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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 12**

**Dealings with medicinal products**

**CHAPTER 3**

**Exemptions**

*Exemptions relating to supply in specific circumstances*

**Exemption for supply etc under a PGD by person conducting a retail pharmacy business**

**233.**—(1) Regulation 214 does not apply to the sale or supply, or administration, of a prescription only medicine by a person lawfully conducting a retail pharmacy business where—

- (a) the person sells, supplies or (as the case may be) administers the prescription only medicine pursuant to an arrangement for the supply or administration of prescription only medicines with—
  - (i) the Common Services Agency,
  - (ii) a health authority or special health authority,
  - (iii) an NHS trust,
  - (iv) an NHS foundation trust,
  - (v) a Primary Care Trust,
  - (vi) a police force in England, Wales or Scotland,
  - (vii) the Police Service of Northern Ireland,
  - (viii) a prison service,
  - (ix) Her Majesty's Forces, or
  - (x) an authority or person carrying on the business of an independent hospital, an independent clinic, an independent medical agency or, in Northern Ireland, a nursing home;
- (b) the prescription only medicine is sold or supplied for the purpose of being supplied or (as the case may be) is administered to a person in accordance with a patient group direction ("PGD"); and
- (c) the following conditions are met.

(2) Condition A is that the PGD relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person lawfully conducting a retail pharmacy business who sells or supplies or (as the case may be) administers the prescription only medicine.

(3) Condition B is that the PGD has effect at the time at which the prescription only medicine is sold or supplied or (as the case may be) administered.

(4) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(5) Condition D is that the PGD is signed—

- (a) in the case of an arrangement with a body referred to in paragraph (1)(a)(i) to (v) (health bodies), on behalf of that body;
- (b) in the case of an arrangement with a police force in England, Wales or Scotland or with the Police Service of Northern Ireland—
  - (i) by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body, and
  - (ii) by a doctor who is not employed or engaged by, and does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;
- (c) in the case of an arrangement with a prison service, by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body;
- (d) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for Her Majesty's Forces;
- (e) in the case of an arrangement with an authority or person referred to in paragraph (1)(a)(x) (independent hospitals etc)—
  - (i) by or on behalf of the registered provider, and
  - (ii) if there is a relevant manager for the establishment or agency in question, by that manager.

(6) Condition E is that, where the prescription only medicine is administered by the person lawfully conducting a retail pharmacy business, the person belongs to one of the classes of individual specified in Part 4 of Schedule 16 and is designated in writing for the purpose of the administration of medicinal products under the PGD—

- (a) in the case of an arrangement with a body referred to in paragraph (1)(a)(i) to (v) (health bodies), on behalf of that body;
- (b) in the case of an arrangement with a body referred to in paragraph (1)(a)(vi) to (ix) (a police force, the Police Service of Northern Ireland, a prison service and Her Majesty's Forces), by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body; and
- (c) in the case of an arrangement with an authority or person referred to in paragraph (1)(a)(x) (independent hospitals etc)—
  - (i) by or on behalf of the registered provider, or
  - (ii) if there is a relevant manager for the establishment or agency in question, by that manager.

(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in relation to it.