

Access to Medical Treatments (Innovation) Bill

EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by the Department of Health on behalf of Chris Heaton-Harris, are published separately as ...

Access to Medical Treatments (Innovation) Bill

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Make provision for access to innovative medical treatments; and for connected purposes.

BE IT ENACTED by the Queen’s most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

Introductory

1 Access to innovative medical treatments [j01]

The purpose of this Act is to promote access to innovative medical treatments by—

- (a) providing for the establishment of a database of innovative medical treatments, and for access to information contained in the database, and
- (b) encouraging responsible innovation by doctors in relation to the carrying out of medical treatment.

Database of innovative medical treatments

2 Database of innovative treatments [j05]

- (1) The Secretary of State may by regulations make provision conferring functions on the Health and Social Care Information Centre (“the HSCIC”) in connection with the establishment, maintenance and operation of a database containing information about—
 - (a) innovative medical treatments carried out by doctors in England, and
 - (b) the results of such treatments.
- (2) For the purposes of this section, medical treatment for a condition is “innovative” if it involves a departure from the existing range of accepted medical treatments for the condition.
- (3) Regulations under subsection (1) may in particular—

- (a) confer power on the HSCIC to make provision about the matters mentioned in subsection (4);
 - (b) make provision for and in connection with access to information recorded in the database.
- (4) The matters referred to in subsection (3)(a) are—
 - (a) the information to be recorded in the database;
 - (b) procedures relating to the recording of information in the database;
 - (c) the form in which information is to be recorded in the database.
- (5) The provision that may be made by virtue of subsection (3)(b) includes, in particular—
 - (a) provision requiring or authorising the HSCIC to disclose information—
 - (i) to specified persons or descriptions of person, or
 - (ii) for use for specified purposes;
 - (b) provision requiring or authorising the HSCIC to impose conditions to be complied with by persons to whom information is disclosed by virtue of paragraph (a) (which may include conditions restricting the use or further disclosure of information).
- (6) Regulations under subsection (1) may be made in relation to innovative medical treatments generally or innovative medical treatments falling within a specified description.
- (7) Before making regulations under subsection (1) the Secretary of State must consult the HSCIC.
- (8) In this section, “specified” means specified in regulations under subsection (1).
- (9) The power to make regulations under subsection (1) is exercisable by statutory instrument; and an instrument containing such regulations is subject to annulment in pursuance of a resolution of either House of Parliament.

Responsible innovation

3 Responsible innovation [\[j02\]](#)

- (1) 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.
- (2) For the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, a doctor must in particular—
 - (a) obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment, with a view to ascertaining whether the treatment would have the support of a responsible body of medical opinion,
 - (b) take full account of the views obtained under paragraph (a) (and do so in a way in which any responsible doctor would be expected to take account of such views),
 - (c) obtain any consents required by law to the carrying out of the proposed treatment,
 - (d) consider—
 - (i) any opinions or requests expressed by or in relation to the patient,

- (ii) the risks and benefits that are, or can reasonably be expected to be, associated with the proposed treatment, the treatments that fall within the existing range of accepted medical treatments for the condition, and not carrying out any of those treatments, and
 - (iii) any other matter that it is necessary for the doctor to consider in order to reach a clinical judgement, having regard in particular to the requirements of patient safety, and
 - (e) take such other steps as are necessary to secure that the decision is made in a way that is accountable and transparent.
- (3) For the purposes of subsection (2)(a), a doctor is appropriately qualified if the doctor has appropriate expertise and experience in dealing with patients with the condition in question.
- (4) The steps that must be taken by virtue of subsection (2)(e) include the recording in the patient's notes of details relating to—
- (a) the views obtained under subsection (2)(a),
 - (b) the doctor's decision to depart from the existing range of accepted medical treatments for the patient's condition, and
 - (c) the proposed treatment.
- (5) Nothing in this section permits a doctor to carry out treatment for any purpose other than the best interests of the patient.

4 Effect on existing law [j03]

- (1) Nothing in section 3—
- (a) affects any rule of the common law to the effect that a departure from the existing range of accepted medical treatments for a condition is not negligent if supported by a responsible body of medical opinion, or
 - (b) is to be read as limiting the circumstances in which any such rule of the common law may be relied on (including, for example, where emergency treatment is required).
- (2) Accordingly—
- (a) any decision by a doctor to depart from the existing range of accepted medical treatments for a condition in accordance with section 3 does not prejudice the doctor's ability, in relation to the departure, to rely on any rule of the common law referred to in subsection (1)(a);
 - (b) a departure from the existing range of accepted medical treatments for a condition is not negligent merely because the decision was taken otherwise than in accordance with section 3.

Interpretation

5 Interpretation etc [j06]

- (1) In this Act—
- (a) “doctor” means a registered medical practitioner;
 - (b) references to treatment of a condition include references to its management (and references to treatment include references to inaction).

- (2) Nothing in this Act applies in relation to treatment carried out for the purposes of medical research.
- (3) Nothing in this Act applies in relation to treatment which is carried out solely for cosmetic purposes.

Final

6 Extent, commencement and short title [j04]

- (1) This Act extends to England and Wales only.
- (2) Sections 1 to 5 come into force on such day or days as the Secretary of State may by regulations made by statutory instrument appoint.
- (3) Regulations under subsection (2) may –
 - (a) appoint different days for different purposes;
 - (b) make transitional or saving provision.
- (4) This section comes into force on the day on which this Act is passed.
- (5) This Act may be cited as the Access to Medical Treatments (Innovation) Act 2016.