STATUTORY INSTRUMENTS

2016 No. 190

MEDICINES
FEES AND CHARGES

The Medicines (Products for Human Use) (Fees) Regulations 2016

Made - - - -	*11th February 2016*
Laid before Parliament	*24th February 2016*
Coming into force - -	*1st April 2016*

The Secretary of State for Health and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations in exercise of the powers conferred on them by section 1(1) and (2) of the Medicines Act 1971 [F1] or, in the case of the Minister, the powers conferred by those provisions and now vested in him [F2].

In so far as these Regulations are not made under section 1(1) and (2) of the Medicines Act 1971, the Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972 [F3] and section 56(1) and (2) of the Finance Act 1973 [F4]. The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products [F5].

The Treasury has consented to the making of these Regulations as required by section 1(1) of the Medicines Act 1971 and section 56(1) of the Finance Act 1973.

In accordance with section 129(6) of the Medicines Act 1968 [F6], the Secretary of State for Health and the Minister for Health, Social Services and Public Safety have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

Textual Amendments

F1 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.

F2 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).

F3 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).

F4 1973 c.51. Section 56(1) was amended by article 6(1)(e) of the Treaty of Lisbon (Changes of Terminology) Order 2011 (S.I. 2011/1043).

F5 *See* article 2(1) of and Schedule 1 to the European Communities (Designation) Order 1972 (S.I. 1972/1811).

F6 Section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Products for Human Use) (Fees) Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations.