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Health and Sport Committee Comataidh Slàinte is Spòrs

Legislative Consent Memorandum on the Medicines and Medical Devices Bill (LCM (S5) 43 and 43a)



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Health and Sport Committee

To consider and report on matters falling within the responsibility of the Cabinet Secretary for Health and Sport.



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Background

1. A Legislative Consent Memorandum (LCM) was originally lodged on 18 August 2020 by the Cabinet Secretary for Health and Sport, Jeane Freeman, in accordance with Rule 9B.3.1 (c) of the Parliament's Standing Orders. The LCM related to the UK Government Medicines and Medical Devices Bill, as amended. The LCM was referred to the Health and Sport Committee.
2. The original LCM stated that the Scottish Government could not recommend consent at that time due to ongoing discussions with the UK Government regarding how regulations to be developed should take account of distinct governance arrangements in Scotland.ⁱ
3. Following a positive conclusion to these discussions, a supplementary LCM was lodged on 19 October 2020 stating that the Scottish Government could now recommend consent to the UK Parliament legislating in this area.ⁱⁱ

ⁱ Legislative Consent Memorandum [Medicines and Medical Devices Bill](#)

ⁱⁱ Supplementary Legislative Consent Memorandum [Medicines and Medical Devices Bill](#)

Medicines and Medical Devices Bill

4. The Medicines and Medical Devices Bill was introduced into the House of Commons on 13 February 2020. The main purpose of the Bill is to provide a legal basis for a range of activities currently subject to EU rules after the end of the implementation period.
5. As introduced, the Bill did not relate to matters within the legislative competence of the Scottish Parliament. Following the UK Government amendment to insert Clause 16 (information systems), legislative consent is required on the basis that the information systems established under the Clause could be used for purposes relating to both reserved and devolved matters.
6. As noted in the original LCMⁱⁱⁱ, the Scottish Government had concerns about the lack of engagement and consultation on the Bill. The supplementary LCM states that the UK Government's tabled amendment to the Bill, made under clause 41 and lodged on 12 October 2020, requires the Secretary of State 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.^{iv}
7. The supplementary LCM further notes that there is also a separate non-legislative commitment from the Department of Health and Social Care to ongoing discussions on the Medical Devices Information System (MDIS) governance arrangements and other operational discussions to ensure that the Scottish Government is engaged in MDIS policy and operational discussions and the development of draft regulations.^v

iii Legislative Consent Memorandum [Medicines and Medical Devices Bill](#)

iv Supplementary Legislative Consent Memorandum [Medicines and Medical Devices Bill](#)

v Supplementary Legislative Consent Memorandum [Medicines and Medical Devices Bill](#)

Scrutiny of the Memorandum

8. At its meeting on 27 October 2020 the Committee considered the LCM and supplementary LCM. The Committee agreed with the Scottish Government view that the relevant provisions which fall within the legislative competence of the Scottish Parliament should be considered by the UK Parliament and agreed that there is no requirement to call for further evidence.
9. The Committee's consideration at that meeting can be found in the Official Report (when available) at the following link:
 - [Health and Sport Committee Official Reports](#)

Conclusion

10. The Committee supports the use of the LCM procedure on this occasion. The supplementary LCM includes a draft legislative consent motion to be lodged by the Cabinet Secretary for Health and Sport in the following terms-

“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.”^{vi}

