LEGISLATIVE CONSENT MEMORANDUM

Access to Medical Treatments (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 Access to Medical Treatments (Innovation) Bill (the "Bill") was introduced in the House of Commons on 24 June 2015. The Bill can be found at: http://services.parliament.uk/bills/2015-16/accesstomedicaltreatmentsinnovation.html

Summary of the Bill and its Policy Objectives

3. The Bill is a Private Member's Bill sponsored by Chris Heaton-Harris MP. The principal policy objective of the Bill is to encourage responsible innovation in medical treatment.

4. The principal purpose of the Bill is to encourage responsible innovation by doctors when providing medical treatment. The Bill also aims to promote access to innovative medical treatments by providing for the establishment of a database of innovative medical treatments. 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 a clinical negligence claim is diminished. The Bill therefore provides another option to the Bolam common law test for doctors to show that they have acted responsibly.

5. Committee Stage in the first house took place on 16 December and Report Stage is scheduled for 29 January 2016.

Provisions in the Bill for which consent is sought

6. Clause 1 of the Bill sets out the purpose of the Bill, namely the promotion of access to innovative medical treatments. The Bill purports to do this in two ways:
   1) by providing for the establishment of a database of innovative medical treatments, (carried out by doctors in England) and
   2) by encouraging responsible innovation by doctors in carrying out medical treatment.

7. Clause 3 makes provision relating to responsible innovation by doctors. Clause 3(1) and 3(2) 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. Clause 3(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 3(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.

8. Clause 4 of the Bill preserves the common law negligence 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 3 of the Bill or in reliance on any common law rule.

9. Clause 5 defines certain terms used throughout the Bill, and states that a doctor means a "registered medical practitioner" and references to treatment of a condition include references to its management (and references to treatment include references to inaction).

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

11. It is the view of the Welsh Government that the above 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

12. In the Welsh Government's view it is not appropriate for provision relating to Wales to be made by means of this Bill insofar as that provision relates to devolved subjects. This is because we consider the Bill to be unnecessary and that it could potentially put vulnerable patients at risk. We consider that it is 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.

13. As with Lord Saatchi's Medical Innovation Bill, first introduced into the House of Lords in the 2013-14 parliamentary session and which ran out of parliamentary time after reaching the Commons, there is considerable opposition to this Bill. The British Medical Association (BMA) is opposed to the Bill. In its briefing [1]dated 16 December 2015 for the Committee Stage of the Access to Medical Treatments (Innovation) Bill, the BMA said that it "believes that this legislation is unnecessary", and "If there is a need for additional support for doctors to innovate in their medical practice, this should be achieved through professional guidance capable of responding to changing circumstances, rather than statute."

14. In addition, certain medical advisory bodies including the Royal College of Surgeons and (RCS) and the Academy of Medical Royal Colleges (AMRC) have questioned the necessity of this Bill. The RCS recognises the good intentions behind the Bill, however, it has significant reservations about

[1] BMA briefing for House of Lords Committee Stage

this Bill. The AMRC stated in its briefing that Innovation cannot, and indeed should not, be separated, from research - which is what the Bill does. There cannot be one system for research and another for innovation. As a result, the Academy of Medical Royal Colleges do not believe that the Bill should be supported. The Royal College of Paediatrics and Child Health would like to see the Bill withdrawn as it believes it is unnecessary but more importantly, poses a real danger to the safety of infants, children and young people in England and Wales.

15. These organisations have joined others to form the Access to Medical Treatments (Innovation) Bill committee. Whilst they all support greater medical innovation they fundamentally disagree that this Bill is a sensible way of achieving this aim. They think that if enacted this Bill will actually harm good innovation by weakening patient protection, adding unnecessary bureaucracy and undermining good scientific practice.[2]

Financial implications

16. There will be financial consequences resulting from implementation of the Bill. These, however, cannot be quantified at this time.

Mark Drakeford AM
Minister for Health and Social Services
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[2] Access to medical treatments (Innovation) Bill Committee