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 **[**F1, imported into Northern Ireland from a country other than an EEA State or Great Britain,

or imported into Great Britain from a country other than an approved country for import or Northern Ireland**]**—

(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 **[**F2imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import**]**—

[F3(a) it is manufactured or assembled in that State or country (as appropriate) by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, the provisions of the 2001 Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, in accordance with the provisions applicable in that country; or**]**

[F4(b) it is manufactured or assembled as an investigational medicinal product in that State or country (as appropriate) by the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, Article 13 of the Clinical Trials Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, regulations 13 and 43 of the Clinical Trials Regulations,**]**

[F5and it is imported by the holder of a wholesale dealer's licence in relation to the product in question.**]**

(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).

Textual Amendments

F1 Words in reg. 167(6) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F2 Words in reg. 167(7) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(i)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F3 Reg. 167(7)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(ii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F4 Reg. 167(7)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(iii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F5 Words in reg. 167(7)(b) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **5(2)(b)** and words in reg. 167(7)(b) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **5(2)(b)**

[F6NIMAR supply to Northern Ireland

167A.—(1) If the following conditions are met—

(a) the prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product sold or supplied, or offered for sale or supply, in Northern Ireland, and

(b) that product is classified in Northern Ireland as a prescription only medicine.

(2) Condition A is that a UK marketing authorisation of a following type is in force for the product—

(a) a UKMA(UK);

(b) a UKMA(GB).

(3) Condition B is that the product is classified as a prescription only medicine in accordance with regulation 5(3) for the purposes of sale and supply in Great Britain.

(4) Condition C is that the product is a listed NIMAR product.

(5) Condition D is that if the product is to be distributed by wholesale dealing by a person ("P") in Northern Ireland, P must be a holder of a wholesale dealer's licence.

(6) Condition E is that if the product is manufactured or assembled in Great Britain, it is supplied to Northern Ireland—

(a) by the holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

(7) Condition F is that if the product is manufactured outside of the UK and imported into Great Britain, it is supplied to Northern Ireland—

(a) by a holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

Textual Amendments

F6 Regs. 167A, 167B inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **14**

List of NIMAR products

167B.—(1) The licensing authority must maintain a list for the purposes of regulation 167A(4).

(2) In relation to each listed NIMAR product, the list must specify the date the NIMAR product was added to the list.

(3) The licensing authority must publish the list and keep it up to date.

(4) A product may only be included on the list if the following conditions are satisfied—

(a) Condition A is that the Secretary of State has in relation to Northern Ireland been provided with at least one of the following—

(i) information requested under regulation 28 (provision of information about availability of health service medicines) of the 2018 Regulations;

(ii) information under regulation 29 (requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines) of the 2018 Regulations;

(b) Condition B is that the holder of a UK marketing authorisation, has notified the Secretary of State that—

(i) in relation to a medicinal product to which a UKMA(UK) relates, the qualified person who is at the disposal of the holder of a manufacturer's licence is unable to secure the matters mentioned in paragraph 12A of Schedule 7 for the purpose of supplying the product into Northern Ireland from Great Britain; or

(ii) in relation to a medicinal product to which a UKMA(GB) relates, the inability of a qualified person who is at the disposal of the holder of a manufacturer's licence to secure the matters mentioned in paragraph 12A of Schedule 7 prevents the holder of the UKMA(GB) from converting it into a UKMA(UK);

(c) Condition C is that the licensing authority considers that clinical needs in Northern Ireland for the product may be unmet.

(5) The licensing authority must remove a product from the list if the licensing authority considers that medicinal products, not including listed NIMAR products, available in Northern Ireland are capable of meeting clinical need.**]**

Textual Amendments

F6 Regs. 167A, 167B inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **14**

[F7Early Access to Medicines Scheme: establishment and licensing authority functions

167C.—(1) The licensing authority must establish and operate a scheme, to be known as the Early Access to Medicines Scheme—

(a) the purpose of which is to give patients with life threatening or seriously debilitating conditions access to medicinal products that may be used for preventing, diagnosing or treating those conditions but which are either not authorised or not authorised for that use; and

(b) which is to include arrangements to support the collection of data about EAMS medicinal products.

(2) The licensing authority has the following functions with regard to the Early Access to Medicines Scheme—

(a) issuing, where appropriate, a designation ("Promising Innovative Medicines designation") in respect of a product under consideration for inclusion in the Scheme to the person who is or may in due course be responsible for placing the product on the market, after concluding based on early clinical and non-clinical data that the medicinal product may be eligible for inclusion in the Scheme because—

(i) there is a life threatening or seriously debilitating condition and a high unmet need,

(ii) the medicinal product is likely to offer a major advantage over methods of preventing, diagnosing or treating the condition already in use in the United Kingdom, and

(iii) the potential adverse effects of the medicinal product are likely to be outweighed by the potential benefits, allowing for a reasonable expectation of a positive risk-benefit balance;

(b) issuing, where appropriate, an opinion ("EAMS scientific opinion") to a holder of a Promising Innovative Medicines designation to the effect that the holder is able—

(i) to demonstrate that there is a life threatening or seriously debilitating condition and a high unmet need,

(ii) to demonstrate that the medicinal product offers a major advantage over methods of preventing, diagnosing or treating the condition already in use in the United Kingdom,

(iii) to demonstrate that the potential adverse effects of the medicinal product are outweighed by the potential benefits, allowing for a reasonable expectation of a positive risk-benefit balance,

(iv) to supply the product to or within the United Kingdom (or a part thereof) for use as part of the Scheme, and

(v) to manufacture, or secure the manufacturing of, the product to a consistent quality standard and in compliance with good manufacturing practice,

as a consequence of which the product is included in and may be supplied as part of the Scheme;

(c) where it issues an opinion under sub-paragraph (b), attaching where appropriate conditions, which may be varied from time to time, to the access to the Scheme that the opinion gives (which may include conditions that are equivalent to requirements of Part 13);

(d) revoking, pursuant to paragraph (3), opinions issued in accordance with sub-paragraph (b); and

(e) renewing opinions issued in accordance with sub-paragraph (b) that would otherwise cease to have effect in accordance with regulation 167D(1).

(3) The licensing authority may, if it is reasonable to do so, revoke an EAMS scientific opinion at any time (as a consequence of which, subject to regulation 167D(2), the product can no longer be supplied as part of the Scheme) if—

(a) there is a breach of the conditions referred to in paragraph (2)(c);

(b) there is a breach of regulation 167E to 167G; or

(c) sufficient grounds no longer exist for inclusion of the product within the Scheme.

(4) For the purposes of this regulation and regulations 167E and 167G, "authorised" has the meaning given in regulation 3(15), and (including the purposes of regulation 43(6)(aa)) "unauthorised" is to be construed accordingly.

Textual Amendments

F7 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

EAMS scientific opinions ceasing to have effect

167D.—(1) Subject to paragraph (2), an EAMS scientific opinion ceases to have effect—

(a) at the end of a period of one year beginning with the date on which it is issued;

(b) on the granting of a marketing authorisation in respect of the product to which the opinion relates (but if the marketing authorisation is to apply in Great Britain only, the opinion can continue to have effect in Northern Ireland and vice versa);

(c) on a variation of an existing marketing authorisation to take account of the advantage, identified in the opinion, because of which the product was included in the Early Access to Medicines Scheme (but if the variation is of a marketing authorisation that applies in Great Britain only, the opinion can continue to have effect in Northern Ireland and vice versa); or

(d) if it is revoked by the licensing authority pursuant to regulation 167C(3).

(2) The licensing authority may provide, in conditions attached in accordance with regulation 167C(2)(c), for a winding down period during which an EAMS scientific opinion is to continue to have effect in specified circumstances or for specified purposes (or both), notwithstanding that it has otherwise ceased to have effect by virtue of paragraph (1).

Textual Amendments

F7 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

EAMS medicinal products: manufacture, assembly, importation, distribution and supply

167E.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to an EAMS 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 the EAMS medicinal product) 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 that relate to the advantage identified in the EAMS scientific opinion in respect of the product;

(d) the EAMS scientific opinion issued in respect of the product and has not ceased to have effect in respect of it in accordance with regulation 167D; and

(e) the conditions in paragraphs (2) to (4) are met.

(2) If the EAMS medicinal product is—

(a) manufactured or assembled (wholly or partly) in the United Kingdom, that manufacture or assembly must be—

(i) by the holder of a manufacturer's licence (which need not relate specifically to the manufacture of special medicinal products) or, if the licensing authority agrees, a manufacturing authorisation (within the meaning given in regulation 36(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004) that relates to the manufacture or assembly of investigational medicinal products, and

(ii) a function permitted by that manufacturer's licence or manufacturing authorisation;

(b) manufactured or assembled (wholly or partly) in an EEA State and imported into Northern Ireland (whether it is for sale or supply in Northern Ireland or Great Britain), that manufacture or assembly must be—

(i) by a holder of a relevant authorisation in relation to the manufacture or assembly of medicinal products that has effect in accordance with the provisions of the 2001 Directive as implemented in that State, or

(ii) if the medicinal product was manufactured or assembled as an investigational medicinal product in that State, by the holder of a relevant authorisation in relation

to the manufacture or assembly of investigational medicinal products that has effect in accordance with the provisions of the EU Clinical Trials Regulation;

(c) manufactured or assembled (wholly or partly) in an approved country for import and imported into Great Britain, that manufacture or assembly must be—

(i) by a holder of a relevant authorisation in relation to the manufacture or assembly of medicinal products that has effect in accordance with the provisions applicable in that country, or

(ii) if the medicinal product was manufactured or assembled as an investigational medicinal product in that country, by the holder of a relevant authorisation in relation to the manufacture or assembly of investigational medicinal products that has effect in accordance with the provisions applicable in that country,

and that importation must be by the holder of a wholesale dealer's licence that permits importation into Great Britain of the product in question; or

(d) manufactured or assembled (wholly or partly) outside the United Kingdom but sub-paragraph (b) or (c) does not apply to the importation of that product, the importation of that product must be—

(i) by the holder of a manufacturer's licence that relates to the importation of special medicinal products or, if the licensing authority agrees, investigational medicinal products, and

(ii) a function permitted by that licence.

(3) Written records of the manufacture or assembly of the EAMS medicinal product must be maintained by the manufacturer or assembler and be available to the licensing authority or to the enforcement authority on request.

(4) If the EAMS medicinal 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 as mentioned in paragraph (2), P must be the holder of a wholesale dealer's licence that permits distribution of the product in question.

(5) Where, with the agreement of the licensing authority, to ensure the ongoing availability of an EAMS medicinal product, an authorised product is assembled as that EAMS medicinal product and is supplied as part of the Scheme—

(a) that authorised product is to be treated—

(i) as an unauthorised product for the purposes of Part 13, and

(ii) as that EAMS product for the purposes regulations 167G and 167H and Part 11; and

(b) in any circumstances where that supply would not be an off label supply to which the prohibitions in regulation 46(2) did not apply (by operation of the common law), that supply is to be treated as an off label supply to which those prohibitions do not apply.

Textual Amendments

F7 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

Advertising of EAMS medicinal products

167F.—(1) No advertisement relating to an EAMS medicinal product may be published by any person in respect of an advantage identified in the EAMS scientific opinion in respect of the product (although this does not preclude a person promoting the Early Access to Medicine Scheme itself).

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

Textual Amendments

F7 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

EAMS medicinal products: pharmacovigilance

167G.—(1) The EAMS scientific opinion holder must comply with the following pharmacovigilance requirements in respect of an EAMS medicinal product—

(a) a risk management system must be agreed with the licensing authority and operated by the EAMS scientific opinion holder in accordance with the risk management plan;

(b) the EAMS scientific opinion holder must record and maintain adverse reaction reports in respect of the EAMS medicinal product and must ensure that these reports are accessible (electronically or physically) at a single point within the United Kingdom;

(c) the EAMS scientific opinion holder must submit electronically to the licensing authority—

(i) a report on all serious suspected adverse reactions that occur within 15 days of receipt, and

(ii) a report on all non-serious suspected adverse reactions that occur in the United Kingdom within 90 days of receipt,

and must ensure that the reports referred to in sub-paragraphs (i) and (ii) are in the format and content specified by Part 6 of Schedule 12A;

(d) the EAMS scientific opinion holder must—

(i) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports, and

(ii) collect follow-up information on reports submitted under sub-paragraphs (c)(i) and (c)(ii) and submit it electronically to the licensing authority by way of an update to the original report within the specified time period;

(e) the EAMS scientific opinion holder must submit periodic reports, in the manner specified in conditions attached under regulation 167C(2)(c), on the use of the EAMS medicinal product to the licensing authority, and where reasonably practicable, these reports must contain—

(i) details of any suspected adverse drug reaction to the medicinal product,

(ii) a summary of any significant new data on the quality, safety or efficacy of the medicinal product concerned,

(iii) any proposed updates to the medicinal product information,

(iv) all data the holder has relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product in the United Kingdom, and

(v) a scientific evaluation of the risk-benefit balance of the medicinal product;

(f) the EAMS scientific opinion holder must notify the licensing authority without delay if it detects any relevant changes in relation to the EAMS medicinal product, and for these purposes, "relevant changes" means—

(i) new risks,

(ii) risks that have changed, and

(iii) changes to the risk-benefit balance; and

(g) the EAMS scientific opinion holder must—

(i) record all pharmacovigilance information required under this regulation,

(ii) maintain those records for at least five years beginning on the date on which the EAMS scientific opinion ceases to have effect in accordance with regulation 167D(1) (subject to any winding down period provided for in accordance with regulation 167D(2)), and

(iii) make those records available to the licensing authority or to the enforcement authority on request.

(2) Nothing in paragraph (1) precludes the meeting of the requirements of that paragraph within systems or other arrangements established for other medicinal products (including for an authorised product the marketing authorisation of which may, in due course, be varied to take account of the advantage identified in the EAMS scientific opinion in respect of the EAMS medicinal product).

Textual Amendments

F7 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

Early Access to Medicines Scheme: data collection

167H.—(1) Data may be collected and handled in respect of patients for the purposes of assessing the quality, safety and efficacy of an EAMS medicine as part of the Early Access to Medicines Scheme without the need for an authorisation granted by the licensing authority under the Clinical Trials Regulations, if—

(a) informed consent is obtained from the patient and such consent is evidenced in writing, dated and signed, or otherwise marked by the patient as to indicate their consent; and

(b) the licensing authority has consented to the data collection.

(2) This is without prejudice to—

(a) the need for the EAMS scientific opinion holder to obtain other approvals in respect of the handling of patient data, where appropriate; and

(b) the powers that the EAMS scientific opinion holder and the licensing authority have to handle patient data (in accordance with the requirements of the Data Protection Act 2018) without the patient's consent.

(3) For the avoidance of doubt, patient consent to data collection or handling is not, and must not be made, a condition of the supply of an EAMS medicinal product to a patient as part of the Early Access to Medicines Scheme.**]**

Textual Amendments

F7 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

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.

[F8(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—

(i) in the case of a product for sale or supply in Northern Ireland, a country other than an EEA State, or

(ii) in the case of a product for sale or supply in Great Britain, a country other than an approved country for import,

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 into—

(i) Northern Ireland 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, or

(ii) Great Britain from an approved country for import—

(aa) it is manufactured or assembled in that country by a person who is the holder of an authorisation in that country in relation to its manufacture or assembly, and

(bb) it is imported by the holder of a wholesale dealer's licence under Part 3 that includes the import of a medicinal product from such a country.**]**

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

Textual Amendments

F8 Reg. 168(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 135** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 103**)

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 **[**[F9]UK marketing authorisation or EU marketing authorisation**]**;

(b) a certificate of registration; or

(c) a traditional herbal registration.

Textual Amendments

F9 Words in reg. 169(9)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 136** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 104**): 2020 c. 1, **Sch. 5 para. 1(1)**

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 **[**F10—

(i) in the case of a product for sale or supply in Northern Ireland, Regulation (EC) No 726/2004, and

(ii) in the case of a product for sale or supply in Great Britain, regulation 49(1).**]**

(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).

Textual Amendments

F10 Reg. 171(2)(c)(i)(ii) substituted for words in reg. 171(2)(c) (31.12.2020) by S.I. 2019/775, **reg. 137** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 105**); 2020 c. 1, **Sch. 5 para. 1(1)**

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.

[F11(2) In this regulation "parallel import licence" has the same meaning as in regulation 48(2).**]**

Textual Amendments

F11 Reg. 172(2) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **18** and reg. 172(2) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **18**

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 **[**F12UK marketing authorisation or EU marketing authorisation**]** is in force; and

[F13(d) for administration—

(i) in England and Wales and Scotland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;

(ii) in Northern Ireland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.**]**

Textual Amendments

F12 Words in reg. 173(c) substituted (31.12.2020) by S.I. 2019/775, **reg. 138** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 106**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Reg. 173(d) substituted (6.2.2018) by The Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322), reg. 1, **Sch. 4 para. 2(2)** (as substituted (6.2.2018) by S.I. 2018/121, regs. 1(2), **2(4)(b)(i)**)

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.

[F14Conditions of temporary authorisations under regulation 174

174A.—(1) Where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis under regulation 174, the licensing authority may attach conditions to that authorisation, those being conditions to which the following are subject—

(a) its recommendation or requirement as to the use of that product for the purposes of regulation 345; and

(b) its authorisation of the sale or supply of that product.

(2) The sale or supply of that medicinal product is not authorised by the licensing authority for the purposes of regulation 174 if—

(a) the sale or supply is for the purpose of any use other than the recommended or required use, as mentioned in paragraph (1)(a); or

(b) a condition attached in accordance with paragraph (1) to the authorisation of the sale or supply is breached.

(3) The use of that medicinal product is not in accordance with a recommendation or requirement of the licensing authority for the purposes of regulation 345 if—

(a) a condition attached in accordance with paragraph (1) to the authorisation of its sale or supply is breached; and

(b) any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person with relevant expertise in the subject matter of the breach would regard the breach as sufficiently serious to justify the licensing authority setting aside the recommendation or requirement.

(4) Notwithstanding paragraph (3), the persons mentioned in regulation 345(3) are not subject to any civil liability resulting from a use of that medicinal product that was (but for the operation of that paragraph) in accordance with the recommendation or requirement of the licensing authority, if those persons were not wholly or partly responsible for the breach in question.

(5) As soon as is reasonably practical after the end of one year beginning on the day on which the first conditions are attached in accordance with paragraph (1), the Secretary of State must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

Textual Amendments

F14 Reg. 174A inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **6** and reg. 174A inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **6**

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 **[**F15167G(1)(g)(ii) (EAMS medicinal products: pharmacovigilance) or**]** 170(1) (records in connection with special medicinal products etc);

(b) make any record available as required by regulation **[**F16167G(1)(g)(iii) or**]** 170(2); or

(c) notify the licensing authority of any suspected serious adverse reaction as required by regulation 170(3) **[**F17or of any relevant changes as required by regulation 167G(1)(f)**]**.

Textual Amendments

F15 Words in reg. 175(3)(a) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **9(2)** (with reg. 19)

F16 Words in reg. 175(3)(b) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **9(3)** (with reg. 19)

F17 Words in reg. 175(3)(c) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **9(4)** (with reg. 19)

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

(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.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 10.