
STATUTORY INSTRUMENTS

2007 No. 2179

MEDICINES

**The Medicines (Sale or Supply) (Miscellaneous
Provisions) Amendment Regulations 2007**

<i>Made</i>	- - - -	<i>24th July 2007</i>
<i>Laid before Parliament</i>		<i>26th July 2007</i>
<i>Coming into force</i>	- -	<i>1st September 2007</i>

The Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations in the exercise of powers conferred upon them by sections 61, 66(1) 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 Provisions) Amendment Regulations 2007 and shall come into force on 1st September 2007.

(2) In these Regulations, “the principal Regulations” means the Medicines (Sale or Supply) Miscellaneous Provisions) Regulations 1980(3).

Amendment of regulation 1 of the principal Regulations

2. In regulation 1 of the principal Regulations (citation, commencement and interpretation), in paragraph (2)(a)—

(a) in the definition of “independent clinic”—

(i) in paragraph (b), for “2001;” substitute “2001, and”, and

(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 instrument are S.I. 2003/698 and 2006/915.

- (ii) after paragraph (b) insert—
 - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003⁽⁴⁾”;
- (b) in the definition of “independent hospital”—
 - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
 - (ii) after paragraph (b) insert—
 - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (c) in the definition of “independent medical agency”—
 - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
 - (ii) after paragraph (b) insert—
 - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (d) after the definition of “nurse independent prescriber” insert the following definition—
 - ““nursing home” has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”.

Amendment of regulation 6 of the principal Regulations

- 3. In regulation 6 of the principal Regulations (pharmacy records)—
 - (a) in paragraph (2), in sub-paragraph (b)—
 - (i) for “Misuse of Drugs Regulations 1973” substitute “Misuse of Drugs Regulations 2001⁽⁵⁾”, and
 - (ii) for “Misuse of Drugs (Northern Ireland) Regulations 1974” substitute “Misuse of Drugs Regulations (Northern Ireland) 2002⁽⁶⁾”; and
 - (b) in paragraph (3), for sub-paragraph (b) substitute—
 - “(b) prescriptions in pursuance of which any prescription only medicine has been sold or supplied, other than—
 - (i) health prescriptions, or
 - (ii) prescriptions for a controlled drug specified in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001;”.

Amendment of Schedule 1 to the principal regulations

- 4. In Schedule 1 to the principal regulations (classes of persons for the purposes of regulation 5), in the paragraph beginning “Authorities or persons carrying on the business of”—
 - (a) in sub-paragraph (a), at the end omit “or”;
 - (b) in sub-paragraph (b), for “clinic.” substitute “clinic, or”; and

(4) S.I. 2003/431 (N.I.9).

(5) S.I. 2001/3998, as amended by S.I. 2003/1432 and 2005/1653.

(6) S.R. (NI) 2002 No 320.

- (c) after sub-paragraph (b), insert—
“(c) in Northern Ireland, a nursing home.”

Signed by authority of the Secretary of State for Health

24th July 2007

24th July 2007

Dawn Primarolo
Minister of State
Department of Health
Andrew McCormick
Permanent Secretary
Department of Health, Social Services and
Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (“the principal Regulations”) which impose restrictions on the sale and supply of medicinal products for human use.

Regulation 5 of, and Schedule 1 to, the principal Regulations specify persons to whom medicinal products may be sold or supplied by way of wholesale dealing, including authorities carrying on the business of an independent hospital, clinic or medical agency. Regulation 2 of these Regulations amends regulation 1 of the principal Regulations to extend the provisions to include independent hospitals, clinics and medical agencies in Northern Ireland. Regulations 2 and 4 amend regulation 1 of, and Schedule 1 to, the principal Regulations to include nursing homes in Northern Ireland.

Regulation 6 of the principal Regulations imposes requirements regarding the records to be kept by retail pharmacies. Regulation 6(3) imposes a requirement on persons conducting a retail pharmacy business to retain prescriptions, other than “health prescriptions”, for a period of two years. Regulation 3 of these Regulations amends regulation 6(3) to provide an exemption from this requirement in relation to controlled drugs specified under the Misuse of Drugs Regulations 2001. Regulation 3 also amends regulation 6 to substitute references to the current legislation on misuse of drugs.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies of the assessment have been placed in the libraries of both Houses of Parliament.