
STATUTORY INSTRUMENTS

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 to assist doctors or dentists

230.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product by an individual belonging to one of the classes specified in Part 4 of Schedule 16 where—

- (a) the individual supplies or (as the case may be) administers the product to assist a doctor in the provision of NHS primary medical services or a dentist in the provision of NHS primary dental services;
- (b) the product is supplied for the purpose of being 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 supply or (as the case may be) administration of a description or class of medicinal product in order to assist the doctor or dentist in providing the services (whether or not it relates to such supply in order to assist any other doctor or dentist).

(3) Condition B is that the PGD has effect at the time at which the product is 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) by the doctor or dentist; or
- (b) where it also relates to supply or administration to assist one or more other doctors or dentists, by one of those doctors or dentists.

(6) Condition E is that the PGD is signed—

- (a) in the case of—
 - (i) NHS primary medical services, or
 - (ii) NHS primary dental services in England or Wales,

on behalf of the health authority or Primary Care Trust with which a contract or agreement for the provision of those services has been made or which provides those services;

- (b) in the case of dental services in Scotland under the National Health Service (Scotland) Act 1978⁽¹⁾, or general dental services in Northern Ireland, on behalf of the health authority with which an arrangement for the provision of those services has been made; and
 - (c) in the case of personal dental services provided under a pilot scheme in Scotland or Northern Ireland, on behalf of the health authority which is a party to the pilot scheme.
- (7) Condition F is that the individual supplying the product is designated in writing for the purpose of the supply or (as the case may be) administration of medicinal products under the PGD—
- (a) by the doctor or dentist; or
 - (b) where it also relates to supply to assist one or more other doctors or dentists, by one of those doctors or dentists.
- (8) Condition G is that when the product 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.

⁽¹⁾ 1978 c.29.