
STATUTORY INSTRUMENTS

2008 No. 1162

MEDICINES

**The Medicines (Sale or Supply) (Miscellaneous
Amendments) Regulations 2008**

<i>Made</i>	- - - -	<i>22nd April 2008</i>
<i>Laid before Parliament</i>		<i>29th April 2008</i>
<i>Coming into force</i>	- -	<i>4th June 2008</i>

The Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations in exercise of powers conferred upon them by sections 66(1), 87(1), 91(2) and 129 (1) and (5) of the Medicines Act 1968⁽¹⁾, or, in the case of the Minister, the powers conferred by those provisions and now vested in him⁽²⁾.

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. In accordance with section 129(7) of that Act, they have consulted and taken into account the advice of the Commission on Human Medicines.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations 2008 and shall come into force on 4th June 2008.

(2) In these Regulations—

“the Sale or Supply Regulations” means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980⁽³⁾; and

“the Child Safety Regulations” means the Medicines (Child Safety) Regulations 2003⁽⁴⁾.

Amendment of the Sale or Supply Regulations

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

-
- (1) 1968 c.67. The expression “the Ministers”, which is relevant to the powers being exercised in the making of these Regulations, is defined in section 1 of the Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, paragraph 1(1) of the Schedule to S.I. 1999/3142 and paragraph 2 of Part 1 of Schedule 8 to S.I. 2006/2407.
- (2) 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) S.I. 1980/1923; relevant amending instruments are S.I. 2003/698, 2005/1520, 2006/914 and 2007/2179.
- (4) S.I. 2003/2317; relevant amending instruments are S.I. 2005/1520 and 2006/914.

- (2) In regulation 1 (citation, commencement and interpretation), in paragraph (2), in sub-paragraph (a)—
- (a) in the definition of “health prescription”, after “a nurse independent prescriber” insert “, an optometrist independent prescriber”; and
 - (b) after the definition of “nursing home” insert the following definition—
 - ““optometrist independent prescriber” means a person—
 - (a) who is a registered optometrist, and
 - (b) against whose name is recorded in the relevant register an annotation that he is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;”.
- (3) In Schedule 2 (particulars in pharmacy records), in paragraph 1—
- (a) after “a nurse independent prescriber” insert “, an optometrist independent prescriber”; and
 - (b) in sub-paragraph (c), after “nurse independent prescriber” insert “, optometrist independent prescriber”.

Amendment of the Child Safety Regulations

3.—(1) The Child Safety Regulations shall be amended as follows.

(2) In regulation 1 (citation, commencement and interpretation), in paragraph (2) after the definition of “ nurse prescriber” insert the following definition—

““optometrist independent prescriber” means a person—

- (a) who is a registered optometrist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;”.

(3) In regulation 3 (exemptions from regulation 2), in paragraph (1), in sub-paragraph (a) after “pharmacist independent prescriber” insert “, optometrist independent prescriber”.

Signed by authority of the Secretary of State for Health.

22nd April 2008

16th April 2008

Dawn Primarolo
Minister of State,
Department of Health
Michael McGimpsey
Minister for Health, Social Services and Public
Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to—

- (a) the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (“the Sale or Supply Regulations”) which impose restrictions on the sale or supply of medicinal products for human use and in particular impose a requirement on persons conducting a retail pharmacy business to record the sale or supply of a prescription only medicine except in specified circumstances in particular where the sale or supply is in pursuance of a “health prescription” ; and
- (b) the Medicines (Child Safety) Regulations 2003 (“the Child Safety Regulations”) which in particular (subject to exemptions) impose requirements relating to the packaging of certain medicinal products.

Regulation 2 amends regulation 1 of the Sale or Supply Regulations, so that a “health prescription” includes a prescription issued by an optometrist independent prescriber under or by virtue of legislation relating to the National Health Service, and amends Schedule 2 to those Regulations, so that the particulars which must be included in pharmacy records kept pursuant to regulation 6(1) must include particulars relating to optometrist independent prescribers.

Regulation 3 amends regulations 1 and 3 of the Child Safety Regulations so that the packaging requirements do not apply to the retail sale, or supply corresponding to retail sale, of a product by a pharmacy, where that sale or supply is in accordance with a prescription given by an optometrist independent prescriber.

An impact assessment has not been produced for this instrument as there is no significant impact on the private or voluntary sectors.