CONTENTS

- Responsible innovation
 Interpretation
 Extent, commencement and short title



Make provision about innovation in medical treatment.

B E 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: –

1 Responsible innovation

- (1) The purpose of this section is to encourage responsible innovation in medical treatment (and accordingly to deter innovation which is not responsible).
- (2) It is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition, in the circumstances set out in subsection (3), if the decision to do so is taken responsibly.
- (3) Those circumstances are where, in the doctor's opinion
 - (a) it is unclear whether the medical treatment that the doctor proposes to carry out has or would have the support of a responsible body of medical opinion, or
 - (b) the proposed treatment does not or would not have such support.
- (4) A responsible decision for the purposes of subsection (2) is one which is based on
 - (a) the doctor's opinion that there are plausible reasons why the proposed treatment might be effective, and
 - (b) consideration by the doctor of -
 - (i) all the matters listed in subsection (5), and
 - (ii) any other matter that appears to the doctor to be appropriate to take into account in order to reach a clinical judgement.
- (5) The matters mentioned in subsection (4)(b)(i) are
 - (a) the relative risks that are, or can reasonably be expected to be, associated with the proposed treatment and other treatments,
 - (b) the likely success rates, in the doctor's reasonable judgement, of the proposed treatment and other treatments,

- (c) the likely consequences, in the doctor's reasonable judgement, of carrying out, or failing to carry out, the proposed treatment and other treatments,
- (d) opinions or requests expressed by or in relation to the patient, and
- (e) opinions expressed by colleagues whose opinions appear to the doctor to be appropriate to take into account.
- (6) A responsible decision for the purposes of subsection (2) is one made in accordance with a process which is accountable, transparent and allows full consideration by the doctor of all relevant matters.
- (7) The factors that may be taken into account in determining whether a process satisfies the requirements of subsection (6) include, in particular
 - (a) whether the doctor has discussed the proposed treatment with the patient and given the patient the explanation that the doctor would in the circumstances be expected to give of the doctor's reasons for carrying out the treatment,
 - (b) whether the decision has been made within a multi-disciplinary team, and
 - (c) whether the doctor has given notification in advance to the doctor's responsible officer (if any).
- (8) Nothing in this section permits a doctor
 - (a) to provide treatment without consent that is otherwise required by law, or
 - (b) to carry out treatment for the purposes of research or for any purpose other than the patient's best interests.

2 Interpretation

- (1) In this Act -
 - (a) "doctor" means a registered medical practitioner;
 - (b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).
- (2) The reference in section 1(7)(c) to a doctor's responsible officer is to the responsible officer (or one of the responsible officers) nominated or appointed under section 45A of the Medical Act 1983 for a designated body with which the doctor has a prescribed connection for the purposes of section 45A of that Act.

3 Extent, commencement and short title

- (1) This Act extends to England and Wales only.
- (2) Sections 1 and 2 come into force on such day or days as the Secretary of State may by order made by statutory instrument appoint.
- (3) An order 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 Medical Innovation Act 2014.