STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

CHAPTER 3

Exemptions

Exemptions in relation to specific kinds of product

Products consisting of or containing aloxiprin, aspirin or paracetamol

236. Regulation 214(1) does not apply to a medicinal product that is a prescription only medicine by virtue of paragraph 1(e) of Schedule 1 (non-effervescent aloxiprin, aspirin or paracetamol) if the quantity of the product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.

Products consisting of or containing pseudoephedrine salts or ephedrine base or salts

237.—(1) Regulation 214(1) does not apply to a medicinal product that is a prescription only medicine by virtue of paragraph 1(f) of Schedule 1 (products consisting of or containing pseudoephedrine salts or ephedrine base or salts) if conditions A and B are met.

(2) Condition A is that the product is not sold or supplied at the same time as another medicinal product that consists of or contains—

(a) in the case of pseudoephedrine salts, ephedrine base or salts; or

(b) in the case of ephedrine base or salts, pseudoephedrine salts.

(3) Condition B is that the medicinal products sold or supplied to a person at any one time do not in total contain more than—

(a) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts; or

(b) in the case of ephedrine base or salts, 180mg ephedrine base or salts.

Administration of certain medicines in an emergency

238. Regulation 214(2) does not apply to the administration of a prescription only medicine specified in Schedule 19 where this is for the purpose of saving life in an emergency.

Administration of smallpox vaccine

239.—(1) Regulation 214(2) does not apply to the administration of smallpox vaccine if condition A or B is met.

(2) Condition A is that—

(a) the vaccine has been supplied by, on behalf of, or under arrangements made by—

(i) the Secretary of State,

(ii) the Scottish Ministers,

(iii) the Welsh Ministers,

(iv) the Department of Health, Social Services and Public Safety, or

(v) an NHS body; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom.

(3) Condition B is that—

(a) the vaccine has been supplied by, on behalf of, or under arrangements made by, Her Majesty's Forces; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus to members of Her Majesty's Forces or other persons employed or engaged by them.

Radioactive medicinal products

240.—(1) Regulation 214(2) does not apply to—

(a) a radioactive medicinal product, administration of which results in a medical exposure; or

(b) any other prescription only medicine if it is being administered in connection with a medical exposure,

if the following conditions are met.

(2) Condition A is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000(**1**) which apply to the exposure.

(3) Condition B is that the medical exposure has been authorised by—

(a) an IRME practitioner; or

(b) where it is not practical for an IRME practitioner to authorise the exposure, by an operator acting in accordance with written guidelines issued by an IRME practitioner.

(4) Condition C is that the IRME practitioner mentioned in paragraph (a) or (b) of paragraph (3) is the holder of a certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978(**2**).

(5) Condition D is that the prescription only medicine is not a controlled drug.

(6) Condition E is that, in the case of a prescription only medicine that is not a radioactive medicinal product, it is specified in the protocols referred to in paragraph (2).

(7) In this regulation—

"IRME practitioner" means, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000;

"medical exposure" has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000; and

"radioactive medicinal product" means a medicinal product which consists of, contains or generates a radioactive substance so that, when the product is administered, the radiation it emits may be used.

(**1**) S.I. 2000/1059, as amended by S.I. 2006/2523.
(**2**) S.I. 1978/1006.

Exemptions in respect of certain herbal remedies

241.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("A") of a herbal medicinal product if—

(a) the product does not contain a substance listed in Part 1 of Schedule 20;

(b) the product does not contain a substance listed in column 1 of Part 2 of that Schedule, unless the product is sold or supplied—

(i) in the case of a product for which there is a corresponding entry in column 2 of that Part, in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in that entry, and

(ii) in the case of a product for which there is a corresponding entry in column 3 of that Part, with the percentage of the substance in the product not exceeding that specified in that entry;

(c) the sale or supply, or offer for sale or supply, takes place on premises occupied by A and from which A can exclude the public; and

(d) the product is for administration to a person ("B") and A has been requested by or on behalf of B and in B's presence to use A's judgment as to the treatment required.

(2) A reference in this regulation to a substance listed in either Part of Schedule 20 is a reference to a substance that is obtained from any botanical source listed in either Part.

Exemption for medicinal products at high dilution

242.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) the medicinal product is neither for parenteral administration nor a controlled drug;

(b) paragraph (2) applies to the medicinal product; and

(c) P has been requested by or on behalf of a particular person and in that person's presence to use P's own judgment as to the treatment required.

(2) This paragraph applies to a medicinal product that consists solely of one or more unit preparations of—

(a) any substance where the unit preparation has been diluted to at least one part in a million (6x);

(b) any substance that is listed in Part 1 of Schedule 21 where the unit preparation has been diluted to at least one part in a thousand (3x); or

(c) any substance that—

(i) is the active substance of a medicine that is subject to general sale;

(ii) is listed in Part 3 of Schedule 21; or

(iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

where the unit preparation has been diluted to at least one part in ten (1x).

(3) Regulation 220 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the medicinal product is neither for parenteral administration nor a controlled drug;

(b) paragraph (4) applies to the medicinal product; and

(c) the conditions in regulation 221 are met.

(4) This paragraph applies to a medicinal product that consists solely of one or more unit preparations of—

(a) any substance where the unit preparation has been diluted to at least one part in a million million (6c);

(b) any substance that is listed in Part 2 of Schedule 21 where the unit preparation has been diluted to at least one part in a million (6x); or

(c) any substance that—

(i) is the active substance of a medicine that is subject to general sale;

(ii) is listed in Part 3 of Schedule 21; or

(iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

where the unit preparation has been diluted to at least one part in ten (1x).

Exemption for certain homoeopathic medicinal products

243.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) a certificate of registration is in force in relation to the product;

(b) the product is not an excluded product; and

(c) P has been requested by or on behalf of a particular person and in that person's presence to use P's own judgment as to the treatment required.

(2) Regulation 220 does not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) a certificate of registration is in force in relation to the product;

(b) the product is not an excluded product; and

(c) the conditions in regulation 221 are met.

(3) In this regulation "excluded product" means a product that is promoted, recommended or marketed—

(a) for use as an anthelmintic;

(b) for parenteral administration;

(c) for use as eye drops;

(d) for use as an eye ointment;

(e) for use as an enema;

(f) for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum; or

(g) for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.