STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 10

Exceptions to requirement for marketing authorisation etc

Exceptions

Supply to fulfil special patient needs

167.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product (a "special medicinal product") if—

(a) the medicinal product is supplied in response to an unsolicited order;

(b) the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;

(c) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and

(d) the following conditions are met.

(2) Condition A is that the medicinal product is supplied—

(a) to a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber; or

(b) for use under the supervision of a pharmacist in a registered pharmacy, a hospital or a health centre.

(3) Condition B is that no advertisement relating to the medicinal product is published by any person.

(4) Condition C is that—

(a) the manufacture and assembly of the medicinal product are carried out under such supervision; and

(b) such precautions are taken,

as are adequate to ensure that the medicinal product meets the specification of the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber who requires it.

(5) Condition D is that written records of the manufacture or assembly of the medicinal product in accordance with condition C are maintained and are available to the licensing authority or to the enforcement authority on request.

(6) Condition E is that if the medicinal product is manufactured or assembled in the United Kingdom or imported into the United Kingdom from a country other than an EEA State—

(a) it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or

(b) it is manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorisation granted by the licensing authority for the purposes of regulation 36 of the Clinical Trials Regulations.

(7) Condition F is that if the product is imported from an EEA State—

(a) it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State; or

(b) it is manufactured or assembled as an investigational medicinal product in that State by the holder of an authorisation in relation to its manufacture or assembly in accordance with Article 13 of the Clinical Trials Directive as implemented in that State.

(8) Condition G is that if the product is distributed by way of wholesale dealing by a person ("P"), who has not, as the case may be, manufactured, assembled or imported the product in accordance with paragraph (6)(a) or (7)(a), P must be the holder of a wholesale dealer's licence in relation to the product in question.

(9) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Use of non-prescription medicines in the course of a business

168.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply to anything done in relation to a medicinal product if the following conditions are met.

(2) Condition A is that the medicinal product is not a prescription only medicine.

(3) Condition B is that the medicinal product is sold or supplied to a person who is a health care professional ("P") exclusively for use by P—

(a) in the course of a business carried on by P, and

(b) for the purposes of administering it or causing it to be administered otherwise than by selling it.

(4) Condition C is that the medicinal product is—

(a) manufactured and assembled in accordance with the specification of P; and

(b) for use by a patient for whose treatment P is directly responsible in order to fulfil the special needs of that patient

(5) Condition D is that if sold or supplied through the holder of a wholesale dealer's licence the medicinal product is sold or supplied to such a person and for such use as mentioned in condition B.

(6) Condition E is that no advertisement relating to the medicinal product is published by any person.

(7) Condition F is that the sale or supply of the medicinal product is in response to an unsolicited order.

(8) Condition G is that if the medicinal product is —

(a) manufactured or assembled in the United Kingdom or imported into the United Kingdom from a country other than an EEA State, it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or

(b) imported from an EEA State, it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State.

(9) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Mixing of general sale medicinal products

169.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply to a medicinal product ("the product") in respect of which the following conditions are met.

(2) Condition A is that the product is manufactured by the mixing of authorised medicinal products with other authorised medicinal products, or with substances that are not medicinal products.

(3) Condition B is that any authorised medicinal product that is so mixed is subject to general sale.

(4) Condition C is that the product is manufactured by a person ("H") who is the holder of a manufacturer's licence that—

(a) relates specifically to the manufacture of medicinal products in accordance with this regulation; and

(b) was granted or renewed not more than five years before the date on which the product is sold or supplied in accordance with paragraphs (5) and (6),

and that the product is manufactured in accordance with the terms of that licence.

(5) Condition D is that the product is sold or supplied by H to a person ("P") for administration to P or to a member of P's household.

(6) Condition E is that P is present and asks H to use H's judgment as to the treatment required.

(7) Condition F is that no advertisement relating to the product is published by any person.

(8) Condition G is that written records of the manufacture of the product and of the sale or supply of the product are maintained and are made available to the licensing authority or to the enforcement authority on request.

(9) In this regulation, "authorised medicinal product" means a medicinal product that is the subject of—

(a) a marketing authorisation;

(b) a certificate of registration; or

(c) a traditional herbal registration.

Record-keeping requirements

170.—(1) Where the sale or supply of a medicinal product relies on the exemptions under regulations 167, 168 or, subject to paragraph (4), 169, the person who sells or supplies the product must maintain for at least five years a record showing—

(a) the source from which and the date on which the person obtained the product;

(b) the person to whom and the date on which the sale or supply was made;

(c) the quantity of the sale or supply;

(d) the batch number of the batch of that product from which the sale or supply was made; and

(e) details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware.

(2) The person must make the records available for inspection by the licensing authority on request.

(3) The person must notify the licensing authority of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

(4) In the case of a medicinal product that is sold or supplied in reliance on the exemption in regulation 169—

(a) the reference in paragraph (1)(a) to "the product" means all the medicinal products that were mixed in the course of the manufacture of the product; and

(b) paragraph (1)(d) shall not apply.

Exempt advanced therapy medicinal products

171.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to an advanced therapy medicinal product (an "exempt advanced therapy medicinal product") if the following conditions are met.

(2) Condition A is that the product is prepared—

(a) on a non-routine basis;

(b) in the United Kingdom; and

(c) according to specific quality standards equivalent to those provided for advanced therapy medicinal products authorised under Regulation (EC) No 726/2004.

(3) Condition B is that the product is used—

(a) in a hospital in the United Kingdom;

(b) under the exclusive professional responsibility of a doctor; and

(c) in order to comply with an individual medical prescription for a product made to order for an individual patient.

(4) Condition C is that no advertisement relating to the medicinal product is published by any person.

(5) Condition D is that the sale or supply of the medicinal product is in response to an unsolicited order.

(6) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation Part 14 advertising).

Parallel import licences

172.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not prevent—

(a) the holder of a parallel import licence from placing the medicinal product to which the licence relates on the market; or

(b) the sale or supply, or offer for sale or supply, of a medicinal product to which a parallel import licence relates, in accordance with the terms of that licence.

(2) In this regulation "parallel import licence" means a licence that—

(a) is granted by the licensing authority in compliance with the rules of European Union law relating to parallel imports; and

(b) authorises the holder to place on the market a medicinal product imported into the United Kingdom from another EEA State.

Exemption for certain radiopharmaceuticals

173. Regulation 46 (requirement for authorisation) does not apply where a radiopharmaceutical is prepared—

(a) at the time when it is intended to be administered;

(b) in accordance with the manufacturer's instructions and by the person by whom it is to be administered;

(c) from radionuclide generators, radionuclide kits and radionuclide precursors in respect of which a marketing authorisation is in force; and

(d) for administration in accordance with regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978(**1**).

Supply in response to spread of pathogenic agents etc

174. The prohibitions in regulation 46 (requirement for authorisation) do not apply where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis in response to the suspected or confirmed spread of—

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which may cause harm to human beings.

Offences

Offences relating to exceptions

175.—(1) A person to whom this paragraph applies is guilty of an offence if the person provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product that is false or misleading in a material particular.

(2) Paragraph (1) applies to any person who for the purposes of regulation 167 (special patient needs)—

(a) sells or supplies the product; or

(b) provides a specification for the product.

(3) A person is guilty of an offence if the person fails to—

(a) maintain any record required by regulation 170(1) (records in connection with special medicinal products etc);

(b) make any record available as required by regulation 170(2); or

(c) notify the licensing authority of any suspected serious adverse reaction as required by regulation 170(3).

Penalties and supplementary provision about offences

176.—(1) A person guilty of an offence under regulation 175 is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(**1**) S.I. 1978/1006, as amended by S.I. 1995/2147 and S.I. 2006/2806; there are other amendments not relevant to these Regulations.

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

(2) It is a defence for a person charged with an offence under regulation 175(1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(3) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (2), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.