These Notes refer to the Medical Innovation Bill [HL]
as introduced in the House of Lords on 3rd December 2012 [HL Bill 61]

MEDICAL INNOVATION BILL [HL]

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Medical Innovation Bill [HL] as introduced in the House of Lords on 3rd December 2012. They have been prepared by Lord Saatchi 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.

2. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a clause or part of a clause does not seem to require any explanation or comment, none is given.

BACKGROUND AND SUMMARY

3. The Bill is designed to codify existing best practice in relation to decisions by medical practitioners to depart from standard practice and to administer innovative treatment. The Bill gives a non-exhaustive list of criteria which a doctor will apply in determining whether to innovate and specifies some features of the process by which the decision should be reached. The Bill states that it is not negligent for a doctor to depart from standard practice where he or she does so by applying criteria, and following procedures, in accordance with the Bill.

COMMENTARY ON CLAUSES

Clause 1 – Responsible Innovation

4. Clause 1 sets out the purposes of the Act. It specifies that the purposes of the Act are to codify existing best practice; to enhance certainty and clarity for doctors and others; to encourage responsible innovation; and to deter irresponsible innovation.

Clause 2 – Innovation in absence of evidence-based treatment

5. Clause 2 applies only where a doctor has reached the conclusion that in determining how to treat a patient's condition it is not possible to make a purely evidence-based decision. This could be because there is no research or other evidence available in relation to the patient's

condition; or it could be because there is available research or other evidence but it is insufficient or uncertain.

6. Clause 2(4) declares that it is not in itself negligent for a doctor to depart from standard practice where the decision to innovate is taken in accordance with the procedure set out in the clause.

7. That procedure has two components.

8. First, subsection (2) sets out a list of criteria to be applied by a doctor in considering whether to depart from the pre-existing range of acceptable treatments for a condition: the factors to be considered include the reasons why there is insufficient research or other evidence to allow the doctor to make a purely evidence-based decision; the risks associated with the innovative treatment and standard treatments; the likely success rates of the innovative treatment and standard treatments; the likely consequences of each treatment; opinions or requests expressed by the patient; and other matters that the doctor considers need to be taken into account.

9. Subsection (3) requires the doctor as well as applying the criteria necessary to enable him or her to form a judgement, to consider what process to adopt in order to ensure that a decision to innovate is made accountably, transparently and with full consideration of all relevant matters. The subsection sets out a non-exhaustive list of features that the process might include: the adoption of a decision to innovate following discussion within a multidisciplinary team; advance notification to the doctor's responsible officer; and discussion with the patient, including discussion of any dissenting opinions within the multidisciplinary team or outside.

10. Subsection (5) clarifies that the clause does not alter the position at law as to when consent is required and how that consent is to be obtained and formed. The subsection also clarifies that nothing in the clause allows a doctor to administer treatment to a patient for any purpose, including research, other than the best interests of that patient.

11. Subsection (7) allows the General Medical Council to issue guidance to the medical profession about the factors to be considered and the processes to be followed by doctors in applying the clause; the guidance is not legally binding, but courts and tribunals may have regard to it where they consider it relevant.

Clause 3 – Statutory functions to be used to support responsible innovation

12. Clause 3 requires a listed class of public authorities with responsibility for public health to have regard to the desirability of supporting responsible innovation where evidence is unavailable or uncertain.

13. The listed bodies are: the National Health Service Commissioning Board; clinical commissioning groups; the Secretary of State; and persons responsible for the provision of medical services in Wales.

MEDICAL INNOVATION BILL [HL]

EXPLANATORY NOTES

These notes refer to the Medical Innovation Bill [HL]
as introduced in the House of Lords on 3rd December 2012
[HL Bill 61]

Order to be Printed,
3rd December 2012

PUBLISHED BY AUTHORITY OF THE HOUSE OF LORDS

LONDON – THE STATIONERY OFFICE LIMITED

Printed in the United Kingdom by
The Stationery Office Limited

£x.00

HL Bill 61—EN 55/2