



In Focus

Access to Medical Treatments (Innovation) Bill HL Bill 93 of 2015–16

Key Provisions

The [Access to Medical Treatments \(Innovation\) Bill](#) is a private member's bill introduced by Chris Heaton-Harris (Conservative MP for Daventry) and sponsored in the House of Lords by Lord Saatchi (Conservative). The Bill completed its House of Commons stages on 29 January 2016 and received its first reading in the House of Lords on 1 February 2016. It is expected to receive its second reading in the House of Lords on 26 February 2016.

The purpose of the Bill is to promote access to innovative medical treatments by providing for the establishment of a database of innovative medical treatments, and access to that database. Clause 2 of the Bill provides that the Secretary of State may make regulations enabling the Health and Social Care Information Centre (HSCIC) to establish, maintain and operate a database containing information about innovative medical treatments carried out by doctors in England and their outcomes. Innovative medical treatment is defined as “medical treatment for a condition that involves a departure from the existing range of accepted medical treatments for the condition” (clause 2(2)). Clause 3 provides supplementary information to clause 2, specifying that ‘innovative medical treatments’ include, but are not limited to, the off-label use of an authorised medicinal product and the use of a medicinal product for which no marketing authorisation is in force. Clause 3 also states that references in clause 2 to medical treatment include treatment carried out for the purposes of medical research. The Bill extends to England and Wales only (clause 4).

Background

The Access to Medical Treatments (Innovation) Bill received its first reading in the House of Commons on 24 June 2015. When it was introduced in the House of Commons, the Bill contained two clauses concerning medical negligence which set out the steps a doctor would need to take in order to show that he or she has acted responsibly in giving innovative treatment.¹ These clauses were removed during report stage in the House of Commons.² These two clauses were largely the same as those contained in the [Medical Innovation Bill \[HL\]](#), which was introduced by Lord Saatchi in the House of Lords on 8 June 2015 and has yet to receive a second reading. A similar Bill was introduced by Lord Saatchi in the House of Lords in the 2014–15 session, however this did not progress beyond first reading in the House of Commons. In a statement ahead of the second reading in the House of Commons of the Access to Medical Treatments (Innovation) Bill, the Bill's sponsor, Chris Heaton-Harris, stated that the purpose of the Bill is to “encourage doctors to pursue responsible innovation in medical treatment”,³ and that the “Bill's influence is derived from Lord Saatchi's Medical Innovation Bill”.

During the second reading of the Bill on 16 October 2015, George Freeman, Parliamentary Under-Secretary of State for Life Sciences, stated that the Government supported the aim of the Bill.⁴ However, the Shadow Secretary of State for Health, Heidi Alexander, said that she did not support the Bill because she was concerned that it would lead to “unsafe treatments” being used, as well as confusion about the legal process for innovation, a reduction in participation in clinical trials and less legal redress for patients who have been victims of negligence.⁵ The Bill was given a second reading on division, with 32 voting for and 19 voting against.⁶ Subsequently, on 3 November 2015, the House of Commons agreed a money resolution, on division, in relation to the additional expenditure required to set up a database of innovative treatments.⁷ A number of amendments were tabled at the House of Commons committee stage on 16 December 2015, but these were either withdrawn or negatived on division.

The House of Commons considered the Bill at report stage on 29 January 2016. Several amendments were agreed, all without division. Chris Heaton-Harris moved amendments 1, 2 and 3, removing those clauses (3 and 4) from the Bill which, as mentioned above, related to medical negligence. In moving the amendments, Chris Heaton-Harris stated that “these clauses have not enjoyed the support of stakeholders”, continuing, “[...] I wanted to maintain the camaraderie built up around the Bill and have been unable to find the support I needed for the more controversial clauses, 3 and 4”.⁸ Amendments 10 and 13 introduced into the Bill an explicit declaration that innovative treatments include the use of drugs to treat a condition other than that for which it is specified, or to treat a person who does not fit the specified description for that medication. These amendments were supported by Conservative, Labour, SNP, DUP and SDLP politicians. In speaking to the amendments, Chris Heaton-Harris stated that the goal of the changes was to increase the use of “off-label drugs”.⁹

Amendment 15, tabled by George Freeman on behalf of the Government, removed clause 5(2) which stated that “nothing in the Act applies in relation to treatment carried out for the purposes of medical research”. During the debate at report stage in the House of Commons, George Freeman explained that this clause was intended to protect the United Kingdom’s regime for the regulation of clinical trials in the context of the original Bill’s provisions regarding medical negligence. However, since amendments had been tabled removing the clauses dealing with medical negligence, the Government advocated removing the exclusion of clinical research, in order to ensure that the database provided for in the Bill covered drugs in research.¹⁰

A number of drafting amendments were also passed.

¹ [Access to Medical Treatments \(Innovation\) Bill](#), HC Bill 8, clause (3–4).

² [HC Hansard, 29 January 2016, col 549.](#)

³ Chris Heaton-Harris, ‘[The Access to Medical Treatments \(Innovation\) Bill](#)’, 13 October 2015.

⁴ [HC Hansard, 16 October 2015, cols 611–12.](#)

⁵ [ibid, col 569.](#)

⁶ [ibid, col 613.](#)

⁷ [HC Hansard, 3 November 2015, cols 922–34.](#)

⁸ [HC Hansard, 29 January 2016, col 549.](#)

⁹ [ibid, col 533.](#)

¹⁰ [ibid, col 582.](#)

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