SUPPLEMENTARY LEGISLATIVE CONSENT MEMORANDUM

(MEMORANDUM NO.2)

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 Senedd Cymru 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 UK Parliament's House of Commons on 13 February 2020 and consideration in the House of Lords commenced on 24 June 2020. House of Lords Committee stages in the House of Lords completed on 19 November 2020. The Bill can be found at:

   https://services.parliament.uk/Bills/2019-21/medicinesandmedicaldevices.html

Policy Objectives

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and Medical Devices Bill is to replace section 2(2) provision of the European Communities Act 1972, which will be repealed on the United Kingdom's exit from the European Union and creates powers to enable the continuation of the main arrangements for regulating human medicines,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

Update since the Publication of the First Legislative Consent Memorandum

6. We laid a Legislative Consent Memorandum on 8 July 2020 based on the Bill as introduced into the House of Lords on 24 June 2020.

7. The Memorandum confirmed we are supportive of the Bill's purpose but has a number of concerns about aspects of the former clause 16 (now clause 18) relating to the introduction of a medical device information system. The concerns included the absence of a specific requirement to consult the devolved administrations (DAs) on the medical device information system (MDIS), the need for four nation oversight of the system, the costs to the Welsh Government and NHS in Wales of participating in the initial stages of the MDIS and ownership of the data and access to the raw non-Welsh data for comparative analyses.

8. As the Bill is enabling legislation, the details of how it will be implemented will be determined by UK regulations. Officials of the DAs have developed a series of principles to which the regulations should conform for discussion with the Department of Health and Social Care (DHSC) and NHS Digital.

Changes to the Bill since the publication of the first Legislative Consent Memorandum for which consent is required

9. House of Lord Committee stage concluded on 19 November. During Lords Committee stage there were no changes to the human or veterinary medicines sections of the Bill which impact on the Senedd's powers.

10. However, a UK Government amendment to the medical device provisions tabled by Lord Bethell on 17 November was agreed in relation to the DAs which is within the Senedd's competence. This amendment is to clause 41 (now clause 43) which replaces the former general power to consult with a statutory requirement that the DAs are consulted before any regulations under clause 16 (now clause 18) are made irrespective of whether the proposed regulations are seen as relating primarily to supporting specific device safety matters or supporting the wider healthcare system.

Welsh Government position on the Bill as amended

11. We support the House of Lords' amendment to clause 41 (now clause 43) which ensures that the DAs, including the Welsh Government, will have an opportunity to engage in the discussions on the design and operation of the MDIS and to highlight any specific arrangements they would like to see reflected in the regulations.

12. The emerging proposals on the design of the MDIS envisage a partnership arrangement between the NHS, patients, regulators, device manufacturers, clinicians, DAs and Department of Health and Social Care (DHSC) and the form and nature of the system is likely to be unclear until early drafts of the regulations are available. The DAs have been given assurances by the UK government of places on the working groups that will design and implement the MDIS, including on the project's steering group and there are also proposals for a four nation working group to look at the MDIS regulations.

13. Discussions continue with UK Government on some areas of the Bill and further assurances and we will set out more detail on our position as the situation develops and further information becomes available.

Follow up from recent Senedd Committee reports on the Legislative Consent Memorandum on the Bill

14. Following scrutiny of the Legislative Consent Memorandum laid on 8 July 2020, by the Health, Social Care and Sport and the Legislation, Justice and Constitution Committees neither committee made a recommendation on whether legislative consent should be given to clause 16 (now 18) but requested further information before reaching a view on whether or not consent should be given.

15. Since the Senedd Committees' reports on 22 October, it should be noted as set out in paragraph 10 above, that following discussions on the DAs principles an amendment has been made to clause 41 (now clause 43) of the Bill, strengthening the requirement to consult with the other UK Ministers. Furthermore, there have been NHS and government official discussions on the informatics and technical issues for the MDIS. Discussions with DHSC's bill team officials on further ministerial assurances are ongoing and are yet to be concluded.

Financial implications

16. As the Bill contains enabling provisions there are no direct financial implications for Wales as a result of taking these provisions in this Bill.

Conclusion

17. The supplementary legislative consent memorandum outlines the relevant changes made to the Bill at Lords stage requiring Senedd consent. The Welsh Government is supportive of the policy behind the Bill, but has concerns about aspects of clause 16 (now clause 18). Much of the concern relates to the absence of firm information on the form and nature of the proposed information system and how it will operate. This reflects the absence of draft regulations and firm views on its form and operations. UK Ministers have emphasised that the DAs views on the regulations will be carefully considered when shaping the new arrangements and the DAs, including Welsh Government and the NHS in Wales, have been offered places on the working groups.

18. The benefits of a UK wide MDIS are recognised and set out in the first Legislative Consent Memorandum on the Bill The Cumberlege Report also recently emphasised the importance of introducing such a system

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