

SUPPLEMENTARY LEGISLATIVE CONSENT MEMORANDUM

MEDICINES AND MEDICAL DEVICES BILL

Introduction

1. This supplementary legislative consent memorandum (LCM) has been lodged by Jeane Freeman MSP, Cabinet Secretary for Health and Sport. This supplementary LCM augments the original LCM on the Medicines and Medical Devices Bill which was lodged on 18 August 2020¹. That LCM identified provisions contained within that Bill that could be used for purposes relating to both reserved and devolved matters. That provision related to the medical device information systems to be established under clause 16.

2. The original LCM confirmed the Scottish Government's intention to pursue discussions with the UK Government regarding how regulations to be developed under clause 16, which would implement that information system, should take account of the distinct governance arrangements around medical devices and patient safety in Scotland. Those discussions have now concluded. The latest version of the Bill can be accessed via the following link:

<https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices.html>

Recommendation and Summary

3. Discussions with the UK Government have reached a positive conclusion. As noted in the earlier memorandum, the Scottish Government had concerns about the lack of engagement and consultation on the Bill. In addition to the amendment made under clause 41 that has been lodged by the UK Government to require that the Secretary of State consults Scottish Ministers, Welsh Ministers and the Department of Health in Northern Ireland when making regulations under clause 16, there is also a separate non-legislative commitment from the Department of Health and Social Care (DHSC) to ongoing discussions on the Medical Devices Information System (MDIS) governance arrangements and other operational details that will ensure that the Scottish Government is engaged in MDIS policy and operational discussions and the development of draft regulations.

4. The DHSC has reiterated its assurance that it and its partners intend to work in full partnership with the Scottish Government and devolved administrations and to ensure full sign-up to all elements of the overall vision. Representatives from the Scottish Government and the NHS in Scotland have been invited to participate in the NHS Digital Steering Group who will be developing plans for the future implementation of the MDIS.

¹ <https://www.parliament.scot/parliamentarybusiness/Bills/115811.aspx>

UK Government Amendment

5. The Annex provides the UK Government's tabled amendment to the Bill ("the amendment") lodged on 12 October 2020. The Bill will start the Committee Stage in the House of Lords on 19 October 2020.

6. Under this amendment made under clause 41, the Secretary of State is required to (a) consult Scottish Ministers, Welsh Ministers and the Department of Health in Northern Ireland when making regulations under clause 16; and (b) requires a public consultation to be undertaken before making any regulations. Regulations under clause 16 enable the Secretary of State to instruct NHS Digital to create and operate an MDIS.

Conclusion

7. The Scottish Government acknowledges that the main purpose of the Medicines and Medical Devices Bill is to provide a legal basis for a range of activities currently subject to EU rules after the end of the implementation period.

8. It remains a matter of regret to the Scottish Government that the UK has withdrawn from the EU. The Scottish Government considers this will have widespread detrimental effects on the UK and Scotland, and has deep concerns over the harm that will be inflicted on Scotland by withdrawal from the European Union.

9. The Scottish Government is committed to the principles of the Medicines and Medical Devices Bill and, now that discussions with the UK have been concluded and the amendment has been tabled, recommends consent.

Draft Legislative Consent Motion

10. The draft motion, which will be lodged by the Cabinet Secretary for Health and Sport is:

"That the Scottish Parliament agrees that the relevant provisions of the Medicines and Medical Devices Bill, introduced into the House of Commons on 13 February 2020, relating to information systems, so far as they fall within the legislative competence of the Scottish Parliament, should be considered by the UK Parliament."

SCOTTISH GOVERNMENT
October 2020

Amendment

Clause 41

LORD BETHELL

Page 24, line 9, leave out “consult such persons as the authority considers appropriate” and insert “carry out a public consultation.

(1A) In relation to proposed regulations under section 16(1), the Secretary of State must specifically consult—

- (a) the Welsh Ministers,
- (b) the Scottish Ministers, and
- (c) the Department of Health in Northern Ireland.

(1B) In relation to proposed regulations under section 1(1), 8(1) or 12(1), the consultation document must include a summary of the relevant authority’s assessment of the matters mentioned in section 1(1A) and (2), 8(1A) and (2) or 12(1A) and (2)(as the case may be).”

Member’s explanatory statement: This amendment requires a relevant authority to carry out a public consultation before making regulations under any provision of Part 1, 2 or 3, and to set out the authority’s assessment of any matter to which the authority must have regard in making the regulations, as well as requiring the Secretary of State to consult the devolved administrations in relation to regulations under clause 16(1).

This Supplementary Legislative Consent Memorandum relates to the Medicines and Medical Devices Bill (UK legislation) and was lodged with the Scottish Parliament on 19 October 2020

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