

## LEGISLATIVE CONSENT MEMORANDUM

### HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

1. This Legislative Consent Memorandum is laid under Standing Order (“SO”) 29.2. SO29 prescribes that a Legislative Consent Memorandum must be laid, and a Legislative Consent Motion may be tabled, before the National Assembly for Wales if a UK Parliamentary Bill makes provision in relation to Wales for any purpose within, or which modifies the legislative competence of the National Assembly.
2. The Health Service Medical Supplies (Costs) Bill (the “Bill”) was introduced in the House of Commons on 15 September 2016. The Bill can be found at:  
<http://services.parliament.uk/bills/2016-17/healthservicemedicalsuppliescosts.html>.

#### Policy Objectives

3. The UK Government’s stated policy objectives are to address a number of concerns that the Government has expressed relating to medicines pricing. These include:
  - That the statutory price regulatory scheme is providing lower savings for the NHS than the voluntary Pharmaceutical Price Regulatory Scheme (PPRS) and the two schemes should be more aligned;
  - That a number of single source unbranded generic medicines manufacturers have recently been able to significantly increase prices; and
  - Strengthening the power of the Secretary of State to obtain information on supply of and costs of medicines from manufacturers, distributors and suppliers of medicines.

#### Summary of the Bill

4. The Bill is sponsored by the Department of Health.
5. The Bill amends the National Health Service Act 2006 to:
  - put beyond doubt that the government can require companies to make payments to control the cost of health service medicines
  - enable the government to require companies to reduce the price of an unbranded generic medicine, or to impose other controls on that company’s unbranded medicine, even if the company is in the voluntary scheme (the Pharmaceutical Price Regulation Scheme) for their branded medicines
  - enable the government to make regulations to obtain information on sales and purchases of health service medicines, medical supplies and

other related products from all parts of the supply chain, from manufacturer to pharmacy, for defined purposes

### **Provisions in the Bill for which consent is required**

6. The consent of the Assembly is sought for certain amendments to the Bill tabled by Mr Phillip Dunne MP, Minister of State at the Department of Health in Parliament on 3 November 2016.
7. The amendments relating to Provision of information to Welsh Ministers amend the National Health Service (Wales) Act 2006 and are included in a new clause (NC1) at page 11 of the notice of amendments given up to and including 3 November 2016.
8. The National Health Service (Wales) Act 2006 is amended to include three new sections (sections 201A, B and C) which provide for the Welsh Ministers to make regulations regarding the provision of information about medical supplies in Wales. The overall effect of the amendment is that:
  - Under section 201A, Welsh Ministers can make regulations which require persons providing primary medical services or pharmaceutical services, under part 4 or part 7 of the National Health Service (Wales) Act 2006, to provide information to the Welsh Ministers regarding prices paid, discounts or rebates given, and revenue or profits accrued in the course of supplying health service products;
  - Information may only be collected by Welsh Ministers for the purposes of determining: payments to persons providing primary medical services; remuneration to persons providing pharmaceutical services; and the consideration of whether adequate supplies of health service products are available and whether the terms on which supplies are made represent value for money;
  - Welsh Ministers may, in the regulations made under this section, make provision for a person who contravenes the regulations, for example by refusing to provide information, to pay a penalty to Welsh Ministers. Where a penalty is imposed under regulations the Welsh Ministers must confer a right of appeal against the decision;
  - Under section 201B, Welsh Ministers are permitted to disclose information obtained by them to any person or description of person prescribed in regulations. Any commercial or confidential information disclosed by Welsh Ministers under this section may not be used for any purpose other than those specified in section 201A, and may not be further disclosed.
  - Under section 201C, Welsh Ministers are required to consult any body which appears to represent persons providing primary medical or pharmaceutical services before making any regulations.
  - Welsh Ministers are given the power to commence sections 201A to C by commencement order.

9. Regulation making powers of the Welsh Ministers are subject to the negative resolution procedure.
10. In addition, the effect of the amendments laid by Mr Phillip Dunne on 3 November 2016, is to amend the Bill to enable the Secretary of State to make regulations requiring manufacturers, distributors and suppliers of health service products to provide him with information on the supply and pricing of such products for defined purposes.
11. The defined purposes included purposes relating to the Secretary of State's reserved medicines pricing functions, but also include providing the Secretary of State with pricing information for devolved health purposes for Wales, Scotland and N Ireland. In relation to Wales (see amendment 3 paragraphs (d) to (f)) the Secretary of State may require information to be provided to him to enable or facilitate:
  - the determination of payments to be made to any persons who provide primary medical services under part 4 of the NHS (Wales) Act 2006;
  - the determination of remuneration to be paid to any persons who provide pharmaceutical services under part 7 of that Act; and
  - The consideration by Welsh Ministers of whether: (i) adequate supplies of Welsh health service products are available; and (ii) the terms on which those products are available represent value for money.
12. The Secretary of State does not have the power to obtain information from pharmacists and GPs in Wales (nor from pharmacists and GPs in Scotland and N Ireland) as these are "excepted persons" (amendment 11). As set out above, the Bill's amendments to the NHS (Wales) Act give Welsh Ministers the power to obtain information directly from pharmacists and GPs in Wales.
13. There is a power for the Secretary of State to share information that he receives from manufacturers, distributors and suppliers with the Welsh Ministers. There is also a power for the Welsh Ministers to disclose any confidential information that is disclosed to them by the Secretary of State to Local Health Boards, Welsh NHS Trusts and persons who provide services to the Welsh Ministers, Local Health Boards or NHS Trusts (amendment 29).
14. Consent is required for these provisions because they fall within the legislative competence of the National Assembly for Wales in so far as they relate to "provision of health services including ... pharmaceutical and ancillary services and facilities .... organisation and funding of the national health service" under paragraph 9 of Part 1, Schedule 7 to the Government of Wales Act 2006.
15. In so far as the provisions listed above confer functions on the Secretary of State to obtain and permit the sharing of information relating to devolved health purposes, consent is required as it is within the legislative

competence of the National Assembly for Wales to confer similar functions on Welsh Ministers in relation to Wales.

### **Reasons for making these provisions for Wales in the Health Service Medical Supplies (Costs) Bill**

16. The Welsh Government is supportive of measures to strengthen the statutory price regulation of medicines and of the need to collect robust information from across the supply chain both to ensure adequate supplies of medicines are available and to ensure the arrangements under which supplies are made represent value for money.
17. Unlike Ministers in the rest of the UK, Ministers in Wales do not currently have powers to require providers of pharmaceutical and primary medical services to provide information regarding the supply of health service products. Making these provisions for Wales in the Bill will ensure that the UK as a whole can take a consistent approach to gathering information from across the entire supply chain.
18. The amendments allow the Secretary of State to obtain information on supply and pricing of health service products from manufacturers, distributors and suppliers for devolved health purposes and for his reserved medicines pricing functions. The Secretary of State has a power to share the information gathered with the Devolved Administrations. Under this arrangement, manufacturers, distributors and suppliers will only have to provide information once to the Secretary of State, rather than receive multiple overlapping requests from all four administrations which could be costly and disproportionate. Furthermore it is unlikely that manufacturers and distributors will have administration specific information
19. Making these provisions for Wales in the Bill recognises both that parts of the supply chain (manufacturers and distributors) operate on a UK wide basis and that the information collected will be used for devolved and non-devolved purposes.
20. Arrangements for reimbursement of medicines supplied by pharmaceutical and primary medical services providers in Wales are the same as those in England at present; however, the policies and priorities for the Welsh and UK Governments do and will continue to vary. The power to collect information regarding supplies of medical products relevant to Wales is necessary to support policies which meet the needs of the citizens of Wales.

### **Financial implications**

21. There are no anticipated direct financial implications for the Welsh Government.

## **Conclusion**

22. It is the view of the Welsh Government that it is appropriate to deal with these provisions in this UK Bill given the information collected as a result will be used for devolved and non-devolved purposes and that it is expedient to seek powers now given imminent changes to community pharmacy contractual arrangements in England and Wales.

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**Cabinet Secretary for Health, Wellbeing and Sport**  
**November 2016**