STATUTORY INSTRUMENTS

2012 No. 2546

MEDICINES
FEES AND CHARGES

The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012

Made - - - -	*4th October 2012*
Laid before Parliament	*10th October 2012*
Coming into force - -	*2nd November 2012*

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) of the Medicines Act 1971 [M1] or, in the case of the Minister, the powers conferred by those provisions and now vested in him [M2].

In so far as these Regulations are not made under section 1(1) 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 [M3] and section 56(1) and (2) of the Finance Act 1973 [M4]. 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 [M5].

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 [M6], 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.

Marginal Citations

M1 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) 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.

M2 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).

M3 1972 c.68.

M4 1973 c.51.

M5 *See* Article 2(1) of and Schedule 1 to the European Communities (Designation) Order 1972 (S.I. 1972/1811).

M6 Section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

Citation and commencement

1. These Regulations may be cited as the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012 and come into force on 2nd November 2012.

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2012

2.—(1) The Medicines (Products for Human Use) (Fees) Regulations 2012 [M7] are amended as follows.

(2) In regulation 20 (applications for multiple variations)—

(a) in paragraph (3)(b)(i), for "7(2)(b)" substitute " 7(2)(c) ";

(b) in paragraph (7), for "Article 7(2)(b)", in each place in which it occurs, substitute " paragraphs (2)(b) and (c) of Article 7 "[M8] .

(3) In regulation 33 (periodic fees), for paragraph (1) substitute—

"(1) Unless paragraph (4), (5) or (6) or Part 16 of, or Part 4 of Schedule 4 to, these Regulations applies, the periodic fee must be paid for each fee period during which the marketing authorization, registration, authorisation or licence is in force, even if it is in force for only part of that fee period.".

Marginal Citations

M7 S.I. 2012/504.

M8 This relates to Article 7 of Commission Regulation (EC) No 1234/2008 (OJ No L 334, 12.12.2008, p7) as amended by Commission Regulation (EU) No 712/2012 (OJ No L 209, 4.8.2012, p4).

Signed by authority of the Secretary of State for Health.

Department of Health
3rd October 2012

Dr Daniel Poulter
Parliamentary Under-Secretary of State,

Edwin Poots
Minister for Health, Social Services and Public Safety

2nd October 2012

David Evennett
Robert Goodwill
Two of the Lords Commissioners of Her Majesty's Treasury

4th October 2012

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Human Use) (Fees) Regulations 2012 ("the 2012 Regulations"). The 2012 Regulations make provision for the fees payable under the Medicines Act 1971 and other fees payable in respect of EU obligations relating to marketing authorisations, licences and certificates in respect of medicinal products for human use.

Regulation 20 of the 2012 Regulations currently refers to Article 7(2)(b) of Commission Regulation (EC) No 1234/2008. From 2nd November 2012, Article 7(2)(b) will be split into Article 7(2)(b) and (c) by virtue of Commission Regulation (EU) No 712/2012. These Regulations update certain cross references to Article 7(2)(b) in regulation 20 of the 2012 Regulations so as to preserve the effect of this regulation.

Regulation 33 of the 2012 Regulations provides for various types of periodic fees that are payable for Authorizations, Registrations, Licences and Authorisations. Regulation 33(1) is amended to clarify that the provision is qualified by the provision in Part 4 of Schedule 4 (types of licences for which only one periodic fee is payable: parallel import licences).

Status:
Point in time view as at 02/11/2012.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2012 (revoked).