LEGISLATIVE CONSENT MEMORANDUM

Medical Innovation 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 a purpose that falls within, or modifies the legislative competence of the National Assembly.

2. The Medical Innovation Bill (the "Bill") was introduced in the House of Lords on 5 June 2014. The Bill can be found at: http://services.parliament.uk/bills/2014-15/medicalinnovation.html

Summary of the Bill and its Policy Objectives

3. The Bill is a Private Members Bill sponsored by the Lord Saatchi. The principal policy objective for the Bill is to encourage responsible innovation in medical treatment.

4. The Bill (as amended in Committee) allows a test of whether innovation is negligent to be applied at the time when the doctor is deciding whether to innovate. The intention is to give doctors confidence that, by following the series of steps set out in the Bill when deciding whether to innovate, they have acted responsibly, so that the risk of claims in clinical negligence is diminished. Overall, then the Bill provides another option in addition to the Bolam test for doctors to show that they have acted responsibly.

5. During Second Reading of the Bill on 27 June, Earl Howe, Parliamentary Under Secretary of State for Quality at the Department of Health expressed UK Government support for the principle of the Bill subject to a number of amendments to make the Bill safe for patients and to avoid adding bureaucracy to innovation.

6. Amendments were agreed at Committee Stage in the first House (the House of Lords) and clause numbers below relate to the Bill as amended by Committee.

Provisions in the Bill for which consent is sought

7. Clause 1 of the Bill makes provision relating to responsible innovation by doctors. Clause 1(1) sets out the purpose of the Bill, while clause 1(2) and (3) set out the key provisions which are intended to allow the negligence test to be applied at the time the doctor is deciding whether to innovate.

8. Clause 1(2) provides that it is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly. Clause 1(3) details the steps that a

doctor must take for the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments.

9. Clause 2 of the Bill preserves the common law position and provides that where a doctor departs from the existing range of medical treatments the doctor may choose to do so in accordance with clause 1 of the Bill or in reliance on any rule of the common law.

10. All the provisions outlined above apply in relation to Wales.

11. The Bill does not confer any powers to make subordinate legislation on Welsh Ministers.

12. It is the view of the Welsh Government that these provisions fall within the legislative competence of the National Assembly for Wales in so far as they relate to treatment and alleviation of disease, illness, injury, disability and mental disorder; provision of health services; clinical governance and standards of health care under paragraph 9 of Part 1, Schedule 7 to the Government of Wales Act 2006.

Whether it is appropriate for provisions to be made by means of the Bill

13. The purpose of the Bill is to set out a series of steps which doctors can choose to take when innovating with the intention of reducing the risk of claims in clinical negligence. The existing common-law test of the support of a responsible body of medical opinion is expressly preserved.

14. It is the UK Government's view, as stated by Earl Howe at Committee stage that

> "The operative provisions of the Bill relate entirely to modifying the law of tort, which is a reserved matter. The Bill can fairly and realistically be classified as relating to a non-devolved subject, and therefore not within the competence of the National Assembly for Wales."

15. In the Welsh Government's view the purpose of the Bill is to encourage the development and use of new medical treatments for illness etc. and therefore to achieve more effective health care services, by aiming to address any concerns doctors may have that they may be sued successfully in negligence if they use novel treatments responsibly.

16. In view of this and to comply with Standing Order 29, I have laid this Memorandum on behalf of the Welsh Government although I have concerns about the provisions in the Bill applying to Wales.

17. I also want to draw your attention to the fact that there is considerable opposition to this Bill. The British Medical Association (BMA) are opposed to the Bill. In its briefing[1] dated 24 October 2014 for House of Lords Committee stage of the Medical Innovation Bill, the BMA said that it

[1] BMA briefing for House of Lords Committee Stage

"believes that this legislation is unnecessary", and "adds nothing of value to the current law – rather, it increases bureaucracy and could create confusion, which may have implications for patient safety".

18. In addition certain medical research and charitable bodies including the Motor Neurone Disease Association, The British Heart Foundation and the Medical Research Council have questioned the necessity and practicality of further legislation as a means of encouraging innovation. In their briefing[2] dated 24 October 2014 for House of Lords Committee stage, they said that "Even with the safeguards provided in the Bill, and in the amendments, we are concerned that the Bill risks subverting the frameworks currently in place to preserve patient safety. There may be unintended consequences for patients who could be at risk when receiving treatments for which the evidence base is not fully established, including treatments which could prove ineffective or harmful".

19. The CMO and the Deputy CMO advise that this Bill is unnecessary and potentially could put vulnerable patients at risk. It is seen to move counter to the direction of our prudent healthcare policy approach which advocates 'to do no harm' in the application of evidence based care and honesty in near end of life discussions. Amendments are not considered sufficiently strong to protect the patient from poor advice and care.

20. As the UK Government is of the view that the Bill relates to non-devolved matters they are currently unwilling to agree that the provisions should not apply to Wales.

21. Before tabling a Motion and deciding whether the Welsh Government will promote it, we will continue to liaise with the Department of Health to gain a greater understanding of the implications of the amendments made to the Bill at Committee stage and the UK Government amendments tabled for Report stage, and whether they provide sufficient safeguards for patients.

Financial implications

22. There will be financial consequences resulting from implementation of the Bill. These, however, as specified within the RIA developed by the Department of Health in England cannot be quantified.

Mark Drakeford AM
Minister for Health and Social Services
December 2014

[2] Medical Research and Charitable Bodies