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STATUTORY INSTRUMENTS

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**2005 No. 1520**

**MEDICINES**

**The Medicines (Sale or Supply) (Miscellaneous  
Amendments) Regulations 2005**

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|-------------------------------|---------|-----------------------|
| <i>Made</i>                   | - - - - | <i>6th June 2005</i>  |
| <i>Laid before Parliament</i> |         | <i>8th June 2005</i>  |
| <i>Coming into force</i>      | - -     | <i>30th June 2005</i> |

The Secretary of State for Health, being a Minister designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to medicinal products, in exercise of the powers conferred on him by the said section 2(2), and, as respects England, Scotland and Wales, the Secretary of State concerned with health in England 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 53(4), 61, 66(1), 87(1), 88(1) and (2), 91(2) and 129(1) and (5) of the Medicines Act 1968<sup>(3)</sup> or, as the case may be, the powers conferred by those provisions and now vested in them<sup>(4)</sup>, 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 the provisions of these Regulations made in exercise of powers in that Act, 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 in respect of the provisions of these Regulations made in exercise of powers in 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 Amendment) Regulations 2005 and shall come into force on 30<sup>th</sup> June 2005.

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(1) [S.I.1972/1811](#).

(2) [1972 c. 68](#).

(3) [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 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](#), by articles 2(1) and 5 of, and the Schedule to, [S.I. 1999/3142](#), and by article 5(1) of, and paragraph 15 of Schedule 1 to, [S.I. 2002/794](#).

(4) 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) of, and paragraph 1 of the Schedule to, [S.I. 1999/3142](#), and articles 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, 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](#)) 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 \(N.I.1\)](#).

(2) In these Regulations—

- (a) “the Child Safety Regulations” means the Medicines (Child Safety) Regulations 2003<sup>(5)</sup>;
- (b) “the Marketing Authorisations Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994<sup>(6)</sup>; and
- (c) “the Sale or Supply Regulations” means the Medicines (Sale or Supply)(Miscellaneous Provisions) Regulations 1980<sup>(7)</sup>.

### **Amendment of regulation 1 of the Marketing Authorisations Regulations**

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

- (a) after the definition of “registered midwife”<sup>(8)</sup>, insert the following definition—
  - ““registered optometrist” means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989<sup>(9)</sup>”;
- (b) in the definition of “relevant register”<sup>(10)</sup>—
  - (i) in paragraph (b) omit “and”;
  - (ii) in paragraph (c), after “that register;” insert “and”; and
  - (iii) after paragraph (c), insert—
    - “(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;
- (c) in the definition of “supplementary prescriber”<sup>(11)</sup>—
  - (i) in paragraph (c), omit “or”;
  - (ii) in paragraph (d), after “radiographers: diagnostic or therapeutic,” insert “or”;
  - (iii) after paragraph (d), insert—
    - “(e) a registered optometrist,”.

### **Amendment of regulation 1 of the Sale or Supply Regulations**

3. In regulation 1 of the Sale or Supply Regulations (citation, commencement and interpretation), in paragraph (2)(a)—

- (a) after the definition of “the Act”, insert the following definition—
  - ““additional supply optometrist” means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register”
- (b) for the definition of “registered ophthalmic optician”, substitute the following definition—
  - ““registered optometrist” means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;
- (c) in the definition of “relevant register”<sup>(12)</sup>—

(5) S.I.2003/2317, amended by S.I. 2004/1771.

(6) S.I. 1994/3144; relevant amending instruments are S.I. 2002/236 and 2004/865, 1016 and 1031 and 2005/768.

(7) S.I. 1980/1923; relevant amending instruments are S.I. 1990/1124, 1994/3142, 2003/698, 2004/1771 and 2005/764.

(8) The definition of “registered midwife” was inserted by S.I. 2005/768.

(9) 1989 c. 44, section 7 was amended by article 7(1) of the Opticians Act 1989 (Amendment) Order 2005; S.I. 2005/848, which will come into force on 30th June 2005.

(10) The definition of “relevant register” was inserted by S.I. 2005/768.

(11) The definition of “supplementary prescriber” was inserted by S.I. 2005/768.

(12) The definition of “relevant register” was inserted by S.I. 2003/698 and amended by S.I. 2004/1771 and 2005/764.

- (i) in paragraph (b), omit “and”;
- (ii) in paragraph (c), after “that register,” insert “; and”; and
- (iii) after paragraph (c), insert—
  - “(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;
- (d) in the definition of “supplementary prescriber”(13)—
  - (i) in paragraph (c), omit “or”;
  - (ii) after paragraph (d), insert—
    - “(e) a registered optometrist,”.

#### **Amendment of regulation 5 of the Sale or Supply Regulations**

**4.** In regulation 5 of the Sale or Supply Regulations (restrictions on persons to be supplied with certain medicinal products), in paragraph (2)—

- (a) in sub-paragraph (c)(14), for “registered ophthalmic optician”, substitute “registered optometrist”; and
- (b) after sub-paragraph (c), insert the following paragraph—
  - “(ca) to an additional supply optometrist, prescription only medicines which are prescription only medicines by reason only that they contain the substance Thymoxamine hydrochloride;”.

#### **Amendment of regulation 8 of the Sale or Supply Regulations**

**5.** In regulation 8 of the Sale or Supply Regulations (pack size on retail sale or supply of certain medicinal products on a general sale list), in paragraph (2A)(15), for “50 tablets” substitute “40 tablets”.

#### **Amendment of regulation 1 of the Child Safety Regulations**

**6.** In regulation 1 of the Child Safety Regulations (citation, commencement and interpretation), in paragraph (2)—

- (a) after the definition of “professional register(16)”, insert the following entry—
  - ““registered optometrist” means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”;
- (b) in the definition of “relevant register(17)”—
  - (i) in paragraph (a) omit “and”;
  - (ii) in paragraph (b), after “the Pharmacy (Northern Ireland) Order 1976;” insert “and”; and
  - (iii) after paragraph (b) insert—
    - “(c) in relation to a person whose name is registered in that part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(18), relating to—

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(13) The definition of “supplementary prescriber” was inserted by S.I. 2003/698 and amended by S.I. 2004/1771 and 2005/764.

(14) Paragraph (2)(c) was amended by S.I. 2005/764.

(15) Paragraph (2A) was inserted by S.I. 1990/1124 and amended by S.I. 2000/2494 and 2005/764.

(16) The definition of “professional register” was amended by S.I. 2004/1771.

(17) The definition of “relevant register” was amended by S.I. 2004/1771.

(18) S.I. 2002/254.

- (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or
  - (iii) radiographers: diagnostic or therapeutic;
- that register; and
- (d) registered optometrists;”;
- (c) in the definition of “supplementary prescriber(19)”—
- (i) in paragraph (b), omit “or”;
  - (ii) after paragraph (c), insert—
    - “(d) a person whose name is registered in that part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001, relating to—
      - (i) chiropodists and podiatrists;
      - (ii) physiotherapists; or
      - (iii) radiographer: diagnostic or therapeutic; or
  - (e) a registered optometrist.”;
- (iii) after “ an annotation” insert “or entry”.

Signed by authority of the Secretary of State for Health

6th June 2005

*Jane Kennedy*  
Minister of State for Quality and Patient Safety,  
Department of Health

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

L.S.

6th June 2005

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

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(19) The definition of “supplementary prescriber” was amended by [S.I. 2004/1771](#).

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

L.S.

3rd June 2005

*Pat Toal*  
Permanent Secretary  
Department of Agriculture and Rural  
Development

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## 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 for medicinal products for human use (“the 2001 Directive”)(**20**). 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 exemption 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 bona 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 amends the definition of “supplementary prescriber” to include certain optometrists, and makes other related amendments to the definitions in the Marketing Authorisations Regulations.

These Regulations also further 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 amends the definition of “supplementary prescriber” in the Sale or Supply Regulations to include certain registered optometrists and makes other related amendments to the definitions in these Regulations. Regulation 4 substitutes the term “registered optometrist” for “registered ophthalmic optician” in regulation 5 of the Sale or Supply Regulations. Regulation 5 amends regulation 8 of the Sale or Supply Regulations. This regulation concerns the maximum number of tablets which may be contained in a pack of tablets for human use which are for sale elsewhere than at a registered pharmacy. The amendment changes the maximum number of tablets which may be contained in a pack containing Bisacodyl, from 50 to 40.

These Regulations also amend the Medicines (Child Safety) Regulations 2003 (“the Child Safety Regulations”) which impose requirements relating to the packaging and colouring of certain medicinal products. Regulation 6 amends the definition of “supplementary prescriber” in the Child Safety Regulations to include certain chiropodists and podiatrists, physiotherapists, diagnostic and therapeutic radiographers and registered ophthalmic opticians.

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 and Healthcare products Regulatory Agency, Information Centre, Room 10-202 Market Towers, 1, Nine Elms Lane, London SW8 5NQ.

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(20) OJNo. L311, 28.11.2001, p.34.