

Northern Ireland Assembly

Business Office
Parliament Buildings
Belfast BT4 3XX
Tel: +44 (0)28 9052 1251

Eilis Haughey
Committee for Health
Room 416
Parliament Buildings
Stormont
BELFAST
BT4 3XX

01 November 2016

Dear Eilis,

Health Service Medical Supplies (Costs) Bill – Legislative Consent Memorandum

The above-named document was laid in the Business Office and may be of interest to your Committee.

Yours sincerely,



Alex Carter
Business Office

FROM THE MINISTER OF HEALTH



Department of
Health

An Roinn Sláinte
Ministère O Fhaisle
www.health-ni.gov.uk

Assembly Business Office
Room 32
Parliament Buildings,
Ballymiscaw,
Stormont,
BELFAST,
BT4 3XX

Castle Buildings
Stormont Estate
Belfast BT4 3SQ
Telephone: 028 9052 0638
email: private.office@health-ni.gov.uk

Our Ref: SUB/1330/2016

Date: 24 October 2016

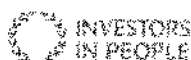
**HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL
– LEGISLATIVE CONSENT MEMORANDUM**

Under the provisions of Standing Order 42A (2), please find attached a Legislative Consent Memorandum relating to the Health Service Medical Supplies (Costs) Bill.

Should the Business Office need to discuss the Memorandum with an official from my Department, the relevant contact is David Lennox who can be contacted on: 028 90 520236 or at David.Lennox@health-ni.gov.uk.

Is mise le meas

MICHELLE O'NEILL MLA
Minister of Health



LEGISLATIVE CONSENT MEMORANDUM

HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

Draft Legislative Consent Motion

1. 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 which amends the National Health Service Act 2006 concerning the price of medicines and other medical supplies, and the collection of information on the medicines supply chain.”

Background

2. This memorandum has been laid before the Assembly by the Minister of Health under Standing Order 42A(2). The Health Service Medical Supplies (Costs) Bill was introduced in the House of Commons on 15 September 2016. The latest version of the Bill can be found at:

<http://services.parliament.uk/bills/2016-17/healthservicemedicalsuppliescosts.html>

Summary of the Bill and its policy objectives

Cost of medicines and medical supplies

3. The Bill is to amend provisions in the National Health Service (NHS) Act 2006 concerning the price of medicines and to include powers to collect information on the medicines supply chain.
4. The Secretary of State (SoS) for Health has powers under the NHS Act 2006 to limit the prices or profits from the sale of medicines supplied to the NHS. The powers provide for the existence of a voluntary scheme made by the SoS in agreement with the Association of the British Pharmaceutical Industry (ABPI), the organisation that represents innovative research-based biopharmaceutical companies.
5. The Department of Health (London) (DH) negotiates with the ABPI on behalf of the Devolved Administrations (DAs) and the current voluntary scheme, the Pharmaceutical Price Regulation Scheme

(PPRS), commenced on 1 January 2014. It is due to end on 31 December 2018 and is designed to ensure that the spending on branded health services medicines is constrained.

6. The cost growth constraint is delivered by individual pharmaceutical companies making payments back to DH in respect of their individual portfolios. The receipts are apportioned by DH to each of the DAs using the apportionment method agreed between the DAs, which is currently based on primary care data spend on licensed branded medicines by each of the DAs.
7. In addition to the voluntary PPRS, there is also a statutory scheme that puts in place statutory price limits on the sales of prescription-only, branded medicines by companies that choose not to be members of the voluntary PPRS agreement. The purpose of the statutory scheme when first established was to safeguard the financial position of the health service.
8. The DH consulted on reforms to the statutory scheme for pricing of branded medicines, with the preferred option to introduce a payment mechanism, broadly similar to that agreed in the 2014 PPRS. Whilst the NHS supported the DH's preferred option, industry responses to the consultation queried whether the DH has sufficient power in primary legislation to introduce a statutory payment mechanism.
9. Following a review of the legislative position, the DH has introduced the Health Service Medical Supplies (Costs) Bill in Westminster to amend the NHS Act 2006 to put beyond doubt that companies in the statutory scheme can be required to make payments to control the cost of health service medicines. These payments can be either instead of, or in combination with, measures to limit prices directly or control their profits. The Bill also allows for penalties to be applied for non-compliance.
10. The NHS Act 2006 also provides the SoS with the power to control the maximum price of medical supplies other than health service medicines. The relevant territorial extent provisions within the NHS Act, however, currently extend only to health service medicines provisions. The Bill includes amendments to extend those provisions to other medical supplies.
11. The Bill will also address a further issue relating to high priced generic medicines without competition. 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.

Information powers

12. The DH collects information on purchases and sales from across the medicines supply chain under different arrangements and for a number of specific purposes. The plethora of arrangements means that the DH has different levels of information about products, but does not have a full set of data about all products and is restricted as to how the information can be used.
13. The Bill includes provisions to bring together the information requirements for health service medicines and other medical supplies. This would enable more informed purchasing and reimbursement decisions and to improve the transparency of medicines spend and cost.
14. The Bill also includes new powers to make regulations to require all parts of the supply chain of NHS medicines (and other supplies) (manufacturers, suppliers, wholesalers, pharmacies and GP practices that dispense/supply medicines through personal administration), to keep and supply information on sales and purchases of medicines when requested by the SoS, with penalties for non-compliance.

Provisions which deal with a Devolution Matter

15. Provisions in the NHS Act 2006 concerning the price of medicines in the NHS Act 2006 are transferred to the north of Ireland (but not Wales or Scotland). The clauses in the Bill extend to the north of Ireland and so a Legislative Consent Motion is required.

Reasons for making the Provisions

16. The market for medicines generally operates across Britain and the north of Ireland and so it is important to maintain consistency in relation to medicines pricing. In particular, the Bill is proposing to move the statutory scheme to a similar payment mechanism as the PPRS which is deemed more efficient and equitable than reducing the list price. It is important that any potential financial benefits that will flow from the provisions within the Bill are maximised.

17. At present, the enforcement provisions within the NHS Act 2006 do not allow for action to be taken if information is not provided by players in the supply chain in relation to medical supplies. It is appropriate that the same enforcement requirements should apply to medicines as medical supplies and the Bill extends powers to control the price of medical supplies.
18. The provision of regulation making powers to collect information on health service medicines and other related products for the health service will ensure that there is a statutory footing to requests by the DH for access to data on all products and all parts of the supply chain. This is necessary to inform operation of the statutory scheme and provide value-for-money for the health service.

Reasons for utilising the Bill rather than an Act of the Assembly

19. It is appropriate on this occasion for the DH to progress legislation on this transferred matter as the existing legislation on the cost of health medicines already extends and applies across Britain and the north of Ireland. Without a LCM agreed by the NI Assembly, the DH would be unable to proceed with the Bill as introduced.
20. It would also not be possible to legislate for the north of Ireland separately within a similar timescale. That would create difficulties in the introduction of a pricing mechanism for the statutory scheme. It could therefore be financially detrimental to the north of Ireland if it was not possible to participate in the statutory scheme. It is also particularly important that there is a consistent approach across Britain and the north of Ireland to pricing of medicines and this Bill provides for that. The most efficient mechanism for amending the legislation on the price of medicines is therefore for this Bill to proceed.

Consultation

21. The DH carried out a consultation to the statutory scheme for branded medicines pricing, following agreement of the then Minister of Health. A summary of the responses to the consultation has been published and is available at:

<https://www.gov.uk/government/consultations/pricing-of-branded-health-service-medicines>
22. There has not been public consultation on the Bill's provisions relating to the collection of information on costs of medicines.

However, the Bill contains mandatory provisions requiring consultation with representative bodies at regulation making stage.

Human Rights and Equality

23. The provisions of the Bill are compatible with the European Convention on Human Rights. No adverse impact on any of the groups listed under section 75 has been identified.

Financial Implications

24. In relation to the public expenditure implications for the north of Ireland, the Bill's proposals, by generating greater savings for the Health Service, should increase the resources available to provide treatments and services to patients.

Summary of Regulatory Impact

25. The DH has published an Impact Assessment which is available from: <https://www.gov.uk/government/publications/health-service-medical-supplies-costs>. No specific impact in the north of Ireland is anticipated on employment, charities, social economy enterprises and the voluntary sector. The affected parties identified largely comprise manufacturers, wholesalers, community pharmacies and dispensing GP practices. Currently, the burden of providing information falls only on those participating in voluntary arrangements. In theory, the proposed legislation could affect any one of those suppliers. However, it is not envisaged that every player in the market would be asked to provide information on all activities. It is more likely that some sectors may be asked to provide selected information at certain times.
26. It is proposed that the power to collect information should only be exercised through regulations following consultation, setting out in more detail what information will be requested and from whom, including proposals in relation to small and micro business. The DH has indicated that this will be accompanied by a full impact assessment when the scope etc. becomes clearer.

Engagement to date with the Committee for Health

27. The Health Committee was informed on 29 September 2016 of the Minister of Health's intention to seek Executive agreement to a Legislative Consent Motion in relation to the Health Service Medical Supplies (Costs) Bill.

Conclusion

28. The view of the Minister of Health is that, in the interests of controlling the costs of Health Services medicines and other medical supplies, in so far as the provisions of the Health Service Medical Supplies (Costs) Bill deal with a devolved matter, they should be considered by Parliament.

Department of Health
[Insert date of laying]