LEGISLATIVE CONSENT MEMORANDUM

MEDICINES AND MEDICAL DEVICES BILL

Introduction

1. This memorandum has been lodged by Jeane Freeman, Cabinet Secretary for Health and Sport, in accordance with Rule 9B.3.1 (c). The Bill and supporting documents can be found at https://services.parliament.uk/Bills/2019-21/medicinesandmedicaldevices.html.This memorandum relates to the Bill as amended during Commons Report stage.

2. The Medicines and Medical Devices Bill ("the Bill") was introduced into the House of Commons on 13 February 2020. The main purpose of the Bill as introduced was to confer power to amend or supplement the law relating to human medicines, veterinary medicines and medical devices. Additionally, it makes provision about the enforcement of regulations, and the protection of health and safety, in relation to medical devices.

3. As introduced, the Bill did not relate to matters within the legislative competence of the Scottish Parliament and accordingly legislative consent was not sought in relation to the Bill after its introduction. Following the UK Government amendment to insert Clause 16 (information systems), legislative consent is required on the basis that the information systems established under that Clause could be used for purposes relating to both reserved and devolved matters.

4. This Bill is necessary as a result of the UK's withdrawal from the EU. The Scottish Government deeply regrets the withdrawal of Scotland, as part of the UK, from the EU on 31 January 2020. This action was taken with no democratic mandate for withdrawal in Scotland. However, the Scottish Government accepts the need to make preparations for the exceptional circumstances which arise as a result of that withdrawal and to ensure that the safety of patients is not adversely affected by the impact of EU exit on medicines and medical device standards.

5. The Scottish Government is not yet in a position to lodge a legislative consent motion in relation to the Bill but it is hoped that this point can be reached after discussions with the UK Government. In line with Rule 9B.3.3(d) of the Standing Orders, the Scottish Government's reasons for not including a draft motion are set out in paragraphs 13-15 below.

Content of the Bill

6. The Explanatory Notes[1] accompanying the Bill set out the UK Government's view of its purpose and main functions. The Bill does four 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 UK's

[1] https://publications.parliament.uk/pa/bills/lbill/58-01/116/5801116en01.htm

departure from the EU[2]; (ii) provides a delegated power to establish one or more information systems in relation to medical devices; (iii) consolidates the enforcement provisions for medical devices and introduces a system of civil sanctions for medical device offences; and (iv) 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.

Clause 16

7. Clause 16 confers a delegated power on the Secretary of State to make regulations providing for a database of information in relation to medical devices to be established and managed by the Health and Social Care Information Centre (commonly called NHS Digital). The Secretary of State may specify in those regulations the information which must be provided to NHS Digital, the form in which information is to be provided and, the persons who must provide information. This delegated power can be used to create and further develop information systems for the purposes of enabling information on medical devices to be analysed and tracked. The information gathered in this way may only be used for purposes relating to the safety, performance and effectiveness of medical devices. Clause 16 extends and applies to Scotland.

8. Currently NHS Digital may only gather information from the NHS in Scotland where there is an agreement in place between NHS Digital and the NHS bodies concerned. If it becomes law, Clause 16 would be the first provision giving NHS Digital a direct statutory power to gather information from the NHS in Scotland.

9. The Scottish Government is committed to improving the safety and standards of medical devices, particularly in relation to ensuring that any risks of specific devices can be identified early. Clause 16 would allow for a system to be put in place to monitor the performance of devices across the UK, enabling patient outcomes to be tracked. The Scottish Government believes this would be valuable in tracking safety issues in relation to medical devices. With an agreement on the arrangements for consultation and engagement in the development of the Regulations the Scottish Government would be content to give support to this clause.

Requirement for legislative consent

10. The Explanatory Notes to the Bill set out the UK Government's view that the legislative consent of the Scottish Parliament is required for the provisions in Clause 16. The Scottish Government agrees with this view on this specific provision.

11. The Scottish Government believes the amendment to the Bill now makes this "a relevant Bill" within Rule 9B.1.1 of Standing Orders, as it makes provision applying to Scotland for purposes within the legislative competence of the Parliament.

[2] Regulations made in these fields were previously made under section 2 of the European Communities Act 1972. Powers under that Act will only be available until the end of the EU exit transition period on 31 December 2020.

12. In particular, the Scottish Government considers that legislative consent is required because regulations may make provision relating to the "clinical effectiveness" of medical devices. The Scottish Government considers that the purpose of collecting or analysing information on the clinical effectiveness of medical devices would be to improve patient outcomes and the health of patients. The Scottish Government notes that the improvement of patient outcomes and the improvement of the health of the people of Scotland are devolved purposes which are within the legislative competence of the Scottish Parliament. It is the opinion of the Scottish Government that Clause 16 confers a delegated power which could be used for devolved purposes.

Consultation and reasons for not recommending legislative consent at this time

13. The Scottish Government was informed of the Bill prior to its introduction. The Scottish Government was informed of the amendment proposing to insert clause 16 the day before it was tabled by the Secretary of State. The Scottish Government therefore had no opportunity to consider the ramifications on the clause prior to its insertion. The view was that consultation had taken place earlier on the Bill and this new amendment would be discussed as soon as possible.

14. The Bill also contains the requirement to consult on the associated regulations (see Clause 41). The Secretary of State must, therefore, consult on information systems regulations but there is no specific requirement to consult with relevant parts of the NHS in Scotland or with the Scottish Ministers. While the Scottish Government supports the creation of a UK-wide database of information in relation to medical devices, it is also of the view that any regulations to be developed under clause 16 to implement that information system must take account of the governance arrangements around medical devices and patient safety in the devolved administrations. Therefore, the Scottish Government and other devolved administrations are working jointly to seek an amendment to the Bill to this effect. The Scottish Parliament would be able to scrutinise any decision by Scottish Ministers to consent to any regulations under clause 16 that would affect devolved interests, in accordance with the arrangements for scrutiny of such decisions agreed between the Scottish Government and the Parliament. Should the UK Government guarantee that appropriate consultation and engagement with the Scottish Government and other devolved administrations will be provided for to ensure that implementation aligns with, and takes account of, devolved healthcare systems, then the Scottish Government will be able to recommend consent to the relevant provisions in the Bill.

15. The Scottish Government is also in discussion with the UK Government to secure representation of Scottish NHS bodies on any steering group convened to oversee the establishment and operation of the information system.

Financial Implications

16. There will be financial implications in implementing the regulations in Scotland. The policy around how the Medical Device Information System (collects the data) and eventual Registry system (links these together to form outcome measurements) will be funded has not yet been developed and the costs of establishing and running the Registries will depend on their respective sizes and functions. This is subject to further

work. Costs will include: set up costs, ongoing operating costs, wider administrative costs as well as the technological solution to provide this in Scotland.

Conclusion

17. 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 that withdrawal from the European Union.

18. Whilst the Scottish Government is committed to the principles of the Medicines and Medical Devices Bill, as outlined in paragraphs 13-15, it cannot recommend consent at this time due to on-going discussions with the UK Government. A supplementary memorandum with a final position on consent will be lodged once those discussions have concluded.

SCOTTISH GOVERNMENT
August 2020

This Legislative Consent Memorandum relates to the Medicines and Medical Devices Bill (UK legislation) and was lodged with the Scottish Parliament on 18 August 2020

MEDICINES AND MEDICAL DEVICES – LEGISLATIVE CONSENT MEMORANDUM

Produced and published in Scotland by the Scottish Parliamentary Corporate Body.

All documents are available on the Scottish Parliament website at: www.parliament.scot/documents