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## **Briefing on the Medical Innovation Bill**

### **House of Commons Second Reading – 6 March 2015**

#### **Summary**

*We, as a coalition of medical research charities, non-commercial organisations and patient groups, believe that the Medical Innovation Bill will not achieve its aim of encouraging medical innovation, and could result in potentially harmful unintended consequences. We believe that this legislation is unnecessary, and, far from protecting doctors from litigation, it could actually increase the risk of litigation faced by doctors by introducing greater complexity into the legal framework. These complex issues need careful consideration, and we call on MPs to object to any motion to pass the Bill without adequate scrutiny and debate.*

#### **Background**

The Medical Innovation Bill is a Private Members Bill introduced by Lord Saatchi, which aims to encourage innovation in medical treatment by clarifying the circumstances under which a doctor may pursue an innovative treatment without fear of litigation. The Bill is currently scheduled to have its second reading in the House of Commons on Friday 27 February.

#### **Key points**

##### ***Is the Bill necessary?***

- The Bill aims to make it easier for doctors to pursue innovative treatments without fear of litigation. However, we are not aware of significant recorded evidence that doctors are being deterred from medical innovation due to the fear of litigation.
- We are not convinced that legislation is the best way to address this issue, given this lack of evidence. There are significant other barriers to medical innovation that the Bill does not address – including funding, regulatory complexity, and clinical training and development. We believe efforts are better focused on understanding and tackling these wider barriers.

##### ***What are the risks?***

- The Bill risks subverting the frameworks currently in place to preserve patient safety. There may be unintended consequences for patients who could be at risk when receiving treatments for which the evidence base is not fully established, including treatments which could prove ineffective or harmful.
- The Bill may discourage patients and their clinicians from participating in clinical trials by encouraging the provision of novel treatments on an ad hoc basis. Without properly controlled studies, it is not possible to develop the evidence of efficacy necessary to support wider adoption of new treatments in the NHS.
- The Bill could introduce a degree of ambiguity to the law governing clinical negligence, potentially placing doctors at risk of further litigation.

### ***What are the alternatives?***

- We believe that the best way to assess the efficacy and safety of treatments is through robust research studies with appropriate clinical monitoring and collection of data and other evidence.
- It is essential that provision is made for collecting and sharing data in order to ensure that information of both beneficial and harmful effects of treatment is captured for the benefit of subsequent patients.
- Other mechanisms already exist to increase access to innovative treatments. We believe efforts are better directed through existing mechanisms, with proportionate regulation and evidence review.

### **Further information and background:**

#### ***Aims and rationale of the Bill***

- The main premise of the Bill is that doctors are being deterred from medical innovation due to the fear of litigation. We are not aware of significant recorded evidence that doctors are currently being deterred. We believe there is a need for a better evidence base to support this premise, and to provide greater clarity on the best way to address this issue.
- The Bill does not address other highly significant barriers to medical innovation within the structural and organisational levels of clinical service. Without addressing these barriers we believe that the Bill cannot achieve its overall aim. They include:-
  - the complexity of the current regulatory system which can make it time-consuming and expensive to set up clinical trials;
  - the lack of financial incentives, clinical engagement and training for the development, adoption and diffusion of innovative approaches and treatments.
- We support other mechanisms that currently exist to increase access to innovative medicines, and believe that efforts are better focused to build upon existing mechanisms such as:-
  - The Medicines and Healthcare Products Regulatory Agency's recent announcement of the Early Access to Medicines Scheme to provide a rapid approval mechanism for innovative medicines when there is a clear unmet medical need and before phase III trials;
  - The European Medicines Agency's decision to provide adaptive licensing through its 'adaptive pathways' pilot project;
  - The 'named patient' provisions of Section 9 of the Medicines Act 1968 also allow doctors to prescribe unlicensed medicinal products; ensuring widespread information about these provisions could also provide a stronger basis for innovation.

#### ***The importance of research in assessing novel treatments***

- The Bill does not make adequate provisions for follow-up or data collection. This is a key aspect of innovation since new interventions require an evidence base to demonstrate safety and efficacy and to ensure effective uptake in practice. A lack of data collection or follow-up could also lead to some practitioners continuing to provide untested and ineffective (or potentially harmful) treatments to patients.

- We are also concerned that the Bill may discourage patients and their clinicians from participating in clinical trials by encouraging the provision of novel treatments on an ad hoc basis, leading to a failure to develop the robust evidence of efficacy necessary to support wider adoption of innovations in the NHS.
- The Bill contains no specific provision for the testing of novel treatments in comparison with existing treatments, as is standard in many research studies. Without appropriate collection and sharing of results - locally and centrally - it would be impossible for the clinical community to learn from existing and new evidence.
- We believe the best way to assess the efficacy and safety of treatments is through full and robust research studies with appropriate clinical monitoring and collection of data and other evidence, on a rigorous statistical basis and with appropriate ethical approval(s).
- We welcomed the commitments made during the debates in the House of Lords about the importance of collecting data and recording the outcomes of innovative treatments. We further welcome that this is now reflected in the draft Bill, in particular the requirement for doctors to comply “with a scheme for capturing the results of innovative treatment (including positive and negative results and information about small-scale treatments and patients’ experiences)” (Clause 1 (e)), and to record details of such treatments in the patient’s medical record. However we consider there remains a need for greater clarity over how such a scheme will work in practice, and the professional requirements for doctors to comply with it.

### ***Relation of the Bill to existing law and regulation***

- Even with the safeguards provided in the Bill, we are concerned that the Bill risks subverting the appropriate frameworks currently in place to preserve patient safety. There may be unintended consequences for patients who could be at risk of receiving treatments for which the evidence base is not well established, including treatments which could prove ineffective or even harmful.
- While we welcome provisions in the most recent amendments to clarify the Bill's intersection with common law, (Clause 2), we feel that the Bill still risks introducing a degree of ambiguity to the law governing clinical negligence, potentially placing doctors at risk of further litigation. We would welcome further clarification of how the Bill will work in practice in relation to, and without conflicting with, existing law or regulation, particularly in relation to research.

### **For further information contact:**

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