STATUTORY INSTRUMENTS

2012 No. 504

MEDICINES
FEES AND CHARGES

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

Made - - - -	*23rd February 2012*
Laid before Parliament	*29th February 2012*
Coming into force - -	*1st April 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) and (2) of the Medicines Act 1971(**1**) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(**2**).

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(**3**) and section 56(1) and (2) of the Finance Act 1973(**4**). 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(**5**).

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(**6**), the Secretary of State for Health and the Minister for Health, Social Services and Public Safety have consulted with such organisations

(**1**) 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(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and the Schedule to, S.I. 1999/3142, by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794 and by regulation 44 of, and Schedule 8 to, S.I. 2006/2407. Section 1(1) of the 1968 Act contains a definition of the expression "the Ministers", which is relevant to the powers being exercised in the making of these Regulations. *See also* regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144) ("the 1994 Regulations"), by virtue of which the 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 include reference to an application for a marketing authorization under the 1994 Regulations or for the variation or renewal of such an authorization.

(**2**) 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).

(**3**) 1972 c.68.

(**4**) 1973 c.51.

(**5**) S.I. 1972/1811.

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

as appear to them to be representative of interests likely to be substantially affected by these Regulations.