STATUTORY INSTRUMENTS

2008 No. 552

MEDICINES
FEES AND CHARGES
CONSUMER PROTECTION

The Medicines (Products for Human Use-Fees) Regulations 2008

Made - - - -	*28th February 2008*
Laid before Parliament	*7th March 2008*
Coming into force - -	*1st April 2008*

The Secretary of State for Health, the Minister for Health, Social Services and Public Safety and the Minister for Agriculture and Rural Development, 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 Ministers, the powers conferred by those provisions and now vested in them(**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.

(**1**) 1971 c.69; as amended by section 21 of the Health and Medicines Act 1988 (c.49). By virtue of section 1(3) of the 1971 Act, expressions used in that section have the same meaning as in the Medicines Act 1968 (c.67); 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, which 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), 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 II 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 and article 3(7) of S.I. 2002/794. In the case of the Minister for Health, Social Services and Public Safety and the Minister for Agriculture and Rural Development, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Departments for which the Ministers are responsible were renamed by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I. 1).

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

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

(**5**) S.I.1972/181.

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

(**6**) C.67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.