LEGISLATIVE CONSENT MEMORANDUM

MEDICINES AND MEDICAL DEVICES BILL

1. This legislative consent memorandum is laid under Standing Order (SO) 29.2. SO29 prescribes that a legislative consent memorandum must be laid, and a legislative consent motion may be tabled, before the Senedd if a UK Parliamentary Bill makes provision in relation to Wales for any purpose within, or which modifies the legislative competence of the Senedd.

2. The Medicines and Medical Devices Bill was introduced into the House of Commons on 13 February 2020. The Bill can be found at: https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices.html

Policy Objectives

3. The stated purpose of the Medicines and Medical Devices Bill is to replace the section 2(2) provision in the European Communities Act 1972, which will be repealed on the United Kingdom's exit from the European Union and creates powers to enable the continuation of the main arrangements for regulating human medicines, human clinical trials, medical devices and veterinary medicines post Brexit.

Summary of the Bill

4. The Bill is sponsored by the Department of Health and Social Care.

5. The Bill makes provision for:
    - Introducing targeted delegated powers in the fields of human medicines, veterinary medicines and medical devices, in anticipation of the UK's withdrawal from the EU;
    - A delegated power to establish one or more information systems in relation to medical devices;
    - Consolidating the enforcement provisions for medical devices and introduces sanctions; and
    - An information gateway to enable the sharing of information held by the Secretary of State about medical devices such as to warn the public about safety concerns.

Provisions in the Bill for which consent is required

6. 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.

7. The purpose of the provision identified above (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.

8. It would also 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.

9. The power to make regulations making broad provision about the establishment and operation of information systems is very broad. The power may be used for reserved matters, relating to regulation and safety of medical devices, but could also be used for health purposes not concerned with product safety and which are devolved, such as improving patient health care outcomes. On this basis, the purpose of clause 16 does relate to non-reserved matters. We therefore consider this provision to be within the legislative competence of the Senedd and as such it is considered that the consent of the Senedd is required in respect of it.

Reasons for making these provisions for Wales in the Medicines and Medical Devices Bill

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

11. In relation to clause 16, the absence of data and information on those who have received surgical implants and experienced complications has been a significant recent issue in the case of a large number of Welsh women who underwent vaginal mesh procedures. The lack of relevant data resulted in the invisibility of the problem for a number of years and minimal remedial action until the Cumberlege review team in 2018 paused some mesh procedures until six conditions had been met including the provision of improved data on implanted devices and the setting up of a registry of implanted devices.

12. Welsh Government's officials have had some opportunity to input into DHSC's data collection proposals and it is considered the design and implementation of a Wales registry is highly unlikely to be feasible within a

reasonable timescale and at comparable cost. A Wales only registry would also not have the advantages in terms of breadth of available data and opportunities for learning, outlined at paragraph 8 above, which would be realised with a UK wide registry.

13. There is also no space in the Welsh Government's current Legislative Programme for a Bill making provision for Wales on these matters, nor is there any Bill in the programme to which such provisions could be included.

14. 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.

Financial implications

15. The purpose of the Legislative Consent Memorandum is to inform the Business Committee and the Members of Senedd that the DHSC provisions impinge on the Welsh Ministers' powers and as such will have no direct financial implications. As the provisions in the Bill relating to the establishment of information systems are enabling powers the regulations will provide the detail of how the information systems will be established and operated and the role which the Welsh Government will have in relation to them. The Department's current plans envisage that the regulations will be discussed and drafted after the Bill has received Royal Assent, most likely in 2021.

16. The DHSC has floated a number of unquantified illustrative proposals for how the information systems could be funded including membership subscriptions, fees, and the sale of data to commercial bodies but nothing firm or authoritative has been shared or agreed with us. There could be financial implications in Wales should there be a requirement for the Welsh Government or health bodies to subscribe for membership of the Information Systems and various registries while the costs incurred by Wales' health bodies in collecting and transferring the data to the Information Systems on a regular basis might involve the need for additional staff resources in data services. Further financial assessment will be undertaken when the likelihood of costs are known and the detail will be provided in a future advice.

17. We currently have a revenue and capital budget for 1 year, 2020-21, the period for which we have a funding settlement from the UK Government. Costs falling within this current financial year will be managed within the HS MEG and any potential future funding will need to be considered within the context of the Comprehensive Spending Review anticipated to take place later in 2020 and investment prioritised within the HSS MEG, once indicative allocations are available.

18. The impact assessment revised for the clause is here: https://publications.parliament.uk/pa/bills/lbill/58-01/116/5801116-IA.pdf

Conclusions

19. 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.

20. 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.

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