

The Welsh Government's Legislative Consent Memorandum on the Medicines and Medical Devices Bill

October 2020

1. Background

The Bill

1. The Medicines and Medical Devices Bill¹ (the Bill) received its first reading in the House of Commons on 13 February 2020. It is sponsored by the Department of Health and Social Care.

2. The explanatory notes to the Bill (as introduced) state:

“The Medicines and Medical Devices Bill (The Bill) does three things: (i) introduces targeted delegated powers in the fields of human medicines, veterinary medicines and medical devices to enable the existing regulatory frameworks to be updated following the United Kingdom’s (UK) departure from the European Union (EU); (ii) consolidates the enforcement provisions for medical devices and introduces sanctions; and (iii) provides an information gateway to enable the sharing of information held by the Secretary of State about medical devices, for example to warn members of the public about safety concerns.”²

3. The Bill completed its stages in the House of Commons on 23 June 2020. It was introduced in the House of Lords on 24 June 2020.

¹ [Medicines and Medical Devices Bill](#)

² Medicines and Medical Devices Bill, [Explanatory Notes](#), paragraph 1



4. At the time of writing this report, the Bill is at Committee stage in the House of Lords.

The Welsh Government's Legislative Consent Memorandum

5. A Legislative Consent Memorandum (LCM) was not required until clause 16 was added to the Bill during Report Stage on 23 June 2020 in the House of Commons.

6. On 8 July 2020 the Welsh Government laid before the Senedd an LCM³ in respect of the Bill.

7. The Business Committee agreed that the Legislation, Justice and Constitution Committee and the Health, Social Care and Sport (HSCS) Committee should report on the LCM by 22 October 2020.⁴

8. On 1 September 2020 the Minister for Health and Social Services (the Minister) wrote to the Chair of the HSCS Committee to provide further clarification about the rationale for laying the LCM.⁵

Provision for which the Senedd's consent is required

9. Clause numbering in the LCM reflects the version of the Bill introduced to the House of Lords.

10. Paragraphs 6 to 9 of the LCM set out the Welsh Government's view of which provisions in the Bill require Senedd consent.

11. The LCM states:

"The provisions within the legislative competence of the Senedd are contained in Clause 16 in the Commons Report stage version of the Bill, and Clause 16 in the House of Lords Bill which 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, which previously had no remit in relation to Wales."⁶

³ Welsh Government, [Legislative Consent Memorandum, Medicines and Medical Devices Bill](#), July 2020

⁴ Business Committee, [Timetable for consideration of the Legislative Consent Memorandum on the Medicines and Medical Devices Bill](#), July 2020

⁵ [Letter from the Minister for Health and Social Services to the Chair of the Health, Social Care and Sport Committee](#), 1 September 2020

⁶ LCM, paragraph 6

Clause 16

12. Clause 16 gives the Secretary of State power to make regulations about information systems. To the extent that the Secretary of State uses the power to make regulations about information systems for the purpose of ensuring the safety of medical devices, legislative consent is not required because the safety of medical devices is reserved.

13. However, clause 16 is a broad power and could be used to make regulations about information systems for the purpose of the safety of patients or the purpose of improving patient outcomes, both of which are devolved matters. Therefore, legislative consent is required for clause 16 and, on this matter, both the Welsh and UK Governments are in agreement.

14. Paragraphs 10 to 14 of the LCM set out the reasons for making the provisions for Wales in the Bill.

15. The LCM states:

“The Welsh Government is supportive of the aims of the Bill and is generally supportive of the principles behind clause 16.”⁷

16. The LCM continues:

“However, there are a number of outstanding concerns that have been raised with the UK Government. Work to resolve these concerns will be progressed as the Bill continues its Parliamentary passage and, if required, a supplementary legislative consent memorandum will be brought forward at the appropriate time.”⁸

17. The letter from the Minister of 11 September 2020 also sets out a number of outstanding concerns in relation to the Bill. These include the extension of NHS Digital's remit to Wales and other nations of the UK, the collection of data for the medical device information system and the subsequent ownership of that data, and the general duty to consult on the associated regulations within the Bill. The letter notes that those concerns have been raised with Lord Bethell, the Department for Health and Social Care's Parliamentary Under Secretary of State, but that a response has not yet been received.

18. The LCM concludes:

⁷ LCM, paragraph 10

⁸ LCM, paragraph 14

“It is the view of the Welsh Government that it is appropriate to deal with these provisions of clause 16 in the UK Bill as it would ensure that the arrangements needed to effectively monitor medical device implants would be in place sooner and at lower cost than if a bespoke Wales only approach could be available.

The establishment of a UK wide registry also has significant benefits in terms of the breadth of data collected and the opportunities for learning from that data.

There will be ongoing dialogue with the UK government in relation to the points of concern during the summer recess.”⁹

2. Committee consideration

19. We considered the LCM at our meeting on 28 September 2020.¹⁰

Our view

20. We note the Welsh Government's assessment that clause 16 of the Bill requires consent. We also note the Welsh Government's reasons as to why, in its view, making provision for Wales in the Bill is appropriate.

21. We also note that the Welsh Government has outstanding concerns in respect of a number of areas, and that a supplementary legislative consent memorandum may be required.

22. Further, we note that an amendment to clause 16 has been tabled at Committee stage in the House of Lords.¹¹ The amendment would require the Secretary of State to consult the devolved governments before making regulations in devolved areas under clause 16.

⁹ LCM, paragraphs 19-21

¹⁰ [Legislation, Justice and Constitution Committee](#), 28 September 2020

¹¹ [Medicines and Medical Devices Bill. House of Lords Committee Stage, Baroness Thornton's amendment to insert a new clause after Clause 16 \(105\)](#)
