STATUTORY INSTRUMENTS

2006 No. 914

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations 2006

Made - - - -	*23rd March 2006*
Laid before Parliament	*3rd April 2006*
Coming into force - -	*1st May 2006*

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

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 Committee on Safety of Medicines(**c**).

In so far as these Regulations are not made under the Medicines Act 1968, the Secretary of State makes these Regulations in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972(**d**). The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act in relation to medicinal products(**e**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations 2006 and shall come into force on 1st May 2006.

(2) In these Regulations—

"the Sale or Supply Regulations" means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**f**);

(**a**) 1968 c.67. The expression "the appropriate Ministers" and the expression "the Health Ministers", which are relevant to the powers being exercised in the making of these Regulations, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, and by articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794.

(**b**) In the case of the Secretary of State for Health, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; and in the case of the Department of Health, Social Services and Public Safety, by virtue of the powers vested in the Ministers in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47), which may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c.1); the Department was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1.).

(**c**) *See* paragraph 1 of Part 2 of Schedule 5 to S.I. 2005/2754.

(**d**) 1972 c.68.

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

(**f**) S.I. 1980/1923; relevant amending instruments are S.I. 2003/698, 2004/1771, 2005/764, 1520 and 2745.

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

"the Child Safety Regulations" means the Medicines (Child Safety) Regulations 2003(**b**); and

"the Traditional Herbal Medicinal Products Regulations" means the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**c**).

Amendment of the Sale or Supply Regulations

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

(2) In regulation 1 (citation, commencement and interpretation), in paragraph (2)—

(a) after the definition of "additional supply optometrist" insert the following definition—

""community practitioner nurse prescriber" means a person—

(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 he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary;";

(b) omit the definition of "district nurse/health visitor prescriber";

(c) omit the definition of "Extended Formulary";

(d) omit the definition of "extended formulary nurse prescriber";

(e) omit the definition of "first level nurse";

(f) in the definition of "health prescription", for "a district nurse/health visitor prescriber or an extended formulary nurse prescriber" substitute "a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber";

(g) after the definition of "independent medical agency" insert the following definition—

""nurse independent prescriber" means a person—

(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 he is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber;";

(h) after the definition of "parenteral administration" insert the following definition—

""pharmacist independent prescriber" means a person—

(a) who is a pharmacist, 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 a pharmacist independent prescriber;";

(i) after the definition of "professional register" insert the following definitions—

""registered midwife" means a person registered in the Midwives' Part of the professional register;

"registered nurse" means a person registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the professional register;";

(j) in the definition of "relevant register", in paragraph (a), for "first level" substitute "registered"; and

(k) in the definition of "supplementary prescriber"—

(**a**) S.I. 1994/3144; relevant amending instruments are S.I. 2005/768 and 1520.
(**b**) S.I. 2003/2317, amended by S.I. 2004/1771 and 2005/1520.
(**c**) S.I. 2005/2750.

(i) in paragraph (a), for "first level" substitute "registered", and

(ii) after "a supplementary prescriber" insert "or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber".

(3) In Schedule 2 (particulars in pharmacy records), in paragraph 1—

(a) for "a district nurse/health visitor prescriber or an extended formulary nurse prescriber" substitute "a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber"; and

(b) in sub-paragraph (c), for "district nurse/health visitor prescriber or extended formulary nurse prescriber" substitute "community practitioner nurse prescriber, nurse independent prescriber or pharmacist independent prescriber".

Amendment of the Marketing Authorisations Regulations

3. In regulation 1 of the Marketing Authorisations Regulations (citation, commencement and interpretation), in paragraph (2)—

(a) omit the definition of "first level nurse";

(b) after the definition of "registered midwife" insert the following definition—

""registered nurse" means a person registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the professional register;";

(c) in the definition of "relevant register", in paragraph (a), for "first level" substitute "registered"; and

(d) in the definition of "supplementary prescriber"—

(i) in paragraph (a), for "first level" substitute "registered", and

(ii) after "a supplementary prescriber" insert "or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber".

Amendment of the Child Safety Regulations

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

(2) In regulation 1 (citation, commencement and interpretation), in paragraph (2)—

(a) omit the definition of "first level nurse";

(b) in the definition of "nurse prescriber"—

(i) in paragraph (a), for "first level" substitute "registered", and

(ii) in paragraph (b), after "appliances" insert "as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber";

(c) after the definition of "nurse prescriber" insert the following definition—

""pharmacist independent prescriber" means a person—

(a) who is a pharmacist, 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 a pharmacist independent prescriber;";

(d) after the definition of "professional register" insert the following definitions—

""registered midwife" means a person registered in the Midwives' Part of the professional register;

"registered nurse" means a person registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the professional register;";

(e) in the definition of "relevant register", in paragraph (a), for "first level" substitute "registered"; and

(f) in the definition of "supplementary prescriber"—

(i) in paragraph (a), for "first level" substitute "registered", and

(ii) after "a supplementary prescriber" insert "or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber".

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

Amendment of the Traditional Herbal Medicinal Products Regulations

5. In Schedule 1 to the Traditional Herbal Medicinal Products Regulations (exemptions and exceptions from the provisions of regulation 4), in paragraph 1 (interpretation)—

(a) omit the definition of "first level nurse";

(b) after the definition of "registered midwife" insert the following definition—

""registered nurse" means a person registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the professional register;";

(c) in the definition of "relevant register", in paragraph (a), for "first level" substitute "registered"; and

(d) in the definition of "supplementary prescriber"—

(i) in paragraph (a), for "first level" substitute "registered", and

(ii) after "as a supplementary prescriber" insert "or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber".

Signed by authority of the Secretary of State for Health

Jane Kennedy
Minister of State,
23rd March 2006 Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

Andrew McCormick
Permanent Secretary,
16th March 2006 Department of Health, Social Services and Public Safety

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 amends 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 for human use. Regulation 6(1) of, and Schedule 2 to, the Sale or Supply Regulations 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". Regulation 2(2) amends regulation 1 of the Sale or Supply Regulations, so that a "health prescription" includes a prescription issued by a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber, under or by virtue of legislation relating to the National Health Service. Regulation 2(2) also makes consequential amendments to regulation 1 of the Sale or Supply Regulations to reflect changes which have been made to the nurses' professional register and to the entries in that register indicating who is qualified to act as a prescriber. Regulation 2(3) amends Schedule 2 to the Sale or Supply Regulations, so that the particulars which must be included in pharmacy records kept pursuant to regulation 6(1) must include certain particulars relating to such prescribers.

Regulation 3 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 for medicinal products for human use ("the 2001 Directive")(**a**). In particular, they implement the provisions of the 2001 Directive which relate to marketing authorisations. Regulation 3 makes consequential amendments to reflect changes which have been made to the nurses' professional register and to the entries in that register indicating who is qualified to act as a prescriber.

Regulation 4 amends the Medicines (Child Safety) Regulations ("the Child Safety Regulations") which in particular impose requirements relating to the packaging of certain medicinal products. Regulation 3 of the Child Safety Regulations specifies certain exemptions from those requirements. Regulation 4 amends regulations 1 and 3 of the Child Safety Regulations so that the 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 a pharmacist independent prescriber. Regulation 4(2) makes consequential amendments to the Child Safety Regulations to reflect changes which have been made to the nurses' professional register and to the entries in that register indicating who is qualified to act as a prescriber.

Regulation 5 amends the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 ("the Traditional Herbal Medicinal Products Regulations") which implement Directive 2004/24/EC of the European Parliament and of the Council(**b**) amending, as regards traditional herbal medicinal products, the 2001 Directive. Regulation 5 makes consequential amendments to the Traditional Herbal Medicinal Products Regulations to reflect changes which have been made to the nurses' professional register and to the entries in that register indicating who is qualified to act as a prescriber.

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.

(**a**) OJ No. L311, 28.11.2001, p34.
(**b**) OJ No. L136, 30.3.2004, p85.

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