogledd Iwerddon eisoes wedi rhoi cydsyniad deddfwriaethol i'r gynigion cyn i cytundeb gael ei wneud gyda Llywodraeth Cymru i symud ymlaen at Femorandwm Cyd-ddealltwriaeth. Yng ngoleuni'r sicrwydd hwn, y cydweddu â materion sylweddol a gedwir yn ôl, buddion sylweddol tebygol y system wybodaeth i ddiogelwch cleifion a gwella ac arloesi ym maes dyfeisiau meddygol yr wyf eisoes wedi'u hamlinellu, rwyf yn bwriadu argymell bod y Senedd yn cymeradwyo'r Cynnig Cydsyniad Deddfwriaethol i'r Bil Meddyginiaethau a Dyfeisiau Meddygol i sicrhau bod Cymru'n cymryd rhan yn llawn yn MDIS. Bydd hyn yn sicrhau bod Cymru'n cymryd rhan yn llawn yn MDIS.

Rwyf wedi ysgrifennu llythyr tebyg at Gadeirydd y Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad, Mick Antoniw AS, ac yn anfon copi o'r llythyr hwn at holl Aelodau'r Senedd,

Yn gywir,

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
London
SW1H 0EU
Tel: 020 7210 4850

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 4th 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 14th 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 12th January.

Yours,

Bethell

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

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

<u>Four UK Nations Working Group for the MDIS Regulations</u>

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