STATUTORY INSTRUMENTS

2009 No. 3063

MEDICINES

The Medicines for Human Use (Miscellaneous Amendments) (No.2) Regulations 2009

Made - - - -	*19th November 2009*
Laid before Parliament	*25th November 2009*
Coming into force - -	*21st December 2009*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**). He has been designated for the purpose of that section in relation to medicinal products(**2**).

In so far as these Regulations are not made under powers conferred under section 2(2) of the European Communities Act 1972, the Secretary of State and the Minister for Health and Social Services and Public Safety, acting jointly, make these Regulations in exercise of powers conferred upon them by sections 61 and 129(4) and (5) of the Medicines Act 1968(**3**), or, in the case of the Minister, the powers conferred by those provisions now vested in the Minister(**4**).

In accordance with section 129(6) of that Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Miscellaneous Amendments) (No.2) Regulations 2009 and shall come into force on 21st December 2009.

(2) In these Regulations—

"the Marketing Authorisations Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**5**);

(**1**) 1972 c.68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and by section 3(3) of and part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (c.7).
(**2**) S.I. 1972/1811.
(**3**) 1968 c.67. The expression "the Ministers", which is relevant to the powers being exercised in the making of this Order, is defined in section 1 of the Act as amended by S.I. 1999/3142 and 2006/2407; section 61 was amended by S.I. 2006/2407.
(**4**) 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 was responsible was renamed by virtue of article 3(6) of S.I. 1999/283 (N.I.1).
(**5**) S.I. 1994/3144.

"the Sale or Supply Regulations" means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**6**).

Amendment of Schedule 1 to the Marketing Authorisations Regulations

2.—(1) Schedule 1 to the Marketing Authorisations Regulations (exemptions and exceptions from the provisions of regulation 3) shall be amended as follows.

(2) In paragraphs 1 and 2(a) and (c)(**7**) for "or supplementary prescriber" substitute ", supplementary prescriber, nurse independent prescriber or pharmacist independent prescriber".

(3) At the end of paragraph 1 add—

"In this paragraph and in paragraph 2—

"nurse independent prescriber" means a person ("N")—

(a) who is a registered nurse or a registered midwife, and

(b) against whose name is recorded in the professional register an annotation signifying that N is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber;

"pharmacist independent prescriber" means a person ("P")—

(a) who is a pharmacist, and

(b) against whose name is recorded in the relevant register an annotation signifying that P is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber.".

Amendment of the Sale or Supply Regulations

3.—(1) The Sale or Supply Regulations shall be amended as follows.

(2) In regulation 1(2) (citation, commencement and interpretation), after the definition of "community practitioner nurse prescriber" insert—

""contact lens specialist" means a person who is a registered dispensing optician and against whose name particulars of the contact lens speciality have been entered in the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989(**8**);";

""registered dispensing optician" means a person registered in the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989;".

(3) In regulation 5 (restrictions on persons to be supplied with certain medicinal products) at the end insert—

"(g) to a registered dispensing optician ("D"), prescription only medicines which—

(i) are required for use by registered optometrists and doctors attending D's practice but only if the medicine contains any one or more of the following substances—

Amethocaine hydrochloride,

Chloramphenicol,

Cyclopentolate hydrochloride,

Fusidic acid,

Lignocaine hydrochloride,

Oxybuprocaine hydrochloride,

(**6**) S.I. 1980/1923.
(**7**) Relevant amending instruments are S.I. 2005/768 and 2005/2759.
(**8**) 1989 c.44; section 7 was amended by S.I. 2005/848, articles 2 and 7(1)(a) and (b).

Proxymetacaine hydrochloride,

Tropicamide;

(ii) are required for use by D in the course of D's professional practice as a contact lens specialist but only if the medicine contains any one or more of the following substances—

Lignocaine hydrochloride,

Oxybuprocaine hydrochloride,

Proxymetacaine hydrochloride.".

Signed by authority of the Secretary of State for Health

Mike O'Brien
Minister of State,
Department of Health

17th November 2009

Michael McGimpsey
Minister of Health, Social Services and Public Safety

19th November 2009

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to certain Regulations relating to the sale or supply of medicines.

Regulation 2 further amends the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the Marketing Authorisations Regulations"). The Marketing Authorisations Regulations implement certain provisions of Directive 2001/83/EC of the European Parliament and of the Council on the community code relating to medicinal products for human use ("the 2001 Directive")(**9**). In particular, they implement the provisions of the 2001 Directive which relate to marketing authorisations.

Schedule 1 to the Marketing Authorisations Regulations exercises the derogation in Article 5 of the 2001 Directive. Schedule 1 contains exceptions to the requirement that no relevant medicinal product may be placed on the market or distributed by way of wholesale dealing unless a marketing authorisation for that product has been granted. The exemptions in paragraphs 1 and 2 provide that no marketing authorisation is required in respect of the sale or supply of a relevant medicinal product in response to a bone fide unsolicited order which is formulated in accordance with the specification of a doctor, dentist or supplementary prescriber and for use by his individual patients on his personal responsibility. Regulation 2 inserts a definition of "nurse independent prescriber" and "pharmacist independent prescriber" into Schedule 1 to the Marketing Authorisations Regulations and adds these to the list of persons to whom the exemptions in paragraph 1 and 2 of that Schedule apply.

These Regulations also amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 ("the Sale or Supply Regulations") which impose restrictions on the sale and supply of medicinal products.

Regulation 3 inserts the definitions of "contact lens specialist" and "registered dispensing optician" into regulation 1(2) of the Sale or Supply Regulations and amends regulation 5 of those Regulations to provide that people in these groups are able to obtain supplies of certain types of prescription only medicines related to their business.

An Impact Assessment has not been prepared in respect of this instrument as there is no impact on the private and voluntary sectors.

(**9**) OJNo. L311, 28.11.2001, p. 67.