Joint briefing on the Access to Medical Treatments (Innovation) Bill

House of Commons Second Reading - 16th October 2015

amrc
ASSOCIATION OF MEDICAL RESEARCH CHARITIES

107 Gray's Inn Road
London WC1X 8TZ

Tel: 020 7685 2620

info@amrc.org.uk
www.amrc.org.uk

Supported by the following:

Summary

We support the principle that patients should have access to effective treatments as quickly and easily as is safely possible. New initiatives that improve access to innovative treatments should be encouraged, provided they do not impact negatively on patient safety, existing innovation or research.

***However, we do not see the need for this legislation** and do not believe the Bill will achieve its aim of encouraging medical innovation. More importantly we are concerned that the Bill in its current form might have significant unintended consequences for patients and medical research.*

In conclusion, we believe this Bill, despite having the best of intentions, as it stands is unnecessary and may adversely impact on patients and medical research, in part because it lacks clarity. We therefore ask you to oppose the Access to Medical Treatments (Innovation) Bill.

Background

The Access to Medical Treatments (Innovation) Bill is a Private Member's Bill, tabled by Chris Heaton-Harris MP, with the intention to build upon provisions in Lord Saatchi's Medical Innovation Bill. The Bill has two aims:

1) **To encourage doctors to pursue innovative treatments without fear of litigation**
2) **To establish a database of innovative medical treatments for doctors**

The Bill is currently scheduled to have its second reading in the House of Commons on Friday 16th October.

KEY ISSUES FOR THE MEDICAL RESEARCH SECTOR

The database of innovative medical treatments

1.1 The proposal to capture innovative medical treatments in a database acknowledges concerns raised in the previous incarnation of the Bill. However, we do not believe that legislation would be needed to establish such a database.

1.2 Furthermore, as framed, it is unclear what this database would add above publishing case reports in the literature, and the non-mandatory nature of entries to this database means that there remains a significant risk that information of both beneficial and harmful effects of treatment would not be captured. We have reservations about the utility and safety of a database that is not mandatory. Existing databases which *are* mandatory, such as the Systemic Anti-Cancer Therapy Database (SACT), are still incomplete. We anticipate that there is little chance of this non-mandatory database being populated to any meaningful level. What is the rationale for not making it mandatory? How will clinicians be incentivised to record data?

Risk to medical research

1.3 We remain concerned that the Bill may inadvertently act to discourage patients and their clinicians from participating in robust research studies, where novel or experimental treatments – especially unlicensed drugs – are prescribed in settings where there are proper arrangements for clinical monitoring and ongoing data collection. Even a doctor 'acting responsibly' might choose to prescribe an innovative treatment to a patient rather than enter them into a clinical trial, particularly as this would guarantee them access to the treatment, whereas in a trial they might be assigned to the control arm.

Premise of the Bill and litigation

1.4 From discussion with experts in the community we do not think the Bill is necessary. In the context of the Bill, any reassurance about perceived fears of litigation needed to change doctors' practice would be better achieved via changes to GMC guidance.

1.5 Furthermore, the Bill potentially adds complexity and confusion to the law surrounding medical negligence rather than fulfilling its intended purpose of reducing perceived fear of litigation. This is particularly so since the judgement in Montgomery v Lanarkshire Health Board [2015] UKSC 11 which moves the informed consent test away from the 'reasonable body of opinion' test to a far more subjective patient-focused test. Arguably the test in the proposed legislation to 'obtain the view of one or more appropriately qualified doctors' does seek to change the law of negligence despite the stated intention not to do so.

KEY UNANSWERED QUESTIONS

Applicability to the patient journey

2.1 What are the restrictions on the type of patient that would be eligible to receive an innovative medical treatment?

2.2 What safeguards exist to ensure that an "innovative treatment" would only be considered for patients whose condition is not adequately treated/managed through existing gold-standard treatment options?

2.3 How would the legislation link with existing practice on end-of-life care? What are the safeguards to ensure that the Bill will not promote over-treatment of patients with drugs rather than discussions about palliative care options?

Patients as partners in their own care

2.4 We understand that patients would not have access to the database created by this Bill. Given this, how will the Bill ensure that patients are properly informed? How will they be able to ascertain the prevalence or otherwise of the use of any innovative treatment being suggested to them?

2.5 Will there be a duty on the prescribing doctor to communicate the opinions of **all** peers/ colleagues from whom the doctor has sought in order to prescribe the treatment?

Independence of prescribing and advising doctors

2.6 How will patients be assured about the independence/potential conflicts of interest of the prescribing doctors and those whose views are sought?

2.7 We also question the proposal that support could come from only one expert in the field. That is at odds with current practice, for example, in cancer care where consultants work in multidisciplinary teams. The level of consultation with peers is also important because not all doctors will be aware of ongoing trials.

2.8 In addition, we also have concerns about the scope of treatments covered by the Bill and the definition "accepted medical treatments".

Conclusion

In conclusion, we believe this Bill, despite having the best of intentions, as it stands is unnecessary and may adversely impact on patients and medical research, in part because it lacks clarity. We therefore ask you to oppose it.

For more information:

Please visit our website for the full set of comments that we sent Chris Heaton-Harris MP and the Bill team or alternatively contact: Katherine Mayes, Policy Officer, Association of Medical Research Charities k.mayes@amrc.org.uk / 020 7685 2633.