

## **DRAFT LEGISLATIVE CONSENT MOTION**

### **HEALTH BILL**

**Motion:** “That the Parliament agrees that the UK Parliament should consider the relevant provisions of the Health Bill, introduced in the House of Commons on 27<sup>th</sup> October 2005, which will legislate in devolved areas in respect of supervisory requirements on community pharmacists and recovery of NHS costs in cases of personal injury compensation; which will include the powers consequential on these amendments; and which will alter the executive competence of the Scottish Ministers to enforce certain provisions in the Medicines Act.”

## **LEGISLATIVE CONSENT MEMORANDUM:**

### **HEALTH BILL**

#### **Background**

1. The Health Bill, which was introduced in the House of Commons on 27<sup>th</sup> October 2005, introduces a number of health improvement and social care measures. The proposed legislative consent motion will seek the consent of the Scottish Parliament to the UK Parliament legislating in devolved areas to enable Scottish Ministers, through regulations, to amend the current supervisory requirements on community pharmacists laid down in the NHS (Scotland) Act 1978. It will also seek consent to the UK Parliament legislating, again in a devolved area, in respect of the scheme to recover NHS costs in cases of personal injury compensation, to amend (i) section 153 of the Health and Social Care (Community Health and Standards) Act 2003 (“the 2003 Act”) to extend the powers of Scottish Ministers to make regulations prescribing the circumstances in which the amount recovered is to be reduced in proportion to any reduction in the compensation payable due to contributory negligence, to cases where a claim is settled in any manner and not just where there is a judicial award, extra-judicial settlement or settlement by a mediation of a prescribed nature and (ii) section 150(7) of the 2003 Act to update certain terminology which has changed in consequence of the Primary Medical Services (Scotland) Act 2004. The motion will seek the Parliament’s consent to the UK Parliament legislating to include in the Bill the conferral on the Scottish Ministers of certain powers consequential on the amendments in devolved areas, and to alter the executive competence of the Scottish Ministers to enforce certain provisions in the Medicines Act. These provisions will be made by Government amendment to the Health Bill.

2. The consequential powers conferred on the Scottish Ministers may be used (subject to procedure in the Scottish Parliament) to amend devolved law, for devolved purposes, when the Bill is amended to re-introduce the proposed devolved provisions in relation to pharmacy services and NHS cost recovery.

3. Scottish Ministers will make the Commencement Orders in respect of the amendment to section 17S of the National Health Service (Scotland) Act 1978 and the amendments to sections 150(7) and 153 of the 2003 Act for Scotland.

#### **Summary of the Bill and its Policy Objectives**

4. Some of the main provisions contained in the Bill are reserved and will extend to Scotland including the supervision of the management and use of controlled drugs. Other major provisions are devolved, but will not extend to Scotland. These relate, among other things, to the prohibition of smoking in certain premises, places and vehicles and to the prevention and control of health care associated infections.

5. The text of the Health Bill can be found at:

<http://www.publications.parliament.uk/pa/cm200506/cmbills/069/2006069.htm>

## **(1) Developing the Range of NHS Pharmacy Services**

6. The provisions to be included in the Health Bill in the area of NHS pharmacy services will be legislation in a devolved area. The Executive considers that it is appropriate to proceed by means of a UK Bill and a legislative consent motion in this instance because there are no appropriate Scottish Bills planned to allow the measures to be introduced within the required timeframe. The measures relating to NHS pharmacy services and enforcement of the Medicines Act in Scotland will complement certain sections of the Smoking, Health and Social Care (Scotland) Act 2005. That Act inserts new provisions into the NHS (Scotland) Act 1978 to introduce a new community pharmacy contract in Scotland, to be phased in from 1 April 2006.

7. The provisions in the Health Bill relating to NHS pharmacy services are minor, technical provisions. They will enable Scottish Ministers, through regulations, to amend the supervisory requirements laid down in the NHS (Scotland) Act 1978 to allow pharmacists in Scotland who provide NHS services under a Pharmaceutical Care Services (PCS) contract to delegate certain tasks to other trained pharmacy staff. It will be for Scottish Ministers to decide if they wish to invoke the power to make regulations and for the Scottish Parliament to exercise control over the use of the power. Without such an enabling amendment those pharmacists who provide NHS services under a PCS contract would be required to continue working under the current more stringent legislative requirements.

8. Alongside the proposed changes to the supervisory requirements on community pharmacists, section 108 of the Medicines Act 1968 is to be amended to provide for the enforcement of a new record keeping requirement. A permanent record is to be kept in every pharmacy identifying the responsible pharmacist at any given time. The record will have to be available for inspection and failure to keep such a record will be a criminal offence.

9. Section 109 of the Medicines Act 1968 provides for enforcement of the Act in Scotland by reference to certain provisions in section 108. Although section 109 itself is not changing, Scottish Ministers' executive competence is affected by the change to section 108.

10. The Bill will also impose other duties on the responsible pharmacist, but some of these duties will be enforceable by the Pharmaceutical Societies instead of by the Secretary of State in England and Wales by virtue of section 108 of the Medicines Act, and the Scottish Ministers by virtue of section 109. Enforcement in these circumstances will be by means of professional regulation and through provisions to be made in the NHS Pharmaceutical Services Regulations in England and Wales, and the corresponding Regulations in Scotland. A power is to be conferred on the Secretary of State (but not the Scottish Ministers) to make regulations to provide that the duty of enforcement in sections 108(1) and 109(1) of the Medicines Act shall not apply to the enforcement of these other duties on the responsible pharmacist which are not enforceable by the Secretary of State/the Scottish Ministers.

## **Background**

11. The subject matter of the Medicines Act 1968 is reserved in terms of Schedule 5 to the Scotland Act 1998. The Medicines Act regulates all activities in relation to the manufacture, importation, sale by retail or wholesale, prescribing, dispensing and administration of medicines. The Act requires that the business of the retail sale and supply of medicines through pharmacies must be under the "*personal control*" of a pharmacist i.e. that medicines,

other than general sale list medicines (which can be bought from outlets such as supermarkets), may only be supplied under the supervision of a pharmacist.

12. However, NHS legislation is devolved. Provisions in the Smoking, Health and Social Care (Scotland) Act 2005 will repeal and replace section 28(2) of the NHS (Scotland) Act 1978 by a new section 17S. This new section requires that all NHS pharmaceutical care services provided under a PCS contract will be provided by, or under the supervision of, a registered pharmacist.

13. Section 17S does not provide a regulation-making power to allow arrangements to be made for the dispensing of medicines by persons other than registered pharmacists. This means that NHS pharmacists in Scotland will be tied to their premises at a time when they are looking to expand the range of services they can provide for the NHS. The new contractual framework for NHS community pharmacy in Scotland (expected to be phased in from 1<sup>st</sup> April 2006) places greater emphasis on the provision of a wider range of quality services within and outside the pharmacy. Pharmacists will need to work in different ways to deliver these services: they will need to be given the scope to delegate some of their current duties to other trained pharmacy staff.

### **Consultation**

14. In 2005, each of the four UK Health Departments consulted on proposals for making better use of the pharmacy workforce. The consultations put forward options for changing the current statutory requirements on pharmacists and pharmacies in relation to the preparation, dispensing, supply and sale of medicines. The proposals included the idea of replacing the requirement that a pharmacist remain at all times in direct “personal control” of his/her pharmacy with the concept of a “responsible pharmacist” who could be absent from the pharmacy for brief periods whilst retaining responsibility. In addition, a new requirement to keep a detailed, daily record of the responsible pharmacist was proposed. The consultation made clear that the proposed changes would not be mandatory: pharmacists who wished to do so would be able to take up the greater freedoms offered at a pace which would support the development of local health care services and suit their individual pharmacy business needs.

15. In Scotland, a total of 67 responses were received. The majority of respondents welcomed the proposed changes in the legislation which would continue to safeguard the public while giving pharmacists greater flexibility and the freedom to use the skills and training of pharmacy staff to deliver services.

### **Proposal**

16. It is proposed to amend section 17S of the NHS (Scotland) Act 1978 (see paragraph 12) to provide for a regulation-making power to allow for the dispensing of medicines by persons other than registered pharmacists. This amendment will bring the NHS Act into line with the proposed changes to the supervisory requirements in the Medicines Act 1968.

17. The proposed amendment to section 17S will enable Scottish Ministers, through regulations, to allow pharmacists in Scotland who provide NHS services under a PCS contract to delegate certain tasks to other trained pharmacy staff. It will be for Scottish Ministers to decide if they wish to invoke the power to make regulations and for the Scottish

Parliament to exercise control over the use of the power. Without such an enabling amendment, those pharmacists who provide NHS services under a PCS contract would be required to continue working under the current, more stringent, legislative requirements.

## **Enforcement of the Medicines Act in Scotland**

### **Background**

18. Although the Medicines Act 1968 is reserved, responsibility for enforcement of the Act in Scotland is devolved to Scottish Ministers. This reflects the different criminal justice system in Scotland and recognises that some enforcement actions involve agencies such as Scottish Local Authorities and the Royal Pharmaceutical Society of Great Britain (RPSGB).

19. Traditionally the Enforcement Group of the UK Medicines and Healthcare products Regulatory Agency (MHRA) had responsibility for Medicines Act enforcement work in Scotland. Since May 2000 they have been authorised by Scottish Ministers to continue to enforce the Medicines Act in Scotland.

### **Proposal**

20. Section 108 of the Medicines Act (which in effect sets out enforcement provisions for Great Britain) is to be amended to provide for enforcement of a new record keeping requirement. This is necessary because as part of the package of reforms a permanent record is to be kept in every pharmacy identifying the responsible pharmacist at any given time. The record will have to be available for inspection and failure to keep such a record will be a criminal offence.

21. Section 109 provides for enforcement of the Act in Scotland by reference to certain provisions in section 108. Although section 109 itself is not being amended, Scottish Ministers' executive competence is affected by the change to section 108 in respect of the new record-keeping requirement. The consent of the Scottish Parliament is sought so that Scottish Ministers can exercise this new enforcement provision

22. The Bill will also impose other duties on the responsible pharmacist, but some of these duties will be enforceable by the Pharmaceutical Societies instead of by the Secretary of State in England and Wales by virtue of section 108 of the Medicines Act, and the Scottish Ministers by virtue of section 109. Enforcement in these circumstances will be by means of professional regulation and through provisions to be made in the NHS Pharmaceutical Services Regulations in England and Wales, and the corresponding Regulations in Scotland. A power is to be conferred on the Secretary of State (but not the Scottish Ministers) to make regulations to provide that the duty of enforcement in sections 108(1) and 109(1) of the Medicines Act shall not apply to the enforcement of these other duties on the responsible pharmacist which are not enforceable by the Secretary of State/the Scottish Ministers.

### **Financial Implications**

23. There are approximately 1150 community pharmacies in Scotland providing NHS pharmaceutical services. NHSScotland community pharmacy remuneration costs are in the region of £115 million each year i.e. the cost of the overall national service and locally negotiated services such as advisory services to care homes.

24. The proposals can help secure improvements in NHS value for money in the provision of community pharmacy services. For example, using pharmacists' skills and knowledge to help relieve burdens on GPs, freeing up their time to concentrate on the healthcare services that only they can deliver.

## **(2) Recovery of NHS Costs in Cases of Personal Injury Compensation**

25. The amendments to the Health Bill proposed in relation to NHS costs recovery constitute legislation in a devolved area:

- Section 153 of the 2003 Act will be amended to address the issue of contributory negligence raised during the consultation and which will apply to the Scheme as it will be administered in Scotland, England and Wales.
- A minor amendment is also required to section 150(7), again within Part 3 of the 2003 Act, as a consequence of the provisions within the Primary Medical Services (Scotland) Act 2004 ("the 2004 Act").

## **Background**

26. Following a consultation in 2002, the Scottish Parliament supported the GB-wide proposal to extend the current Road Traffic Accident scheme to allow for the recovery of NHS costs in all cases where personal injury compensation is paid. The legislative framework for the extended scheme is contained in Part 3 of the 2003 Act and is explained in greater detail in the Sewel memorandum at:

<http://www.scotland.gov.uk/Topics/Government/Sewel/SessionTwo> .

27. The 2003 Act received Royal Assent on 20<sup>th</sup> November 2003 but the introduction of the NHS Costs Recovery Scheme has been postponed three times – from 1<sup>st</sup> April 2004 until 1<sup>st</sup> November 2004 at the request of the Department for Work and Pensions (DWP) following publication of the final report on the review of Employers' Liability Compulsory Insurance (ELCI) in December 2003; again from 1<sup>st</sup> November 2004 until 1<sup>st</sup> April 2005 for administrative reasons within the Department of Health (DH), in particular new procedures to scrutinise regulatory proposals that have cost implications for businesses; and lastly from 1<sup>st</sup> April 2005 to October 2006 as a result of issues raised in the responses to the consultation exercises on the draft regulations for the Scheme, which were undertaken simultaneously by the Scottish Executive and Department of Health between September and December 2004.

28. Contributory Negligence – During the consultation exercise, DWP and other key stakeholders expressed concern about proposals within the regulations to deal only through the courts or by an approved form of mediation in cases of contributory negligence (i.e. where the compensation payment made to the injured person is reduced to reflect his/her personal responsibility for the accident and the NHS charges payable would be reduced accordingly). DWP felt this policy would increase costs, especially in smaller claims, and could be seen as undermining the work currently underway by DWP to streamline lower value ELCI claims. These views were shared by other respondents to the consultation, particularly as arrangements for resolving personal injury claims had changed significantly since the 2003 Act was first drafted.

29. Insurers would prefer a mechanism that promotes speedy and economic pre-action settlement of claims. Such a mechanism would also avoid the mediation process proposed in the regulations which could be seen as impractical in the vast majority of straightforward, low-value personal injury claims that, in practice, are almost invariably resolved by global offers and settlements.

30. Section 150(7) Amendment – In addition to the amendment to section 153 of the 2003 Act, a minor amendment is required to section 150(7), also within Part 3 of the 2003 Act, as a consequence of the provisions within the 2004 Act. Section 150(7) of the 2003 Act excludes general medical services or personal medical services provided at a hospital from being treatment in respect of which recovery of NHS costs can be made. Following the 2004 Act, the references to the section under which services of that type are provided, and the name of the services themselves, are no longer correct.

### **Proposal**

31. The proposed amendment to section 153 of the 2003 Act will remove reference to “mediation” and instead provide a more general enabling power, exercisable by Scottish Ministers, to make regulations prescribing the circumstances in which the amount recovered is to be reduced in proportion to any reduction in the compensation payable due to contributory negligence, in cases where a claim is settled in any manner. The proposed amendment to section 150(7) of the 2003 Act will correct the references to those services for which NHS costs are recoverable.

32. DH has looked at various ways of doing this but has opted to amend the 2003 Act through the Health Bill. As there are no appropriate Scottish Bills planned to allow the introduction of the scheme, GB-wide, by October 2006, the Executive is seeking the consent of the Scottish Parliament to allow the necessary amendments to sections 150(7) and 153 of the 2003 Act, as they affect Scotland, to be made in the Health Bill.

### **Financial Implications**

33. The Scheme when introduced will replace the existing Road Traffic Accident Scheme. DH has estimated that, once fully bedded in, the extended Scheme will recover in total around £250 million a year for the NHS, which means that NHSScotland’s share could be around £18m to £25m (based on Scotland’s share being between 7% and 10% of the total).

34. It is impossible to estimate reliably what the effect will be on NHS costs recovery when contributory negligence is taken into account in settling claims, as there are no useful figures available for the number of personal injury compensation claims where it is a factor. Notwithstanding, it is reasonable to assume that even with a substantial reduction in the costs that NHSScotland can recover, the wider policy implications, including increased adherence to health and safety standards in the workplace, seem sufficiently compelling to justify the amendment.