



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.

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:
0300 0604400

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1SN

Gohebiaeth.Vaughan.Gething@llyw.cymru
Correspondence.Vaughan.Gething@gov.wales

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.

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,

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