
STATUTORY INSTRUMENTS

2003 No. 698

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2003

<i>Made</i>	- - - -	<i>13th March 2003</i>
<i>Laid before Parliament</i>		<i>14th March 2003</i>
<i>Coming into force</i>	- -	<i>4th April 2003</i>

As respects England, Scotland and Wales, the Secretary of State, and, as respects Northern Ireland, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, in exercise of the powers conferred on them by sections 61, 66(1) and 129(1) and (5) of the Medicines Act 1968(1) or, as the case may be, the powers conferred by those provisions and now vested in them(2), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations, pursuant to section 129(6) of that Act, and after taking into account the advice of the Committee on Safety of Medicines and the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2003 and shall come into force on 4th April 2003.

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

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- (1) 1968 c. 67; the expression “the appropriate Ministers” and the expression “the Ministers”, which are relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 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.
- (2) In the case of the Secretary of State, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and article 3(1)(c) and (7) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794; in the case of the Northern Ireland Departments, by virtue of the powers vested in the Ministers in charge of those Departments 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 Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Departments were renamed by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I.1).
- (3) S.I. 1980/1923; relevant amending instruments are S.I. 1982/28, 1990/1124, 1994/2411, 1995/3215, 1997/2045, 1999/644 and 2510, 2000/1070, 1918 and 2494, and 2001/3849.

Amendment of regulation 1 of the principal Regulations

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

(a) after the definition of “controlled drug”, insert the following definition—

““district nurse/health visitor prescriber” means—

(a) a person who—

- (i) is registered in Part 1 or 12 of the professional register, and
- (ii) has a district nursing qualification additionally recorded in the professional register under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983(4); or

(b) a person who is registered in Part 11 of the professional register as a health visitor,

against whose name (in each case) is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances for patients;”;

(b) after the definition of “excepted person”(5), insert the following definitions—

““Extended Formulary” means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary;

“extended formulary nurse prescriber” means a person—

- (a) who is a first level nurse, 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 Extended Formulary;

“first level nurse” means a person registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;”;

(c) after the definition of “Health Authority”(6), insert the following definition—

““health care” means services for or in connection with the prevention, diagnosis or treatment of disease;”;

(d) in the definition of “health prescription”, for “or dentist” substitute “, a dentist, a supplementary prescriber, a district nurse/health visitor prescriber or an extended formulary nurse prescriber”;

(e) after the definition of “health prescription”, insert the following definitions—

““independent clinic”—

- (a) in relation to England and Wales, has the meaning given by section 2(4) of the Care Standards Act 2000(7), and
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001(8);

“independent hospital”—

- (a) in relation to England and Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000, and

(4) The rules were approved by S.I. 1983/873; there are amendments to the rules which are not relevant to this Order.

(5) The definition of “excepted person” was inserted by S.I. 2000/1918.

(6) The definition of “Health Authority” was inserted by S.I. 2000/1918.

(7) 2000 c. 14.

(8) 2001 asp 8.

- (b) in relation to Scotland, means—
 - (i) an independent hospital, or
 - (ii) a private psychiatric hospital,
as defined by section 77(1) of the Regulation of Care (Scotland) Act 2001;
“independent medical agency”—
- (a) in relation to England and Wales, has the meaning given by section 2(5) of the Care Standards Act 2000, and
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;”;
- (f) in the definition of “prescription only medicine”, for “Prescription Only Order” substitute “Prescription Only Medicines Order”;
- (g) for the definition of “the Prescription Only Order”, substitute the following definition—
““the Prescription Only Medicines Order” means the Prescription Only Medicines (Human Use) Order 1997(9);”;
- (h) after the definition of “Primary Care Trust”(10), insert the following definitions—
““prison service” means—
 - (a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952(11)),
 - (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989(12)), and
 - (c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953(13));“professional register” means the register maintained by the Nursing and Midwifery Council(14) pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(15);”;
- (i) after the definition of “registered ophthalmic optician”, insert the following definition—
““relevant register” means—
 - (a) in relation to a first level nurse, the professional register, and
 - (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(16) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(17);”;
- (j) after the definition of “Special Health Authority”(18), insert the following definition—
““supplementary prescriber” means—
 - (a) a first level nurse, or

(9) S.I. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2899 and 3231, 2001/2777, 2889 and 3942, and 2002/549 and 2469.

(10) The definition of “Primary Care Trust” was inserted by S.I. 2000/1918.

(11) 1952 c. 52.

(12) 1989 c. 45.

(13) 1953 (c. 18 (N.I.)).

(14) See article 3 of the Nursing and Midwifery Order 2001, S.I. 2002/253.

(15) S.I. 2002/253.

(16) 1954 c. 61.

(17) S.I. 1976/1213 (N.I.22).

(18) The definition of “Special Health Authority” was inserted by S.I. 2000/1918.

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

Amendment of regulation 5 of the principal Regulations

3. Regulation 5 of the principal Regulations (restrictions on persons to be supplied with certain medicinal products), in paragraph (2)—

- (a) in sub-paragraph (a), for “column 1 of Schedule 4 to the Prescription Only Order” substitute “column 1 of Schedule 5 to the Prescription Only Medicines Order”;
- (b) in sub-paragraph (b), for “Article 8 of the Prescription Only Order” substitute “Article 10 of the Prescription Only Medicines Order”; and
- (c) sub-paragraph (d) is omitted.

Amendment of regulation 6 of the principal Regulations

4. In regulation 6 of the principal Regulations (pharmacy records)(19)—

- (a) in paragraph (1), in sub-paragraph (b), for “Article 6(1) of the Prescription Only Order” substitute “Article 8(1) of the Prescription Only Medicines Order”; and
- (b) in paragraph (3), in sub-paragraph (d), for “column 3 of Schedule 4 to the Prescription Only Order” substitute “column 3 of Schedule 5 to the Prescription Only Medicines Order”.

Amendment of Schedule 1 to the principal Regulations

5. In Schedule 1 to the principal Regulations (classes of persons for the purposes of regulation 5)

- (a) for the entry “Authorities or persons carrying on the business of a hospital or health centre” substitute the following entry—
 - “Authorities or persons carrying on the business of—
 - (a) an independent hospital, independent clinic or independent medical agency, or
 - (b) a hospital or health centre which is not an independent hospital or independent clinic.”; and
- (b) at the end add the following entry—
 - “A person other than an excepted person who carries on a business consisting (wholly or partly) of the supply or administration of medicinal products for the purpose of assisting the provision of health care by or on behalf of, or under arrangements made by—
 - (a) a police force in England, Wales or Scotland,
 - (b) the Police Service of Northern Ireland,
 - (c) a prison service, or
 - (d) Her Majesty’s Forces.”.

(19) Regulation 6 was revoked, in relation to retail sales of veterinary medicinal products, by S.I. 2000/7.

Amendment of Schedule 2 to the principal Regulations

6. In Schedule 2 to the principal Regulations (particulars in pharmacy records)(20)—
- (a) in paragraph 1—
 - (i) for “a practitioner or under Article 6(1) of the Prescription Only Order” substitute “a practitioner, a supplementary prescriber, a district nurse/health visitor prescriber or an extended formulary nurse prescriber, or under Article 8(1) of the Prescription Only Medicines Order”,
 - (ii) in sub-paragraph (c), after “the practitioner” insert “, supplementary prescriber, district nurse/health visitor prescriber or extended formulary nurse prescriber”, and
 - (iii) in sub-paragraph (f), for “Article 6(1) of the Prescription Only Order” substitute “Article 8(1) of the Prescription Only Medicines Order”;
 - (b) in paragraph 3, for “Article 6(3) of the Prescription Only Order” substitute “Article 8(3) of the Prescription Only Medicines Order”; and
 - (c) in paragraph 4, for “Article 6 of the Prescription Only Order” substitute “Article 8 of the Prescription Only Medicines Order”.

Signed by authority of the Secretary of State for Health

13th March 2003

Hunt
Parliamentary Under Secretary of State,
Department of Health

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

11th March 2003

D.C. Gowdy
Permanent Secretary,
Department of Health, Social Services and
Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development

13th March 2003

P.J. Small
Permanent Secretary,
Department of Agriculture and Rural
Development

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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.

Regulation 6 of, and Schedule 2 to, the principal Regulations imposes a requirement on persons conducting a retail pharmacy business to record the sale or supply of a prescription only medicine except in specified circumstances such as the sale or supply having been made pursuant to a prescription issued under or by virtue of legislation relating to the National Health Service. Regulations 2(a), (b), (d) and (h) to (j), 4 and 6 of these Regulations amends these provisions so as to include references to prescriptions written by supplementary prescribers, district nurse/health visitor prescribers and extended formulary nurse prescribers.

Schedule 1 to the principal Regulations specifies persons who may, subject to exemptions specified in the principal Regulations, be supplied with certain medicinal products. Regulation 5 of these Regulations adds—

- (a) authorities or persons carrying on the business of independent hospitals, clinics and medical agencies, and
- (b) persons who carry on a business consisting (wholly or partly) of the supply or administration of medicinal products for the purpose of assisting the provision of health care by the police, the prison services or the armed forces,

to the list of bodies specified in Schedule 1.

Regulations 2, 3, 4 and 6 make minor and consequential amendments to the principal Regulations. In particular, these include the removal of references to the Medicines (Prescription Only) Order 1980⁽²¹⁾ and the substitution of references to the Prescription Only Medicines (Human Use) Order 1997⁽²²⁾.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines Control Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

⁽²¹⁾ S.I. 1980/1921 revoked by S.I. 1983/1212.

⁽²²⁾ S.I. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2899 and 3231, 2001/2777, 2889 and 3942, and 2002/549 and 2469.