
EXPLANATORY NOTE

(This note is not part of the Order)

This Order is made under section 1 of the Legislative and Regulatory Reform Act 2006 (c.51) to amend section 60 of the Patents Act 1977 (c.37) on infringement of patents. Section 60(5)(b) of the Patents Act 1977 provides an exemption from infringement in relation to acts done for experimental purposes relating to the subject-matter of the invention.

Article 2 amends section 60 to ensure that the exception to patent infringement in subsection (5)(b) applies to anything done in or for the purposes of a medicinal product assessment. Article 2 inserts new subsections (6D) to (6G) in section 60.

New subsection (6D) provides that anything done in or for the purposes of a medicinal product assessment is to be regarded as done for experimental purposes relating to the subject-matter of the invention.

New subsection (6E) defines what is meant by “medicinal product assessment”. A medicinal product assessment includes acts done in the United Kingdom or the Isle of Man in testing or in a course of testing or other activity undertaken with a view to providing data for a specified purpose.

The purposes specified are as follows—

- 1) obtaining or varying an authorisation for a medicinal product to sell or supply, or offer to sell or supply a medicinal product (whether in the United Kingdom or elsewhere);
- 2) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;
- 3) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—
 - providing healthcare on behalf of such a government or public authority, or
 - providing advice to, or on behalf of, such a government or public authority about the provision of health care,

to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.

New subsection 6(F) defines the meaning of “medicinal product” by reference to Directives 2001/82/EC and 2001/83/EC defined currently in section 60(7).

New subsection (6G) provides that nothing in subsections (6D) to (6F) is to be read as affecting the application of subsection (5)(b) in relation to any act of a kind not falling within subsection (6D).

A full impact assessment of the effect that this Order will have on the cost of business is available from the Intellectual Property Office, Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ and is annexed to the Explanatory Document which is available alongside the instrument on the Legislation UK website at www.legislation.gov.uk.