ACCESS TO MEDICAL TREATMENTS (INNOVATION) ACT 2016

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Access to Medical Treatments (Innovation) Act 2016 (c. 9) which received Royal Assent on 23 March 2016.

- These Explanatory Notes have been prepared by the Department of Health in order to assist the reader in understanding the Act. They do not form part of the Act and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Act will mean in practice; provide background information on the development of policy; and provide additional information on how the Act will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Act. They are not, and are not intended to be, a comprehensive description of the Act.

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Overview of the Act

1 The Access to Medical Treatments (Innovation) Act 2016 seeks to promote access to innovative medical treatments including the off-label use of medicines and the use of unlicensed medicines.

2 The Act provides for the establishment of a database of innovative medical treatments, and for access to information contained in that database. The database would provide doctors with the ability to record details about innovative treatments and enable other doctors to access that information to improve the sharing of knowledge about innovations.

Policy background

3 The Access to Medical Treatments (Innovation) Act 2016 provides for the establishment of a database of innovative medical treatments including the off-label use of medicines and the use of unlicensed medicines.

4 The Act follows Lord Saatchi's Medical Innovation Bill ("the MIB"), which was first introduced into the House of Lords in the 2013-14 parliamentary session. The objective of the MIB was to clarify the legal position for doctors wishing to carry out innovative treatments by providing that it is not negligent for a doctor to depart from standard treatments, so long as the decision to do so is made responsibly. The intended effect was to reduce doctors' concerns about claims in clinical negligence, meaning that they would be more confident to innovate.

5 During its passage through the Lords, 22 amendments were made to the MIB. One of these – successfully tabled by Lord Hunt of Kings Heath – was to provide for a data registry as a means of recording innovations carried out in reliance on the Bill and to enable this information to be made accessible to medical practitioners. Whilst the Government agreed with the spirit of this amendment, it resisted it on the basis that it raised a number of complex issues in relation to the establishment and enforcement of a data registry which would need to be resolved through further dialogue with the medical community. Nonetheless, the amendment was accepted by the House.

6 The Access to Medical Treatments (Innovation) Bill as introduced by Chris Heaton-Harris sought to build on the MIB by making provision to encourage responsible innovation by doctors, and to establish a database of innovative medical treatments. The majority of lawyers, clinicians and patient representatives were united in their opposition to the provisions relating to clinical negligence, citing concerns that the provisions would undermine the existing common law "Bolam" test and that they would remove patient safeguards. Chris Heaton-Harris, and the Government, remained convinced that these provisions were a safe and appropriate way to give greater certainty to innovating doctors, but acknowledged (following extensive consultation with lawyers and clinicians) that this view was not universal. Consequently, Chris Heaton-Harris tabled amendments at Report stage to remove these provisions, which were accepted by the House.

7 The Act provides a regulation-making power for the establishment of a database of innovative medical treatments by the Health and Social Care Information Centre ("the HSCIC"). It is intended that information relating to innovative medical treatments, and the outcomes of those treatments, carried out by doctors in England will be passed to the HSCIC through the use of coding in patient notes. The detailed design of the database would be consulted upon with professional bodies and organisations. It is envisaged that the patient's right to privacy would be respected and the data securely managed. The database would be searchable by other doctors to use as a knowledge base of innovation. Again it is intended that the exact

detail of how the access to the database would be granted would be consulted upon with professional bodies and organisations. The database would support the Government's emphasis on increased transparency and sharing of innovation and learning.

8 The Act also provides that the database can cover innovative medical treatments carried out for the purpose of research (including, for example, in the context of a clinical trial) but makes it clear that this will have no impact on the regulation of medical research.

9 The Act makes it clear that it may include medicines being used off-label and the use of unlicensed medicines. The Act defines off-label as meaning the use of a drug for a purpose for which its use is not specified (i.e. a different condition), for a person for whom its use is not specified (e.g. giving children a product licensed only for adults), or use in a way which it is not specified (e.g. a different dose or route of administration). It defines the term "marketing authorisation" (MA) with reference to the Human Medicines Regulations 2012, and defines "authorised medicinal product" as one for which a MA is in force.

Legal background

10 The HSCIC, on which functions can be conferred by section 2 in connection with the database of innovative medical treatments, is a body corporate established by section 252 of the Health and Social Care Act 2012. It has functions relating to the establishment and maintenance of information systems as well as the collection, analysis, publication and dissemination of information; and functions relating to the quality of health and adult social care information as detailed under Part 9 and Schedule 18 to that Act.

Territorial extent and application

11 Section 4 sets out the territorial extent of the Act. The Act extends to England and Wales only. Section 2, which provides for a database of innovative treatments, only applies in relation to innovative medical treatments carried out by doctors in England.

Commentary on provisions of Act

Section 1: Access to innovative medical treatments

12 Section 1 provides that the purpose of the Act is to promote access to innovative medical treatments (including the off-label use of medicines or the use of unlicensed medicines) by making provision for a database of innovative medical treatments, and for access to information contained in that database.

Section 2: Database of innovative treatments

13 Subsection (1) gives the Secretary of State a power to make regulations conferring functions on the HSCIC in connection with the establishment, maintenance and operation of a database. The database will contain information about innovative medical treatments carried out by doctors in England, and the results of those treatments. Before making regulations the Secretary of State must consult the HSCIC (subsection (6)).

14 Subsection (2) provides that "innovative medical treatment" means medical treatment for a condition that involves a departure from the existing range of accepted medical treatments for the condition. This will include the use of medicines and medical devices in innovative ways, and would include treatments where only part of the treatment is innovative.

15 Subsection (3)(a) provides that the regulations can confer on the HSCIC the power to make provision about the information to be recorded in the database and procedures relating to how it is recorded.

16 Subsections (3)(b) and (4) provide that the regulations can make provision about access to information recorded in the database, including provision requiring or authorising the HSCIC to disclose information, and to impose conditions on those to whom information is disclosed. It is intended that the regulations will make provision for other doctors to access information recorded in the database for the purpose of sharing knowledge about innovative medical treatments and encouraging learning.

17 Subsection (8) provides that the regulations are subject to the negative resolution procedure.

18 Information about treatments will only be able to be disclosed where this is in accordance with the law, in particular the common law duty of confidentiality and the Data Protection Act 1998.

Section 3: Section 2: supplementary

19 Subsections (1) and (6) are self-explanatory.

20 Subsection (2) provides that the use of certain types of medicinal products may be "innovative medical treatment" (and therefore covered by the database to be established pursuant to section 2), namely the use of medicinal products outside of their licensed indications (off label use) and the use of unlicensed medicines (e.g. UK manufactured "specials"). Whilst the description of innovative medical treatment in section 2(2) would in any event have been broad enough to include these types of treatment, this subsection makes it explicit that these uses may be innovative. These kinds of treatments are not necessarily always innovative, however, and off label use of medicines in particular may be part of standard care for some conditions.

21 Clinicians are currently free to prescribe off-label and unlicensed medicinal products where this is in the best interests of a patient, and in accordance with relevant legislation and guidance. The Medicines and Healthcare Products Regulatory Agency (MHRA) and the General Medical Council have published guidance on the "hierarchy" for the use of licensed medicinal products, off-label use and use of unlicensed medicines. The guidance states that prescribers should first consider using a licensed medicine within its licensed indications, where possible; if that is not possible, then a licensed medicine off-label should be used, and only if neither of these is available should an unlicensed medicine be considered. The guidance explains that licensed products have been assessed by the MHRA and evidence has been provided to demonstrate that the quality, safety and efficacy of the product are acceptable for the therapeutic, diagnostic or preventative use for which the product is licensed. If licensed products are used 'off-label', some of this assessment may not apply, but some will still be valid. This is lower risk than using an unlicensed product for which no evidence of safety, quality and efficacy have been submitted to regulatory authorities for review. Lower cost cannot justify off label use or the use of an unlicensed medicine when an alternative licensed product exists. The provisions of the Act have no impact on this hierarchy.

22 Subsection (3) includes further explanation about what is understood by the off label use of medicines. It may involve the use of an authorised product (that is, a product in relation to which a marketing authorisation is in force) for a purpose, or condition, other than the one which is specified in the product's marketing authorisation. It might also involve other departures from the product's marketing authorisation, such as different target patient populations (e.g. use in children of a product authorised only for use in adults) and different doses or formulations. Subsection (4) cross-refers to certain definitions in the Human Medicines Regulations 2012/1916, which provide the legal framework in the UK for the regulation of medicinal products.

23 Subsection (5) ensures that the database established by section 2 may contain information about treatments carried out for the purposes of medical research (including, for example, in the context of a clinical trial). Such inclusion does not affect the regulation of medical research.

Commencement

24 All of the Act's provisions are to be brought into force by regulations made by the Secretary of State, other than section 4 (which comes into force on Royal Assent).

Annex A - Territorial extent and application

Provision	England	Wales		Scotland		Northern Ireland	
	Extends to E & W and applies to England?	**Extends to E & W and applies to Wales?**	**Legislative Consent Motion required?**	**Extends to Scotland?**	**Legislative Consent Motion required?**	**Extends to Northern Ireland?**	**Legislative Consent Motion required?**
Section 1	Yes	Yes	No	No	No	No	No
Section 2	Yes	No	No	No	No	No	No
Section 3	Yes	Yes	No	No	No	No	No
Section 4	Yes	Yes	No	No	No	No	No

Annex B – Hansard references

25 The following table sets out the dates and Hansard references for each stage of the Act's passage through Parliament.

Stage	Date	Hansard Reference
House of Commons		
Introduction	24 June 2015	Vol. [597] Col. [903]
Second Reading	16 October 2015	Vol. [600] Col. [558]
Money Resolution Debate	03 November 2015	Vol. [601] Col. [922]
Public Bill Committee	16 December 2015	PBC (Bill 008) 2015 - 2016
Report and Third Reading;	29 January 2016	Vol. [605] Col. [529]
House of Lords		
Introduction	01 February 2016	Vol. [768] Col. [1589]
Second Reading	26 February 2016	Vol. [769] Col. [547]
Order of Commitment discharged	11 March 2016	Vol. [769] Col. [1523]
Third Reading	22 March 2016	Vol. [769] Col. [2234]
Royal Assent	23 March 2016	Vol. [607] Col. [1714]

Annex C – Progress of Act Table

26 This Annex shows how each section of the Act was numbered during the passage of the Bill through Parliament.

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 1	Clause 1	Clause 1	Clause 1	Clause 1	Clause 1
Section 2	Clause 2	Clause 2	Clause 2	Clause 2	Clause 2
Section 3	Clause 5	Clause 5	Clause 3	Clause 3	Clause 3
Section 4	Clause 6	Clause 6	Clause 4	Clause 4	Clause 4

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