STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

CHAPTER 2

Sale and supply of medicines

Prescription only medicines

Sale or supply of prescription only medicines

214.—(1) A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.

(2) A person may not parenterally administer (otherwise than to himself or herself) a prescription only medicine unless the person is—

(a) an appropriate practitioner other than an EEA health professional; or

(b) acting in accordance with the directions of such an appropriate practitioner.

(3) The following are appropriate practitioners in relation to any prescription only medicine—

(a) a doctor;

(b) a dentist;

(c) a supplementary prescriber;

(d) a nurse independent prescriber; and

(e) a pharmacist independent prescriber.

(4) A community practitioner nurse prescriber is an appropriate practitioner in relation to a prescription only medicine specified in Schedule 13.

(5) An optometrist independent prescriber is an appropriate practitioner in relation to any prescription only medicine other than—

(a) a medicinal product that is a controlled drug; or

(b) a medicinal product that is for parenteral administration.

(6) An EEA health professional is an appropriate practitioner in relation to any prescription only medicine other than a controlled drug.

(7) This regulation is subject to Chapter 3 (exemptions).

Prescribing and administration by supplementary prescribers

215.—(1) A supplementary prescriber ("S") may not give a prescription for a prescription only medicine unless S meets conditions A and C.

(2) A supplementary prescriber ("S") may not—

(a) parenterally administer a prescription only medicine; or

(b) give directions for the parenteral administration of a prescription only medicine,

unless S meets conditions B and C.

(3) Condition A is that S is acting in accordance with the terms of a clinical management plan that—

(a) relates to the patient to whom the product is prescribed;

(b) has effect when the prescription is given; and

(c) includes the particulars specified in Schedule 14.

(4) Condition B is that S is acting in accordance with the terms of a clinical management plan that—

(a) relates to the patient to whom the product is, or is to be, administered;

(b) has effect when the product is administered or (as the case may be) the direction is given; and

(c) includes the particulars specified in Schedule 14.

(5) Condition C is that S has access to health records that—

(a) are the health records of the patient to whom the plan relates; and

(b) are used by any doctor or dentist who is a party to the plan.

(6) This regulation is subject to regulation 216.

(7) In this regulation—

"clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates;

(b) the doctor or dentist who is a party to the plan; and

(c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

"health record" has the meaning given by section 68(2) of the Data Protection Act 1998(**1**).

Exceptions to regulation 215

216.—(1) Regulation 215 does not apply if—

(a) S is a community practitioner nurse prescriber; and

(b) the prescription only medicine prescribed or administered, or in respect of which S gives directions for administration, is specified in Schedule 13.

(2) Regulation 215(2) does not apply if S is acting in accordance with the directions of another person who is an appropriate practitioner (other than a supplementary prescriber or an EEA health professional) in relation to the prescription only medicine in question.

Requirements for prescriptions: general

217.—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner unless the following conditions are met.

(**1**) 1998 c.29.

(2) Condition A is that the prescription is signed in ink by the appropriate practitioner giving it.

(3) Condition B is that the prescription—

(a) is written in ink or otherwise so as to be indelible; or

(b) in the case of a health prescription which is not for a controlled drug, is written as described in sub-paragraph (a) or by means of carbon paper or similar material.

(4) Condition C is that the prescription contains the following particulars—

(a) the address of the appropriate practitioner giving it;

(b) the appropriate date;

(c) an indication of the kind of appropriate practitioner giving it;

(d) the name and address of the person for whose treatment it is given; and

(e) if that person is under 12, that person's age.

(5) Condition D is that the prescription—

(a) is not dispensed after the end of the period of six months beginning with the appropriate date; or

(b) in the case of a repeatable prescription—

(i) it is not dispensed for the first time after the end of that period, and

(ii) it is dispensed in accordance with the directions contained in the prescription.

(6) Condition E is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—

(a) it is not dispensed on more than two occasions, or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the appropriate date.

(7) In this regulation "appropriate date" means, subject to paragraph (8)—

(a) in the case of a health prescription, whichever is the later of—

(i) the date on which it was signed by the appropriate practitioner giving it, or

(ii) a date indicated by the appropriate practitioner as the date before which it should not be dispensed; and

(b) otherwise, the date on which the prescription was signed by the appropriate practitioner giving it.

(8) This regulation—

(a) does not apply to a prescription given by an EEA health professional (as to which see regulation 218); and

(b) is subject to regulation 219 (electronic prescriptions).

Requirements for prescriptions: EEA health professionals

218.—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner who is an EEA health professional unless the following conditions are met.

(2) Condition A is that it is an EEA prescription.

(3) Condition B is that the prescription is signed in ink by the EEA health professional giving it.

(4) Condition C is that the prescription is written in ink or otherwise so as to be indelible.

(5) Condition D is that the prescription contains the following particulars—

(a) the address of the EEA health professional giving it;

(b) the date on which it is signed by the EEA health professional;

(c) an indication of whether the EEA health professional is a doctor or dentist; and

(d) the name of the person for whose treatment it is given.

(6) Condition E is that the prescription—

(a) is not dispensed after the end of the period of six months beginning with the date on which it is signed by the EEA health professional; or

(b) in the case of a repeatable prescription—

(i) it is not dispensed for the first time after the end of that period, and

(ii) it is dispensed in accordance with the directions contained in the prescription.

(7) Condition F is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—

(a) it is not dispensed on more than two occasions; or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the date on which it is signed by the EEA health professional.

(8) This regulation is subject to regulation 219 (electronic prescriptions).

Electronic prescriptions

219.—(1) This regulation applies to a prescription that is not a health prescription for a controlled drug.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an appropriate practitioner other than an EEA health professional if—

(a) conditions A and B in regulation 217 are not met; but

(b) the conditions in paragraph (4) of this regulation and conditions C to E in regulation 217 are met.

(3) A prescription only medicine is also sold or supplied in accordance with a prescription given by an EEA health professional if—

(a) conditions B and C in regulation 218 are not met, but

(b) the conditions in paragraph (4) of this regulation and conditions A and D to F in regulation 218 are met.

(4) The conditions mentioned in paragraphs (2)(b) and (3)(b) are that the prescription is—

(a) created in electronic form;

(b) signed with an advanced electronic signature; and

(c) sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries).

(5) In this regulation "advanced electronic signature" means an electronic signature that is—

(a) uniquely linked to the person ("P") giving the prescription;

(b) capable of identifying P;

(c) created using means that P can maintain under P's sole control; and

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