STATUTORY INSTRUMENTS

2022 No. 352

The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022

New regulations 167C to 167H

8. After regulation 167B(**1**) (list of NIMAR products) insert—

"**Early 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,

(**1**) Inserted by S.I. 2021/1452.

(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.

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).

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(**2**)) 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(**3**) 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

(**2**) S.I. 2004/1031; there are no relevant amending instruments.
(**3**) Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L311, 28.11.2001, p. 67).

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.

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).

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).

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(**4**)) 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.".

(**4**) 2018 c. 12.