# ACCESS TO MEDICAL TREATMENTS (INNOVATION) BILL

# EXPLANATORY NOTES

## What these notes do

These Explanatory Notes relate to the Access to Medical Treatments (Innovation) Bill as introduced in the House of Commons on 24 June 2015 (Bill 8).

- These Explanatory Notes have been prepared by the Department of Health, with the consent of Chris Heaton-Harris, the Member in charge of the Bill, in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill. So where a provision of the Bill does not seem to require any explanation or comment, the Notes simply say in relation to it that the provision is self-explanatory.

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# Overview of the Bill

1 The purpose of the Access to Medical Treatments (Innovation) Bill is to promote access to innovative medical treatments.

2 The Bill:

- provides for the establishment of a database of innovative medical treatments, and for access to information contained in that database. The database would provide doctors with the ability to record details about innovative treatments and enable other doctors to access that information to improve the sharing of knowledge about innovations.
- encourages responsible innovation by doctors in relation to the carrying out of medical treatment, by providing that a doctor is not negligent when departing from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly, in accordance with a series of steps set out in the Bill.

# Policy background

3 The Bill is intended to build upon provisions in Lord Saatchi's Medical Innovation Bill ("the MIB"), which was first introduced into the House of Lords in the 2013-14 parliamentary session. In a statement to the House of Commons in November 2013, the Secretary of State for Health, Jeremy Hunt, undertook to carry out a full consultation on the issues raised by the MIB. The objective of the MIB was to clarify the legal position for doctors wishing to carry out innovative treatments by providing that it is not negligent for a doctor to depart from standard treatments, so long as the decision to do so is made responsibly. The intended effect was to reduce doctors' concerns about claims in clinical negligence, meaning that they would be more confident to innovate.

4 A public consultation ran from February to April 2014 and the Government's response was published in July 2014. The MIB successfully passed through the House of Lords, but ran out of parliamentary time after reaching the Commons.

5 During its passage through the Lords, 22 amendments were made to the MIB. One of these – successfully tabled by Lord Hunt of Kings Heath – was to provide for a data registry as a means of recording innovations carried out in reliance on the Bill and to enable this information to be made accessible to medical practitioners. Whilst the Government agreed with the spirit of this amendment, it resisted it on the basis that it raised a number of complex issues in relation to the establishment and enforcement of a data registry which would need to be resolved through further dialogue with the medical community. Nonetheless, the amendment was accepted by the House.

6 The Access to Medical Treatments (Innovation) Bill takes on board this history and seeks to promote access to innovative medical treatments by making provision about negligence, along the lines of the MIB, and by providing for the establishment of a database of innovative medical treatments.

7 The Bill therefore provides a regulation-making power for the establishment of a database of innovative medical treatments by the Health and Social Care Information Centre ("the HSCIC"). It is intended that information relating to innovative medical treatments, and the outcomes of those treatments, carried out by doctors in England will be passed to the HSCIC through the use of coding in patient notes. The detailed design of the database would be consulted upon with professional bodies and organisations. It is envisaged that the patient's

right to privacy would be respected and the data securely managed. The database would be searchable by other doctors to use as a knowledge base of innovation. Again it is intended that the exact detail of how the access to the database would be granted would be consulted upon with professional bodies and organisations. The database would support the Government's emphasis on increased transparency and sharing of innovation and learning.

8 The Bill also makes provision to encourage responsible innovation by doctors. Under the current law a doctor will not be negligent when departing from the existing range of medical treatments if he can show that his decision is supported by a responsible body of medical opinion. This is called the "Bolam"[1] test and has been developed by the courts.

9 The Bill gives a doctor the option of following a series of steps to show that he has acted responsibly. The steps are intended to reflect the steps under the current law which a responsible doctor could be expected to take when innovating. The Bill therefore seeks to offer clarity for doctors in advance of offering innovative treatment about the steps that they need to take to demonstrate that the decision to innovate was taken responsibly, rather than requiring doctors to wait for this to be determined by a court at a later date if their actions are challenged.

10 The provisions relating to negligence apply only to doctors (and not to other healthcare professionals) because they respond to concerns specifically raised by doctors.

# Legal background

11 The HSCIC, on which functions can be conferred by clause 2 in connection with the database of innovative medical treatments, is a body corporate established by section 252 of the Health and Social Care Act 2012. It has functions relating to the establishment and maintenance of information systems as well as the collection, analysis, publication and dissemination of information; and functions relating to the quality of health and adult social care information as detailed under Part 9 and Schedule 18 to that Act.

12 The relevant legal background on clinical negligence is explained in the policy background section of these Notes.

# Territorial extent and application

13 Clause 6 sets out the territorial extent of the Bill. The Bill as introduced extends to England and Wales only. Clause 2, which provides for a database of innovative treatments, only applies in relation to innovative medical treatments carried out by doctors in England.

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[1] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

# Commentary on provisions of Bill

## Clause 1: Access to innovative medical treatments

14 Clause 1 provides that the purpose of the Bill is to promote access to innovative medical treatments by:

a. making provision for a database of innovative medical treatments, and for access to information contained in that database, and

b. encouraging responsible innovation by doctors in relation to the carrying out of medical treatment.

## Clause 2: Database of innovative treatments

15 Subsection (1) gives the Secretary of State a power to make regulations conferring functions on the HSCIC in connection with the establishment, maintenance and operation of a database. The database will contain information about innovative medical treatments carried out by doctors in England, and the results of those treatments. Before making regulations the Secretary of State must consult the HSCIC (subsection (6)).

16 Subsection (2) provides that a treatment is "innovative" if it involves a departure from the existing range of accepted medical treatments for a condition. This will include the use of medicines and medical devices in innovative ways, and would include treatments where only part of the treatment is innovative.

17 Subsection (3)(a)(i) and (ii) provide that the regulations can confer on the HSCIC the power to make provision about the information to be recorded in the database and procedures relating to how it is recorded.

18 Subsections (3)(b) and (4) provide that the regulations can make provision about access to information recorded in the database, including provision requiring or authorising the HSCIC to disclose information, and to impose conditions on those to whom information is disclosed. It is intended that the regulations will make provision for other doctors to access information recorded in the database for the purpose of sharing knowledge about innovative medical treatments and encouraging learning.

19 Subsection (8) provides that the regulations are subject to the negative resolution procedure.

20 Information about treatments will only be able to be disclosed where this is in accordance with the law, in particular the common law duty of confidentiality and the Data Protection Act 1998.

## Clause 3: Responsible innovation

21 Subsection (1) 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. Subsection (2) sets out a series of steps that doctors must take to show that they have acted responsibly (and thus not negligently).

22 Subsections (2)(a) and (b) and (3) require the decision-making process to include consultation with appropriately qualified colleagues, who must have expertise and experience in dealing with patients with the relevant condition, with a view to ascertaining whether the proposed medical treatment would have the support of a responsible body of medical opinion.

23 Subsection (2)(c) requires the decision-making process to include obtaining any consents

required by law; the Bill does not affect the legal requirement for a doctor to obtain a patient's informed consent to any treatment proposed.[2]

24 Subsection (2)(d)(i) requires the decision-making process to include consideration of opinions or requests expressed by the patient or on behalf of the patient (for example, by family members in the case of a patient who is unable to communicate his or her own opinions). This is intended to ensure that such views are taken into account by the doctor as part of making a responsible decision as to whether to offer an innovative medical treatment to a patient.

25 Subsection (2)(d)(ii) requires the decision-making process to include a risk-benefit analysis including comparison of the innovative medical treatment with the standard treatment for the condition, and with no treatment at all.

26 Subsections (2)(e) and (4) require the doctor to take any other steps necessary to ensure that decisions to innovate are accountable and transparent. Those steps expressly include recording in the patient's notes details of the colleagues whose views were obtained, what those views were, and the proposed innovative treatment.

27 Subsection (5) is self-explanatory.

### Clause 4: Effect on existing law

28 Clause 4(1) and (2) expressly preserve the common law Bolam test, so that a doctor who chooses to innovate in reliance on that rather than on clause 3 of the Bill is able to do so. They also confirm that the availability of the Bolam test is not limited by clause 3.

29 Clause 4(3) provides that compliance with clause 3 will not protect a doctor from liability in negligence if the way in which the medical treatment was actually provided was negligent.

### Clause 5: Interpretation etc.

30 Subsection (1)(a) is self-explanatory.

31 Subsection (1)(b) provides that references in the Bill to treatment of a condition include references to its management (and references to treatment include references to inaction).

32 Subsection (2) confirms that nothing in the Bill applies to treatment carried out for the purposes of medical research (such as in the context of a clinical trial). This is because such research is subject to its own separate regulatory regime. Nor do the provisions extend to treatment which is carried out solely for cosmetic purposes (subsection (3)). This reflects debates in the House of Lords on the MIB, during which strong views were expressed in favour of limiting the clinical negligence provisions to medical treatments that offer clinical benefits for patients.

## Commencement

33 All of the Bill's provisions are to be brought into force by regulations made by the Secretary of State, other than clause 6 (which comes into force on Royal Assent).

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[2] The Supreme Court have recently clarified the law of consent in the case of *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

## Financial implications of the Bill

34 An impact assessment will be published in advance of Committee stage.

## Parliamentary approval for financial costs or for charges imposed

35 A money resolution in the House of Commons will be required to authorise expenditure resulting from the establishment and operation of the database of innovative treatments.

## Compatibility with the European Convention on Human Rights

36 This is a Private Member's Bill and the Government is not required to give a statement of compatibility with the Human Rights Act 1998 in accordance with section 19(1)(a) of that Act.

37 The Department of Health has, nevertheless, considered the question of compatibility and has concluded that the Bill is compatible with the European Convention on Human Rights.

# Annex A - Territorial extent and application

| Provision | England | Wales | | Scotland | | Northern Ireland | |
|---|---|---|---|---|---|---|---|
| | **Extends to E & W and applies to England?** | **Extends to E & W and applies to Wales?** | **Legislative Consent Motion required?** | **Extends to Scotland?** | **Legislative Consent Motion required?** | **Extends to Northern Ireland?** | **Legislative Consent Motion required?** |
| Clause 1 | Yes | Yes | No | No | No | No | No |
| Clause 2 | Yes | No | No | No | No | No | No |
| Clause 3 | Yes | Yes | No | No | No | No | No |
| Clause 4 | Yes | Yes | No | No | No | No | No |
| Clause 5 | Yes | Yes | No | No | No | No | No |
| Clause 6 | Yes | Yes | No | No | No | No | No |

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