FROM THE MINISTER OF HEALTH

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HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL – LEGISLATIVE CONSENT MOTION

Thank you for the Committee's invitation for officials to brief the Committee on Thursday 6 October 2016 at 10.30 am in relation to the proposed Legislative Consent Motion for the Health Service Medical Supplies (Costs) Bill.

The officials that will attend are as follows:

Mrs Cathy Harrison, Senior Principal Pharmaceutical Officer, DoH
Dr David Lennox, Medicines Policy Branch, DoH
Mrs Margaret Glass, Medicines Policy Branch, DoH
Mr Craig Allen, Legislation, Equality and Human Rights Branch, DoH.

In advance of the meeting, I enclose a briefing paper for members which I trust is helpful.

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Michelle O'Neill

MICHELLE O'NEILL MLA
Minister of Health

BRIEFING PAPER FOR MEETING OF HEALTH COMMITTEE - Thursday 6th October 2016

HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL – LEGISLATIVE CONSENT MOTION

Summary

1. The Committee was previously advised of the Minister of Health's intention to seek the Executive's agreement to a Legislative Consent Motion in relation to the provisions of the Health Service Medical Supplies (Costs) Bill which was introduced in Parliament on 15 September 2016. A copy of the Bill introduced by the Department of Health (London) (DH) and the Explanatory Notes are available from: http://services.parliament.uk/bills/2016-17/healthservicemedicalsuppliescosts.html

2. In summary, the Health Service Medical Supplies (Costs) Bill amends and extends existing provisions of the National Health Service Act 2006 ("the NHS Act") which relate to:
    - the control of the cost of health service medicines and other medical supplies;
    - the provision of pricing and other information to the Secretary of State by those manufacturing, distributing or supplying health service medicines or other related products required for the purposes of the health service; and,
    - the disclosure of the information referred to in the preceding paragraph in specified circumstances.

3. The pricing of medicines is a devolved matter here (although reserved as far as Scotland and Wales is concerned). A Legislative Consent Motion is therefore required to allow the DH to progress legislation that will amend the price of medicines provisions in the NHS Act.

4. At its meeting on 29 September 2016, the Executive agreed to the Bill extending to the north of Ireland and plans are in place to table a Legislative Consent Memorandum in the Assembly. Specifically, the proposed Legislative Consent Motion will:

a. allow the powers relating to the control of the cost of health service medicines, and other medical supplies, to be clarified;

b. enable the DH to take action where there are excessive prices rises/profit levels on an unbranded medicine; and

c. provide enabling powers to make Regulations for the collection of information on the costs of sales and purchases across the supply chain.

Policy Background

Medicine prices

5. The Secretary of State (SoS) for Health has powers under the National Health Service Act 2006 to limit the prices or profits from the sale of medicines supplied to the NHS. In particular, 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.

6. The 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 health service branded medicines is constrained.

7. The cost growth constraint is delivered by individual pharmaceutical companies making payments back to the DH in respect of their individual portfolios. The receipts are apportioned by the 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.

8. 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.

9. The DH has 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. However, industry responses to the consultation queried whether there are sufficient powers in primary legislation to introduce a statutory payment mechanism.

10. Following a review of the legislative position, the 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 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 would also allow for penalties to be applied for non-compliance.

11. The NHS Act also currently 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 only apply to the health service medicines provisions. The Bill includes amendments to extend those provisions to other medical supplies.

12. In addition, 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.

<u>Information on costs</u>

13. 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.

14. The Bill includes provisions to bring together the information requirements for health service medicines and other supplies in the NHS Act. This would enable more informed purchasing and reimbursement decisions and to improve the transparency of medicines spend and cost for the Government.

15. The Bill also includes new powers to make regulations to require all parts of the supply chain (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 (and other supplies) when requested by the SoS, with penalties for non-compliance.

Consultation

16. The north of 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. However, those are enabling powers and the Bill contains mandatory provisions requiring consultation with representative bodies at regulation making stage.

Future Government amendments to the Bill

17. Another important part of the medicines supply chain is the drugs dispensed by community pharmacists and dispensing doctors (although in the north of Ireland there are less than 10 dispensing doctors). The DH is proposing to legislate to provide the SoS with powers to require such information from pharmacies and dispensing GP practices, with penalties for non-compliance. It is proposed that the information would be used to complement that collected from manufacturers and suppliers for the purposes of setting reimbursement prices for pharmaceutical services and also improving the efficiency and effectiveness of the supply chain.

18. The Bill could be used as a vehicle to provide powers to allow collection of information from pharmacies and dispensing GP practices for devolved purposes, such as setting remuneration for pharmacy contractors and payments to dispensing GP practices. Subject to Executive and Assembly agreement, these provisions would be incorporated within the Bill through later Government amendments. As the provisions are outside the scope of the Bill as introduced, a second LCM would be required.