Briefing on the Medical Innovation Bill
House of Lords Second Reading – 27 June 2014

We support the broad aims of the Medical Innovation Bill in seeking to ensure that patients have access to innovative, safe and effective treatments in a timely manner. However, we are concerned that the Bill, as currently drafted, will not achieve its overall aim of encouraging medical innovation, and could result in potentially harmful unintended consequences.

Patients should have access to the best possible treatments, which should be informed by high-quality medical research. Doctors should, in turn, be able to draw on the most effective and safe treatments and to innovate responsibly in the best interests of their patients without fear of litigation. We know that innovation and its adoption can be slow and there is much that can be done to improve this. As organisations that support research and innovation to improve health, we welcome initiatives to encourage medical innovation. However, we have concerns about some of the detail within the Bill and its implications. These specific concerns, outlined below and detailed in our individual responses to the Department of Health's consultation on the draft Bill, have not been addressed in the revised Bill.

Key points

- While we support the aims of the Bill in seeking to encourage medical innovation, we believe there are other important barriers to medical innovation that the Bill as currently drafted does not address. Without addressing these barriers we are concerned that the Bill would not achieve its overall aim.
- We are concerned that, even with the safeguards provided in the Bill, there may be unintended consequences for patients who could be at risk of receiving treatments for which the evidence base is not well established.
- 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. We would prefer to see novel or experimental treatments - especially unlicensed drugs - prescribed in such settings.
- We are also concerned that the Bill may discourage patients and their clinicians from participating in clinical trials if they are aware that treatments can be provided without the necessity to do so, leading to a failure to develop evidence for patients and professionals as well as to support adoption by the NHS .

Barriers to innovation

- There are highly significant barriers to medical innovation in the structural and organisational levels of clinical service, and these need to be addressed to encourage innovation. Such barriers include the cost of innovative products and budgetary constraints, the complexity of the current regulatory system which can make it time-consuming and expensive to set up clinical trials, and the lack of financial incentives, clinical engagement and training for the development, adoption and diffusion of innovative approaches and treatments. Without addressing these barriers we are concerned that the Bill would not achieve its overall aim.
- We support other mechanisms that currently exist to increase access to innovative medicines where these are based on robust regulatory mechanisms and appropriate evidence review; for example, 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, as well as the European Medicines Agency's decision to provide 'adaptive licensing' through its 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 main premise of the Bill is that doctors are being deterred from medical innovation due to the fear of litigation. In many of our individual responses to the Department of Health's consultation on the draft Bill, we stated that we were 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 clarify the best way to address this issue.

Importance of research in assessing novel treatments

- The Bill is concerned with medical innovation yet does not itself deal with the conduct of research. We feel that innovation and research are intimately linked since innovation requires an evidence base if it is to be put into practice, which is unachievable using data obtained from a single patient (or a small number of patients without structured follow-up information).
- We are concerned that the Bill does not make provisions for follow-up or data collection. This could lead to some practitioners continuing to provide untested and ineffective (or potentially harmful) treatments to numerous patients. The lack of data collection is also counter to the concept of innovation, which should be linked to research as part of the landscape for development of new effective and safe treatments.
- Furthermore there is no 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 fully appreciate that not all treatments are available in large-scale clinical trials and we support the need for a more flexible approach to assessing the impacts of innovative approaches, particularly in rare and life-limiting disorders. However, we are concerned with the current lack of provisions in the Bill for data

collection and clinical follow-up which would allow the UK to evolve an environment where such innovative approaches could start to be evaluated.

- 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.

For further information contact:
Will Greenacre, Policy Officer, The Wellcome Trust
w.greenacre@wellcome.ac.uk / 020 7611 8490

Helen Haggart, Head of Policy, Association of Medical Research Charities
h.haggart@amrc.org.uk / 020 7685 2626

Our individual responses to the Department of Health's consultation on the draft Bill are available at the links below:

Academy of Medical Sciences / Medical Research Council / Wellcome Trust joint response:
http://www.acmedsci.ac.uk/download.php?f=file&i=29391
or
http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtp056583.pdf

Association of Medical Research Charities:
http://www.amrc.org.uk/publications/amrc-submission-to-the-department-of-health-consultation-on-legislation-to-encourage

Motor Neurone Disease Association:
http://www.mndcampaigns.org/assets/0003/0040/Medical_Innovation_Bill_-_consultation_response_by_the_MND_Association.pdf

Muscular Dystrophy Campaign:
http://www.muscular-dystrophy.org/assets/0004/9890/Medical_Innovation_Bill_Consultation_Response.pdf