



Access to Medical Treatments (Innovation) Act 2016

2016 CHAPTER 9

Database of innovative medical treatments

PROSPECTIVE

3 Section 2: supplementary

- (1) In section 2, “doctor” means a registered medical practitioner.
- (2) For the purposes of section 2(2), the kinds of medical treatment that may be innovative medical treatments include (amongst other things)—
 - (a) the off-label use of an authorised medicinal product, and
 - (b) the use of a medicinal product in respect of which no [F¹UK] marketing authorisation is in force.
- (3) In subsection (2)(a), the reference to the off-label use of an authorised medicinal product is a reference to the use of the product—
 - (a) for a purpose other than one for which its use is specified,
 - (b) in relation to a person who is not within a description of persons for whom its use is specified, or
 - (c) in any other way in which its use is not specified.
- (4) In this section—
 - (a) “authorised medicinal product” means a medicinal product in respect of which a [F²UK] marketing authorisation is in force;
 - (b) “[F³UK] marketing authorisation” and “medicinal product” have the same meanings as in the Human Medicines Regulations 2012 (S.I. 2012/1916);
 - (c) “specified”, in relation to a medicinal product, means specified in its [F⁴UK] marketing authorisation.

Status: This version of this provision is prospective.

Changes to legislation: There are currently no known outstanding effects for the Access to Medical Treatments (Innovation) Act 2016, Section 3. (See end of Document for details)

- (5) References in section 2 to medical treatment include references to treatment carried out for the purposes of medical research (but nothing in section 2 is to be read as affecting the regulation of medical research).
- (6) Nothing in section 2 applies in relation to treatment which is carried out solely for cosmetic purposes.

Textual Amendments

- F1** Word in s. 3(2)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 2**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in s. 3(4)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 2**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Word in s. 3(4)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 2**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in s. 3(4)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 2**; 2020 c. 1, Sch. 5 para. 1(1)

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Changes to legislation:

There are currently no known outstanding effects for the Access to Medical Treatments (Innovation) Act 2016, Section 3.