STATUTORY INSTRUMENTS

2008 No. 1692

MEDICINES

The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008

Made - - - -	*26th June 2008*
Laid before Parliament	*2nd July 2008*
Coming into force - -	*3rd November 2008*

The Secretary of State makes the following Regulations in the exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**). He has been designated for the purpose of section 2(2) of the European Communities Act 1972(**2**) in relation to medicinal products.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 and shall come into force on 3rd November 2008.

(2) In these Regulations—

"the Act" means the Medicines Act 1968(**3**);

"controlled drug" means any substance or product for the time being specified in Part I, II or III of Schedule 2 (controlled drugs) to the Misuse of Drugs Act 1971(**4**);

"EEA health professional" means—

(a) a doctor who is lawfully engaged in medical practice in a relevant European State; or

(b) a dentist who is lawfully engaged in dental practice in a relevant European State (including a person whose formal qualifications as a doctor are recognised for the purposes of the pursuit of the professional activities of a dental practitioner under Article 37 of Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications)(**5**), and

(**1**) 1972 c.68.
(**2**) S.I.1972/ 1811.
(**3**) 1968.c.67
(**4**) 1971.c.38; amendments to Schedule 2 have been made by S.I.1973/771, 1975/421, 1977/1243, 1979/299, 1983/765, 1984/859, 1985/1995, 1986/2230, 1989/1340, 1990/2589, 1995/1966, 1996/1300, 1998/750, 2001/3932, 2003/1243, 2003/3201,2005/3178 and 2006/3331 and the Drugs Act 2005, s 21(c. 17).
(**5**) OJ No. L 255, 30.9.2005, p22.

who is not a doctor or dentist within the meaning of the Act(**6**);

"medicinal product" means a product of a description or class specified in article 3 (medicinal products on prescription only) of the Prescription Only Medicines (Human Use) Order 1997(**7**), except a medicinal product that is a controlled drug;

"relevant European State" means—

(a) an EEA State other than the United Kingdom, or

(b) Switzerland; and

"repeatable prescription" means a prescription which contains a direction that it may be dispensed with more than once.

Appropriate practitioner for purposes of section 58 of the Medicines Act 1968

2. In relation to a medicinal product, an EEA health professional is an appropriate practitioner for the purposes of section 58(2)(a) (restriction on sale and supply) of the Act(**8**).

Prescriptions given by EEA health professionals

3.—(1) Subject to regulations 4 and 5, a prescription given by an EEA health professional for a medicinal product counts as a prescription for the purposes of section 58(2)(a) of the Act only if—

(a) it is an EEA prescription; and

(b) the conditions in paragraph (2) are fulfilled in relation to the prescription.

(2) The conditions referred to in paragraph (1) are that the prescription–

(a) is signed in ink with his own name by the EEA health professional giving it;

(b) is, without prejudice to sub-paragraph (a), written in ink or otherwise so as to be indelible;

(c) contains the following particulars—

(i) the address of the EEA health professional giving it,

(ii) the date on which the prescription is signed by the EEA health professional,

(iii) such particulars as indicate whether the EEA health professional is a doctor or a dentist, and

(iv) the name, address and the age, if under 12, of the person for whose treatment it is given; and

(d) is not dispensed after the end of the period of six months from the date on which the prescription is signed by the EEA health professional giving it, unless the prescription is a repeatable prescription which is not being dispensed for the first time.

(3) For the purposes of this regulation a prescription for a medicinal product is an EEA prescription if the prescription is given in a relevant European State.

(**6**) In section 132 of the Act, the definition of dentist has been amended by the Dentists Act 1984, s 54 (1), Sch 5, para 2 (c.24) and the definition of doctor was substituted by the Medical Act 1983, s 56(1), Sch 5, para 5 (c.54).

(**7**) S.I. 1997/1830; article 3 has been substituted by S.I. 2002/549 and amendments have been made to it by S.I. 2003/696 and 2008/464.

(**8**) 1968.c.67; amendments to section 58 have been made by section 1 of the Medicinal Products: Prescription by Nurses etc Act 1992 (c.28); section 63(1) - (6) of the Health and Social Care Act 2001(c.15) and by S.I. 2002/253, 2003/1590, 2005/1094 and 2006/2407.

Prescriptions in electronic form

4.—(1) For the purposes of regulation 3(1) the conditions specified in paragraph (2) below may be fulfilled in relation to the prescription instead of those specified in paragraphs (2)(a) and (b) of regulation 3.

(2) The conditions referred to in paragraph (1) are that the prescription is created in electronic form and signed with an advanced electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries).

(3) In this regulation—

"advanced electronic signature" means an electronic signature which is—

(a) uniquely linked to the signatory;

(b) capable of identifying the signatory;

(c) created using means that the signatory can maintain under his sole control; and

(d) which is linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"electronic communication" means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

(a) by means of an electronic communications network; or

(b) by other means but while in an electronic form; and

"signatory" means the EEA health professional giving the prescription.

Repeatable prescriptions given by EEA health professionals

5.—(1) A repeatable prescription given by an EEA health professional for a medicinal product counts as a prescription for the purposes of section 58(2)(a) of the Act only if, in addition to the requirements specified in regulation 3, the conditions specified in paragraph (2) are fulfilled in relation to the prescription.

(2) The conditions referred to in paragraph (1) are that the repeatable prescription–

(a) is not dispensed for the first time after the end of the period of six months from the date on which it is signed by the EEA health professional giving it;

(b) without prejudice to sub-paragraph (a), is dispensed in accordance with any directions contained in the prescription; and

(c) is dispensed on not more than two occasions if it is a repeatable prescription which does not specify the number of times it may be dispensed, unless it is a prescription for an oral contraceptive, in which case it may be dispensed six times before the end of the period of six month from the date on which the prescription is signed by the EEA health practitioner giving it.

Exemption in case of due diligence

6. Section 58(2)(a) of the Act does not apply to the sale or supply of a medicinal product by a person lawfully conducting retail pharmacy business where the sale or supply is in accordance with a prescription in relation to which the requirements in regulations 3 to 5 appear to be but are not fulfilled and the person selling or supplying the product, having exercised all due diligence, believes on reasonable grounds that those requirements have been fulfilled.

Exemption in case of emergency sale or supply

7.—(1) With the exception of paragraphs (2)(d) and (5), article 8 (exemptions for emergency sale and supply) of the Prescription Only Medicines (Human Use) Order 1997(**9**) applies to the sale or supply of a medicinal product made, pursuant to a request by an EEA health professional or in circumstances where treatment with the medicinal product has on a previous occasion been prescribed by an EEA health professional, by a person lawfully conducting a retail pharmacy business.

(2) For the purpose of paragraph (1) those terms in article 8 which are listed in paragraph (3) shall have the meanings ascribed to them in paragraph (3).

(3) The terms referred to in paragraph (2) are—

(a) "prescription only medicine" means "medicinal product";

(b) "doctor" includes an "EEA health professional"; and

(c) "prescription" includes a prescription given by an EEA health professional in a relevant European State.

Signed by authority of the Secretary of State for Health.

Dawn Primarolo
Minister of State,
Department of Health

26th June 2008

(**9**) S.I. 1997/1830; amendments to article 8 have been made by S.I.1998/2081, 2002/549, 2003/696, 2006/915.

EXPLANATORY NOTE

(This note is not part of these Regulations)

These Regulations provide that subject to the fulfilment of certain conditions in relation to the prescriptions which they give, doctors and dentists who give a prescription for a medicinal product (other than one which is a controlled drug) in an EEA State other than the UK or in Switzerland are appropriate practitioners within the meaning of section 58(2)(a) of the Medicines Act 1968 ("the Act"). The effect of this is to enable the sale or supply in circumstances corresponding to retail sale, of a medicinal product (other than a controlled drug) in accordance with a prescription given by such a doctor or dentist, provided the conditions in relation to the prescription are complied with (regulations 2-5).

Regulation 6 provides that section 58(2)(a) of the Act does not apply to the sale or supply of a medicinal product by a person lawfully conducting retail pharmacy business where the sale or supply is in accordance with a prescription in relation to which the requirements in regulations 3 to 5 appear to be but are not fulfilled and the person selling or supplying the product, having exercised all due diligence, believes on reasonable grounds that those requirements have been fulfilled. The effect of this is that in such circumstances the sale or supply will not contravene section 58(2)(a) of the Act.

Regulation 7 provides that the provisions of article 8 of the Prescription Only Medicines (Human Use) Order 1997 shall apply so that a person lawfully conducting retail pharmacy business may in an emergency situation lawfully sell or supply a medicinal product other than in accordance with a prescription given by an EEA health professional if the conditions set out in article 8 are satisfied.

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