



Northern Ireland
Assembly

Committee for Health

Report on the Health Service Medical Supplies (Costs) Bill: Legislative Consent Motion

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Introduction

1. The Health Service Medical Supplies (Costs) Bill ('the Bill') was introduced in the House of Commons on 15 September 2016. The Bill will make a number of amendments to the National Health Service (NHS) Act 2006 affecting price-controls on medicines and medical supplies, and includes powers to collect information on the medicine supply chain.
2. The Bill completed its Public Bill Committee Stage on 15 November 2016. The Bill is due to have its Report Stage and Third Reading on 6 December 2016. Further information on the Bill can be found at:
<http://www.parliament.uk/business/news/2016/october/commons-health-service-medical-supplies-costs-bill>.
3. As the control of medicines and collection of related information is a devolved matter in Northern Ireland and the relevant clauses in the NHS Act 2006 and the Bill extend to Northern Ireland, a Legislative Consent Motion is required to progress the Bill through Parliament.
4. The Minister of Health wrote to the Health Committee on *26 September 2016* to advise that she was seeking Executive agreement on a Legislative Consent Motion to ask the Assembly to endorse the extension of the provisions of the Health Service Medical Supplies (Costs) Bill to Northern Ireland. At its meeting on 29 September 2016, the Executive agreed that the provisions in the Bill should be extended to Northern Ireland. A Legislative Consent Memorandum detailing a draft motion was subsequently laid in the Assembly Business Office on 1 November 2016. The LCM was withdrawn on 18 November and a revised LCM was laid on 22 November and referred to the Committee.

Background to the Health Services Medical Supplies Bill

5. The cost of branded medicines to the NHS is regulated in the UK through two schemes, the voluntary Pharmaceutical Price Regulation Scheme (PPRS) and a Statutory Scheme, which use different mechanisms to control the price of branded medicines sold to the NHS. The Secretary of State for Health (SoS) is responsible for both schemes through powers under the NHS Act 2006.
6. Manufacturers and suppliers of branded medicines can choose to sign up to the PPRS or will automatically fall under the control of the Statutory Scheme for their branded medicines. The NI Health Minister's correspondence of 26 September 2016 provides greater detail on both schemes and their operation.
7. The provisions within the Health Service Medical Supplies (Costs) Bill are intended to address a number of concerns that the Westminster Government have expressed relating to medicines pricing. These include that the Statutory Scheme is providing lower savings for the NHS than the PPRS and that the two schemes should be more aligned.
8. Following a review of the legislative position, the Department of Health (London) (DH) has decided to amend the NHS Act 2006 to put beyond doubt that companies in the statutory scheme can be required to make payments back to the DH to control the cost of medicines to the health service, as occurs under the PPRS. Such payments could be required instead of, or in addition to, measures to limit prices directly or to control profits. The Bill will also allow for penalties to be applied for non-compliance.

9. The NHS Act also currently provides the SoS for Health with the power to control the maximum price of medical supplies other than health service medicines but this power was not fully extended to Northern Ireland under the relevant territorial extent provisions of the Act. The current Bill includes amendments to extend to Northern Ireland provisions regulating the cost of other medical supplies.
10. In addition, the Bill will address a further issue relating to high-priced generic medicines. Currently if a member of the PPRS manufactures a mixed portfolio of medicines (branded and unbranded), no statutory price controls can be applied to their unbranded products. There is evidence that companies are making unjustified price uplifts to unbranded products where there is no competition in the market to keep prices down. The amendments will enable the DH to require companies to reduce the price of a specific unbranded medicine, or impose other controls on that company's unbranded medicine, even if the company is a member of the voluntary scheme for their branded medicines.
11. Other provisions in the Bill relate to the power to collect information on purchases and sales across the medicine supply chain. The Bill will bring together more clearly the information requirements for health service medicines and other supplies in the NHS Act. This will improve the transparency of medicines spend and cost for the Government.
12. In connection with this, the Bill also includes new powers to make regulations to requires all parts of the supply chain to keep and supply information on sales and purchases of medicines when requested by the SoS, with penalties for non-compliance.

Consultation

13. Northern Ireland was included within a DH consultation on reforms to the statutory scheme for branded medicines pricing. There has not been public consultation on the Bill's provisions relating to the collection of information on costs of medicines. These are enabling powers, however, and the Bill contains mandatory provisions requiring consultation with representative bodies at regulation-making stage.

Further Government amendments to the Bill

14. The NI Department of Health advised the Committee that the DH was proposing to legislate, through later Government amendments, to provide the SoS with powers to require information on drugs dispensed by community pharmacists and dispensing GP practices, with penalties for non-compliance. This is intended to complement the information being collected from others in the medicines supply chain. The Committee was advised that this would require a second LCM since the provisions were outside the scope of the Bill as introduced. In the event, the original LCM was withdrawn and a revised LCM was tabled as detailed below.

Revised Legislative Consent Motion

15. The Minister of Health wrote again to the Committee on 9 November 2016 to advise of her intention to seek Executive agreement to a revised LCM, which would take account of amendments to the information powers in the Bill, being put forward by the DH at Committee Stage of the Bill.
16. The DH amendments aim to provide additional powers to use information collected by it, for devolved purposes. The amendments apply across all the Devolved Administrations but, in particular, would allow confidential or commercially sensitive information collected by the DH, for its own purposes, to be shared for devolved purposes; and allow the DH to

collect information on behalf of the NI Department of Health across certain parts of the medicines and medical supplies chain, which would be used for devolved purposes.

17. The NI Health Minister believes that it is appropriate for the Bill to be amended to ensure that NI would be able to maximise the value of information being collected by the DH and also to be able to inform what information is being collected. As these additional provisions deal with devolved matters outside of the scope of the original LCM, a revised LCM was necessary.
18. At its meeting on 17 November 2016 the Committee noted the Minister's intention, pending the tabling of the revised LCM.
19. A revised LCM was laid on 22 November 2016, to take account of the amendments to the information powers in the Bill.
20. The revised LCM will provide for the application of provisions in the Bill to Northern Ireland relating to:
 - the amendment of existing powers within the NHS Act 2006 to control the cost of medicines and other medical supplies to the health service;
 - clarification of existing powers, and the introduction of new powers, within the NHS Act 2006, to make regulations for the collection of information on sales and purchases of health service medicines and medical supplies;
 - allow confidential or commercially sensitive information collected by the DH for their purposes to be shared with the NI Department of Health for devolved purposes; and
 - allow the DH to collect information on behalf of the NI Department of Health across certain parts of the medicines and medical supplies chain which would be used for devolved purposes.

Committee Consideration

21. As noted earlier, the Health Minister wrote to the Health Committee on 26 September 2016 to advise that she was seeking Executive agreement for a LCM in relation to the Health Service Medical Supplies (Costs) Bill. Departmental officials briefed the Committee on the Bill as introduced, on 6 October 2016 and the Committee considered an accompanying departmental written briefing paper. A copy of the Hansard of the evidence session with the departmental officials can be found at <http://aims.niassembly.gov.uk/officialreport/minutesofevidencereport.aspx?AgendaId=19287&eveID=10851>.
22. Further to the departmental briefing, the Committee requested additional information from the officials on the negotiations with the pharmaceutical industry on the Bill; clarification of the definition of ‘medical supplies’; and the anticipated impact of the Bill on GP practices.
23. A response dated 5 December 2016 from the Department outlined the consultation that took place with representatives of the pharmacy industry which led to the introduction of the Bill. The Department also provided further detail regarding the definition of ‘medical supplies and equipment’ and confirmed that the regulation making powers to obtain information from dispensing GPs was not expected to impact significantly on local practices. The Department also confirmed that the GP representative bodies would be included in the scope of the consultation on any proposed regulations. The Committee noted the Department’s response at its meeting on 8 December 2016.
24. A Legislative Consent Memorandum in respect of the Bill was laid in the Assembly on 1 November 2016 and referred to the Committee for consideration.

25. The Minister subsequently wrote to the Committee on 9 November to advise that she was seeking Executive agreement for a revised LCM that would take account of amendments made to the information provisions of the Bill made at Committee Stage in Westminster (and discussed earlier in this report).
26. The original LCM was withdrawn on 18 November 2016 and a revised LCM was laid on 22 November 2016 and referred to the Health Committee.
27. At its meeting on 24 November 2016, the Committee for Health agreed that it was content with the Minister of Health's rationale for the revised Legislative Consent Motion in relation to the Health Service Medical Supplies (Costs) Bill.
28. The draft motion, which will be tabled by the Minister of Health is:

“That this Assembly endorses the principle of the extension to the north of Ireland of the provisions of the Health Service Medical Supplies (Costs) Bill as introduced in the House of Commons on 15 September 2016 and as subsequently amended, concerning the price of medicines and other medical supplies, and the collection of information on the medicines supply chain.”

29. The reason provided in the Legislative Consent Memorandum for utilising a LCM instead of an Act of the Assembly, and accepted by the Committee, is that the existing legislation on the cost of health service medicines, already extends and applies across Britain and Northern Ireland and that, without a LCM agreed by the Assembly, the DH would be unable to proceed with the Bill. The Bill also provides an opportunity for a consistent approach across Britain and NI to the pricing of medicines and medical supplies. It would also not be possible for the NI Department of

Health to progress separate legislation through the Assembly in a timescale to align with the DH Bill.

Links to relevant papers

The Health Service Medical Supplies (Costs) Bill and Explanatory Memorandum, as introduced in the House of Common on 15 September 2016 can be viewed *here*

Correspondence of 26 September 2016 from the Minister of Health can be viewed *here*

Department of Health briefing paper of 5 October 2016 can be viewed *here*

Hansard of the oral evidence session with official from the Department of Health on 6 October 2016 can be viewed *here*

First LCM in relation to the Health Service Medical Supplies (Costs) Bill laid on 1 November 2016 can be viewed *here*

Correspondence of 9 November 2016 from the Minister of Health regarding a revised LCM can be viewed *here*

Revised LCM in relation to the Health Service Medical Supplies (Costs) Bill laid on 22 November 2016 can be viewed *here*

Correspondence of 5 December 2016 from the Minister of Health can be viewed *here*

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