
STATUTORY INSTRUMENTS

2013 No. 1855

MEDICINES

The Human Medicines (Amendment) Regulations 2013

Made - - - - *22nd July 2013*

Laid before Parliament *29th July 2013*

Coming into force in accordance with regulation 1

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in the exercise of the powers conferred by—

- section 2(2) and (5) of the European Communities Act 1972(1), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(2);
- section 58(1), (4), (4A) and (5) of the Medicines Act 1968(3);
- section 1(1) and (2) of the Medicines Act 1971(4) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(5).

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- (1) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act 2006 (2006 c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (2008 c.7). Section 2(5) was amended by section 41(1) of and Part 1 of Schedule 6 to the Northern Ireland Constitution Act 1973 (1973 c.36).
- (2) See S.I. 1972/1811 regarding the designation of Ministers.
- (3) 1968 c.67. Relevant amendments to section 58(1) have been made by S.I. 2006/2407 and 2012/1916. Relevant amendments to section 58(4) have been made by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28) and S.I. 2006/2407 and 2012/1916. Section 58(4A) has been amended by S.I. 2012/1916. Relevant amendments to section 58(5) have been made by the Medicinal Products: Prescription by Nurses etc. Act 1992 and the Health and Social Care Act 2001 (c.15).
- (4) 1971 c.69; as amended by regulation 45(2) of S.I. 2008/2297 and section 21 of the Health and Medicines Act 1988 (c.49). By virtue of section 1(3) of the Medicines Act 1971 (“the 1971 Act”), expressions used in that section have the same meaning as in the Medicines Act 1968 (c.67) (“the 1968 Act”). See therefore section 1 of the 1968 Act, as substituted by paragraph 2 of Schedule 34 to the Human Medicines Regulations 2012 (S.I. 2012/1916) (“the 2012 Regulations”) which provides the meaning of the expression “the Ministers”, which is relevant to the powers being exercised in the making of these Regulations. By virtue of regulation 348 of, and paragraph 36 of Schedule 34 to, the 2012 Regulations, references in section 1(1) and (2) (b) of the 1971 Act to an application for a licence, or for the variation or renewal of such a licence under Part 2 of the 1968 Act, shall have effect as a reference to any application under Parts 3 to 8 of the 2012 Regulations.
- (5) In the case of the Secretary of State, by virtue of article 2(1) of S.I. 1999/3142. In the case of the Minister for Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Department for which the Minister is responsible was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).