Welsh Parliament
Health, Social Care and Sport Committee

Legislative Consent Memorandum: Medicines and Medical Devices Bill

October 2020

Background

1. On 8 July 2020, the Minister for Health and Social Services laid a Legislative Consent Memorandum (LCM) for the Medicines and Medical Devices Bill currently before the UK Parliament.

2. On 13 July, the Business Committee referred the LCM to the Health, Social Care and Sport Committee, and the Legislation, Justice and Constitution Committee for consideration. In referring the Memorandum, the Business Committee set a reporting deadline of 22 October 2020.

The LCM

3. Paragraphs 3 to 5 of the Legislative Consent Memorandum summarise the Bill and its policy objectives. Paragraphs 6 to 9 set out the provisions in the Bill for which consent is sought. Paragraphs 10 to 14 set out the reasons for using the UK Bill to make provision for Wales, and paragraphs 19 to 21 set out the Welsh Government's view on using the UK's Bill to deal with these provisions.

Provisions in the Bill for which consent is sought

4. The provisions within the Bill for which consent is sought are contained in clause 16. This clause confers a delegated power on the Secretary of State for

Health and Social Care to make regulations for a database of information in relation to medical devices to be established and managed by NHS Digital.

5. The LCM states that the purpose of clause 16 is:

> "to improve the safety and standards of medical devices by ensuring that better information can be captured and shared on the performance of implanted devices in order to identify risks of specific devices early on. This would apply to the NHS and private health providers in Wales.
>
> By improving the data available on medical devices as part of post-market surveillance, the Medicines and Healthcare products Regulatory Agency (MHRA), will be better able to take action earlier and more effectively as part of their regulation of devices in the UK, including Wales."

6. The LCM also states that the provisions in clause 16 would mean that, in the event of a recall, "it would be possible to rapidly identify which devices had been implanted into specific patients":

> With the establishment of a registry a UK wide information depository holding data on a wider variety of cases reflecting a diverse range of clinical practices would be likely be more effective in generating learning than a smaller Wales focussed body."

Reasons for making these provisions for Wales in a UK Bill

7. The Welsh Government's rationale for supporting the inclusion of these provisions for Wales in a UK Bill is two-fold. First, that the design and implementation of a Wales registry of implanted devices is "highly unlikely to be feasible within a reasonable timescale and at comparable cost." It would also not have the advantages in terms of the breadth of data it could hold and the learning opportunities that a UK registry would provide.

8. Second, there is no space within the Welsh Government's current legislative programme to bring forward a Bill on this subject, and there is no other Bill already in the programme into which the provisions could be inserted.

Approach to scrutiny

9. The Committee first considered the LCM on 16 July and agreed:

- to issue an open call for written evidence and to seek the views of a number of professional bodies;
- to write to the Minister for Health and Social Services for further information on a number of "outstanding concerns" referred to in paragraph 14 of the Memorandum but for which no details had been provided. A copy of that letter and the Minister's reply is attached at Annexe A.

10. Written responses were received from BMA Cymru, the Welsh NHS Confederation and RCN Cymru.

11. The Committee subsequently heard oral evidence from the Minister on 30 September, and Members took the opportunity to question him further about these concerns. Following that meeting, the Committee wrote again to the Minister. A copy of that letter and the Minister's reply is attached at Annexe B.

Consideration of the LCM

12. The Minister confirmed that the Bill is an enabling measure and, as such, its detailed implementation will be a matter for regulations. He said there was no timeline for the regulations, but that "it is unlikely" that a draft would be available for comment until well after the Bill receives Royal Assent.

13. The Minister has secured an agreement from Lord Bethell (the UK Parliamentary Under Secretary of State, leading on the Bill in the House of Lords) to table an amendment to require consultation with Welsh Ministers and the other devolved administrations when making regulations. Whilst he acknowledged that this was a step forward, the Minister said he was looking for something that went "beyond consulting":

14. He confirmed that his officials were working on a set of broad principles which would shape the regulations in a way that would be acceptable to the devolved administrations collectively and that these would form the basis of negotiations with the UK Department of Health and Social Care (DHSC). If these principles could be agreed by all parties and reflected in the regulations, the Minister said this would largely address his concerns.

15. Discussions on these principles are currently at an early stage and they have not been shared with DHSC.

16. In our evidence session on 30 September, the Minister said that, whilst the process of seeking legislative consent had started, the Welsh Government was "not yet in a position to recommend agreement."[1] The LCM itself states that work to resolve the outstanding concerns has been progressed and that a supplementary legislative consent memorandum will be brought forward at the appropriate time if required.[2]

Financial implications

17. We questioned the Minister on the financial implications of the LCM, following some concerns raised by RCN Wales in its evidence. The Minister told us that the cost estimates had been prepared by the UK DHSC, covered the whole system, and were hypothetical because the system is not yet agreed. He went on to say:

> "It's also worth reflecting that, whilst there will be costs of implementing a new system, we expect there will be significant benefits, not only in terms of harm reduction, but in terms of direct costs for that, whether that's by corrective procedures, or, indeed, litigation costs."[3]

Conclusion

18. As the Minister has made clear, this LCM represents the beginning of the process of seeking legislative consent in this area. Much of the detail has still to be worked out and is the subject of on-going discussions between the Welsh Government, UK Department of Health and Social Care and the other devolved administrations.

19. We note that a supplementary LCM may be brought forward further down the line, subject to progress being made with these discussions.

20. At the time of producing this report, the Committee does not have all the information needed to be able to form a view on the merits of the LCM. We are

[1] (https://record.senedd.wales/Committee/6443#C312972)

[2] Paragraph 14

[3] (https://record.senedd.wales/Committee/6443#C312915)

therefore not able to make a recommendation to the Senedd about whether to support this LCM or otherwise.

21. We do, however, take the opportunity provided by this report to make available to Members the work we have undertaken so far, including the correspondence we have received.

Annexe A

Senedd Cymru
Y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon

—

Welsh Parliament
Health, Social Care and Sport Committee

Vaughan Gething MS
Minister for Health and Social Services

23 July 2020

Dear Minister

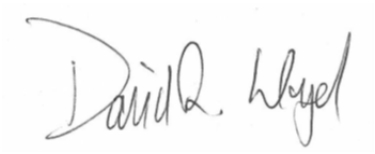
The Committee will be considering the Legislative Consent Memorandum (LCM) for the Medicines and Medical Devices Bill early in the autumn term to meet the reporting deadline of 22 October. To assist our consideration we have written to professional bodies seeking their views.

The LCM sets out the Welsh Government's rationale for including provisions for Wales in the UK Medicines and Medical Devices Bill ('the UK Bill'). Reasons given include the feasibility of developing a Wales registry and lack of time within the Senedd's legislative programme to bring forward a Bill making provision for Wales on these matters. We would be grateful if you could expand on your rationale for including provisions for Wales in the UK Bill, beyond that set out in the LCM.

The LCM also states that there are a number of outstanding concerns that have been raised with the UK Government and work to resolve these concerns will be progressed as the Bill continues its Parliamentary passage. Can you please provide us with more information on what these concerns are, why you are concerned about them and what you are seeking to achieve in your discussions with the UK Government.

It would be helpful if you could let us have your response by 28 August.

Yours sincerely



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

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Ein cyf/Our ref MA-P/VG/2171/20

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

1 September 2020

Dear Dr Lloyd,

I refer to your letter of 23 July seeking clarification about the rationale for submitting a Legislative Consent Memorandum to the Senedd for the Medicines and Medical Devices Bill, which provides a power by regulation to enable the NHS in Wales to participate in a medical device information system (MDIS) operated by NHS Digital.

The amendment introducing the MDIS was approved by the House of Commons and incorporated as Clause 16 in the House of Lords' Bill, and if enacted would impinge on the Welsh Government's devolved powers relating to data collection, control and use in relation to health matters.

There is clear benefit to Wales participating in the UK-wide MDIS. It is a response to the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Cumberlege, which looked at how the health system responded to reports from patients about harmful side effects from medicines and medical devices. A large number of Welsh women were adversely affected by the two medicines and mesh devices the review team examined.

The intention is that the information system would be established to support the efficiency and safety of medical devices and patients who have received or been tested with a medical device, or into whom the medical device has been implanted. The information system by identifying when the outcomes of medical device use fall below the expected performance would provide an impetus for prompt investigations and follow-up action leading to the recall of the devices, their improvement or changes in the clinical techniques employed. It would also enable patients and clinicians to identify the risks associated with specific devices early on enabling them to select the best treatments and provide patients with the type and quality of information required to enable them to give their informed consent to clinical procedures. The Bill's provisions requires the data to be provided by both the NHS and private health providers.

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In summary , the capturing of data identifying a specific medical device and data from a patient's information record (such as clinician details, location, device information) means that in future we will be better able to track and trace medical devices if a safety concern arises and also recognise, at an early stage, issues relating to patient safety.

Your letter questions why the arrangements in the Bill should not be introduced separately for Wales using Welsh Government legislation rather than UK legislation. The reasons for preferring a UK-wide approach rather than one limited to Wales include:

- the higher patient numbers and range of clinical techniques involved would enable more meaningful and useful comparisons to be made enhancing the potential for learning;
- facilitating the sharing of costs, expertise, and the development of common data standards and procedures for collecting, sharing and analysing the data. In addition, utilising UK bodies such as registries which are unavailable in Wales. The design and implementation of an equivalent Wales only medical device information system would be highly unlikely within a reasonable timescale and at comparable cost.
- the opportunity to "piggy back" on the policy, modelling and practical implementation work that DHSC has devoted to delivering its proposals, including the finding of Parliamentary legislative time .

As I mentioned in the Legislative Consent Memorandum I have a number of concerns about the provisions in the Bill. I am concerned that DHSC intend to extend NHS Digital's remit to Wales and the other nations of the UK, where it currently has no locus. I believe that the MDIS should be collectively owned and subject to four nations' governance, with accountability and reporting to the Ministers of Health in each of the four nations.

I also believe that the MDIS should have the power to "request" rather than "require" data from health bodies in the nations of the UK. Ideally, the information should be collected by each nation, in Wales' case by NHS Wales' Informatics Service (NWIS) from LHBs, and transferred to NHS Digital. This would ensure that Wales retained its data, which could, if required, be incorporated in a Wales implant registry.

On a related point, I have concerns about the ownership of the data, in particular whether NHS Wales would have access to all the data, including that of the other nations, to undertake its own analyses. I understand that NHS Digital currently propose that although Wales could retain its own data, it would not have direct access to the raw data from England and the other nations of the UK to undertake its own analyses, but would have to rely instead on NHS Digital's "insights" into the data. I am also uncertain how Wales would benefit should there be any commercial sales of the data, either directly by NHS Digital or via another organisation such as the MHRA. There is also the related question of whether the economic development benefits resulting from the data source would be equally accessible to all UK nations' health science sectors.

Finally, there is only a general duty to consult on the associated regulations within the Bill. There is no specific requirement to consult with the other national governments of the UK, nor the health bodies that will be impacted by the MDIS provisions, and engagement during the Bill process constitutes consultation. Officials, along with those from the other nations of the UK, have been pursuing with the DHSC an amendment to strengthen the commitment to engagement and consultation.

I wrote to Lord Bethell, the DHSC's Parliamentary Under Secretary of State, who is leading on the Bill in the House of Lords about my concerns on 7 July but have not yet received a response from him. I have asked my officials to liaise with officials from the other nations of the UK, who have similar concerns.

I am copying this letter to the Chair of the Legislation, Justice and Constitution Committee.

Yours sincerely,

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

Annexe B

Senedd Cymru
Y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon

—

Welsh Parliament
Health, Social Care and Sport Committee

Vaughan Gething MS
Minister for Health and Social Services
Welsh Government

6 October 2020

Dear Minister

Thank you for your recent attendance at Committee and the answers you provided to our questions on the LCM for the Medicines and Medical Devices Bill.

There are a few further points that we wish to raise with you prior to producing our report, which we are required to do by 22 October.

During the session, you confirmed that you had received a response from Lord Bethell on 14 August. I would be grateful if you would make a copy of that letter available to the Committee to help our discussions.

You noted that the response, whilst constructive, did not provide all the answers you were looking for. Notably, you said you were not yet in a position to recommend agreement of legislative consent.

One of the areas you highlighted as being subject to further discussions with the UK Government was in relation to the involvement of Welsh Ministers in the making of regulations. You confirmed that Lord Bethel had agreed to table an amendment that would require the relevant Secretary of State to consult Welsh Ministers when making regulations. You said you were looking for something that went beyond consulting, and instead involved seeking the agreement of Ministers in devolved governments. This will be the subject of further negotiations. If there has been any progress in this area prior to our reporting deadline, we would be grateful to hear from you.

Additionally, in your earlier written response to us (16 September), you identified a number of other concerns with the provisions of the Bill, namely -

> *"I am concerned that DHSC intend to extend NHS Digital's remit to Wales and the other nations of the UK, where it currently has no locus. I believe that the MDIS should be collectively owned and subject to four nations' governance, with accountability and reporting to the Ministers of Health in each of the four nations."*

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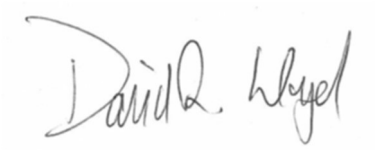
"I also believe that the MDIS should have the power to "request" rather than "require" data from health bodies in the nations of the UK. Ideally, the information should be collected by each nation, in Wales' case by NHS Wales' Informatics Service(NWIS) from LHBs, and transferred to NHS Digital. This would ensure that Wales retained its data, which could, if required, be incorporated in a Wales implant registry."

"I have concerns about the ownership of the data, in particular whether NHS Wales would have access to all the data, including that of the other nations, to undertake its own analyses."

Could you please provide an update on the progress of discussions between you and the UK Government on each of these concerns.

You will appreciate that our reporting deadline is approaching. As such, I would be grateful to receive your **response by 12 October**.

Yours sincerely



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Ein cyf/Our ref VG/0340/20

Dr Dai Lloyd MS
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12 October 2020

Dear Dai,

Thank you for your letter of 6 October seeking further clarification of progress in relation to my concerns about the provisions on the medical device information system in the Medicines and Medical Devices Bill.

As I mentioned in the Health, Social Care and Sport Committee last week the Bill is an enabling measure the implementation of which will be determined by regulations which have not yet been drafted. Although there is no timeline for the regulations I understand it is unlikely that there will be a draft available to comment on until well after the Bill receives Royal Assent, which is likely to be, at the earliest, towards the end of this year.

In the absence of the draft regulations and in order not to have to rely alone on the assurance in Lord Bethell's letter of 14 September that the Devolved Governments "particular considerations" will be taken into account when drafting the regulations, I have asked my officials to identify a series of broad principles which would shape the regulations in a way that would be acceptable to the devolved administrations collectively and form the basis of our negotiations with the Department. I attach the list which is currently being considered by Scottish and Northern Irish officials.

If these principles were to be agreed by the other Devolved Governments, DHSC and reflected in the regulations I believe that they would largely address my concerns. But the discussions on the principles with the Devolved Governments are at an early stage and they have not yet been shared with the Department.

I am optimistic that we may be able to make some progress with DHSC as my officials consider that they have shown a willingness to work collaboratively with us and the other Devolved Governments on the regulations.

When it is clear that the Devolved Governments can agree on a common line I will write again to Lord Bethell to ask him to give urgent consideration to accepting the principles and

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to incorporate them in the regulations, hopefully before the Health, Social Care and Sport Committee finalises its report on 22 October.

I also attach Lord Bethell's letter of 14 September which you requested.

Yours sincerely,

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)

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

LIST OF PRINCIPLES RELATING TO THE OPERATION OF THE MEDICAL DEVICE INFORMATION SYSTEM

Governance

- To ensure joint four UK nation agreement to and control over the MDIS database, but with each nation retaining control over their own data;

- To have joint four UK nation agreement on the strategy, function, operation and direction to be followed by the proposed MDIS by close engagement in the development of regulations so that all can contribute to ensure the best possible integration of the MDIS with their national data collection arrangements.

- To be involved in agreeing the MDIS' reporting arrangements and procedures for handling disagreements /conflicts and how they would be resolved.

- To ensure that the full costs of setting up and operating the MDIS, including those to be incurred by the four UK nations, are accurately recorded and that full provision is made for them in the appropriate financial settlements.

- To have full involvement in the setting of common information standards such as data collection, quality and retention standards;

- To have full involvement in key decisions such as whether there should be a UK wide medical device registry and its specifications, sales of data to commercial organisations;

- To retain control of whether, when and by whom enforcement action should be taken and penalties imposed within each nation's jurisdiction.

Operational/Data

- To set up a joint agreement between the four UK nations for the identification of the data to be collected, how, by whom, the flow and usage of the data and provide for equal access to it, including the raw data, so that no one nation can do more with the data than another nation/country;

- To ensure early and meaningful engagement with patients, clinicians, the public and industry about the MDIS so that it is understood how their data is collected and used, recognising issues of consent and privacy and to agree how patients, clinicians, the public, industry and others could best access the data.