Draft Regulations laid before Parliament and the Northern Ireland Assembly under section 47(3) and (6)(c) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament and the Northern Ireland Assembly.

DRAFT STATUTORY INSTRUMENTS

2022 No. 000

MEDICINES

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

Made - - - -	***
Coming into force - -	***

The Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland, make the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(a) to (e), (h) to (k), 5(1)(b), 6(1)(b) and 43 of the Medicines and Medical Devices Act 2021(**1**), after having considered the matters in section 2(2) to (4) of that Act.

The Secretary of State and the Department of Health in Northern Ireland have carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 47(3) and (6)(c) of that Act, a draft instrument was laid before Parliament and the Northern Ireland Assembly and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022.

(2) These Regulations come into force on the 28th day after the day on which they are made.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**2**) are amended in accordance with Regulations 3 to 14.

(**1**) 2021 c. 3. The powers in section 2(1) of the Medicines and Medical Devices Act 2021, and in the provisions that relate to it, are exercisable by the "appropriate authority". *See* section 2(6) of that Act, which contains the definition of "appropriate authority" that is relevant to the powers being exercised.

(**2**) S.I. 2012/1916, as amended.

Amendment of regulation 6

3. In regulation 6(1) (the licensing authority and the Ministers), after "certificates" insert ", designations, opinions".

Amendment of regulation 8

4. In regulation 8(1)(**3**) (general interpretation), at the appropriate places insert—

""EAMS medicinal product" means a medicinal product that—

(a) has been included in the Early Access to Medicines Scheme by means of the licensing authority issuing an EAMS scientific opinion in respect of it; and

(b) remains in the scheme by virtue of the EAMS scientific opinion not ceasing to have effect in respect of it by virtue of regulation 167D;";

""EAMS scientific opinion" is to be construed in accordance with regulation 167C(2)(b);";

""EAMS scientific opinion holder" means the holder of a EAMS scientific opinion, and accordingly, is the person who places on the market the product to which the opinion relates;";

""Early Access to Medicines Scheme" means the scheme of that name established and operated under regulation 167C(1);"; and

""EU Clinical Trials Regulation" means Regulation EU No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products, and repealing Directive 2001/20/EC(**4**);".

Amendment of regulation 37

5.—(1) Regulation 37(**5**) (manufacturing and assembly) is amended as follows.

(2) In paragraph (6)—

(a) omit "and" at the end of sub-paragraph (a); and

(b) after sub-paragraph (a) insert—

"(aa) in the case of a product for supply as an EAMS medicinal product, the conditions attached to the EAMS scientific opinion in respect of the product; and".

(3) In paragraph (10), after "applies" insert "or an EAMS medicinal product to which regulation 167E(1) to (4) (EAMS medicinal product: manufacture, assembly, importation, distribution and supply) applies".

Amendment of regulation 41

6. In regulation 41(**6**) (requirements as to qualified persons), after paragraph (11) insert—

"(12) The licence holder is not obliged to meet the requirements of this regulation in relation to any activities under the licence which relate to EAMS medicinal products, unless the conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) provide otherwise.".

(**3**) Amended by S.I. 2013/1855 and 2593, 2015/534 and 1503, 2016/186, 190 and 696, 2017/715, 2018/199, 2019/62, 593, 703, 775 and 1094, 2020/349 and 1125 and 2021/1452.
(**4**) OJ L 158, 27.5.2014, p. 1.
(**5**) Amended by S.I. 2013/1855, 2019/775 and 2021/1452.
(**6**) Amended by S.I. 2020/1125.

Amendment of regulation 43

7. In regulation 43(6)(**7**) (obligations of licence holder), after sub-paragraph (a) insert—

"(aa) the supply, or offer for supply, of an unauthorised EAMS medicinal product in the United Kingdom;".

New regulations 167C to 167H

8. After regulation 167B(**8**) (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,

(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,

(**7**) Amended by S.I. 2016/186 and 2019/775.
(**8**) Inserted by S.I. 2021/1452.

(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(**9**)) 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(**10**) 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,

(**9**) S.I. 2004/1031; there are no relevant amending instruments.
(**10**) 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).

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(**11**)) 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.".

Amendment of regulation 175

9.—(1) Regulation 175 (offences relating to exceptions) is amended as follows.

(2) In paragraph (3)(a), after "required by regulation" insert "167G(1)(g)(ii) (EAMS medicinal products: pharmacovigilance) or".

(3) In paragraph (3)(b), after "required by regulation" insert "167G(1)(g)(iii) or".

(4) In paragraph (3)(c), after "regulation 170(3)" insert "or of any relevant changes as required by regulation 167G(1)(f)".

Amendment of regulation 177

10. In regulation 177(**12**) (application of this Part and interpretation), after paragraph (1A) insert—

"(1B) Regulations 178 and 179 apply in relation to EAMS medicinal products.".

Amendment of regulation 346

11. In regulation 346(2)(c)(xxviiiaza)(**13**) (review), for "and 167B" substitute "to 167H".

Amendment of Schedule 1

12.—(1) Schedule 1 (further provisions for classification of medicinal products) is amended as follows.

(2) In Part 1(**14**) (descriptions of certain medicinal products to be available only on prescription), in paragraph 1—

(a) omit "and" at the end of sub-paragraph (g);

(**11**) 2018 c. 12.
(**12**) Amended by S.I. 2013/1855, 2014/1878 and 2019/775.
(**13**) The relevant amending instrument is S.I. 2021/1452.
(**14**) Amended by S.I. 2014/490, 2019/775 and 2020/1125.

(b) insert "; and" at the end of sub-paragraph (h); and

(c) after sub-paragraph (h) insert—

"(i) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, the product is classified as a prescription only medicine.".

(3) In Part 2(**15**) (descriptions of certain medicinal products to be available only from a pharmacy), in paragraph 3—

(a) omit "and" at the end of sub-paragraph (c);

(b) insert "; and" at the end of sub-paragraph (d); and

(c) after sub-paragraph (d) insert—

"(e) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, it is only to be available from a pharmacy.".

Amendment of Schedule 3

13. In Schedule 3(**16**) (applications for licences under Part 3), in paragraph 3(3)(d), after sub-paragraph (i) insert—

"(ia) EAMS medicinal products,".

Amendment of Schedule 4

14.—(1) Schedule 4 (standard provisions of licences under Part 3) is amended as follows.

(2) After paragraph 14A(**17**), insert—

"**14B.** A licence holder may only manufacture or assemble EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(3) In paragraph 22(**18**)—

(a) in sub-paragraph (5), after "special medicinal products" insert "or EAMS medicinal products";

(b) in sub-paragraph (7), after "special medicinal product" insert "or EAMS medicinal product";

(c) in sub-paragraph (8) after "special medicinal product" insert "or EAMS medicinal product"; and

(d) in sub-paragraph (9), after "special medicinal product" insert "or EAMS medicinal product".

(4) After paragraph 23A(**19**), insert—

"**23B.** A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(5) After paragraph 33, insert—

(**15**) Amended by S.I. 2019/775 and 2020/1125.
(**16**) Relevant amendments have been made by S.I. 2019/775.
(**17**) Inserted by S. 2019/775.
(**18**) Amended by S.I. 2019/775.
(**19**) Inserted by S.I. 2019/775.

"**33A.** A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(6) In paragraph 37, after "special medicinal products" insert "or EAMS medicinal products".

(7) In paragraph 39, after "special medicinal product" insert "or EAMS medicinal product".

(8) In paragraph 40, after "special medicinal product" insert "or EAMS medicinal product".

(9) In paragraph 41, after "special medicinal product" insert "or EAMS medicinal product".

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

15. The Medicines for Human Use (Clinical Trials) Regulations 2004(**20**) are amended in accordance with regulations 16 to 18.

Amendment of regulation 2

16. Regulation 2(1)(**21**) (interpretation), at the appropriate places in the alphabetical order insert—

""EAMS medicinal product" means a medicinal product that—

(a) has been included in the Early Access to Medicines Scheme by means of the licensing authority issuing an EAMS scientific opinion in respect of it; and

(b) remains in the scheme by virtue of the EAMS scientific opinion not ceasing to have effect in respect of it by virtue of regulation 167D of the 2012 Regulations;";

""EAMS scientific opinion" is to be construed in accordance with regulation 167C(2)(b) of the 2012 Regulations;"; and

""Early Access to Medicines Scheme" means the scheme of that name established and operated under regulation 167C(1) of the 2012 Regulations;".

Amendment of regulation 43

17.—(1) Regulation 43(**22**) (qualified persons) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (b), after "United Kingdom," insert "except, in relation to a EAMS medicinal product, to the extent that conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) of the 2012 Regulations provide otherwise,"; and

(b) after "in paragraph" insert "(1A) or".

(3) After paragraph (1), insert—

"(1A) The qualified person is responsible for ensuring that, in relation to an EAMS medicinal product, if conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) of the 2012 Regulations require the qualified person to carry out any duties in respect of that product, that qualified person carries out those duties.".

(4) In paragraph (4), after "with paragraph" insert "(1A) or".

(**20**) S.I. 2004/1031.
(**21**) Amended by S.I. 2004/3224, 2006/562 and 1928, 2007/3101, 2008/941, 2010/231, 2011/2581, 2012/1641 and 1916, 2013/235, 2016/696, and 2019/593, 744 and 1094, and by S.R. 2008 No. 192.
(**22**) Amended by S.I. 2019/744.

Amendment of Schedule 7

18.—(1) Schedule 7 (standard provisions for manufacturing authorisations) is amended as follows.

(2) In Part 2 (provisions which may be incorporated in an authorisation relating to the manufacture or assembly of investigational medicinal products)—

(a) in paragraph 1(a), after "investigational medicinal products" insert "or EAMS medicinal products";

(b) in paragraph 2, after "investigational medicinal products", at each place where it occurs, insert "or EAMS medicinal products";

(c) in paragraph 9(**23**)—

(i) after "investigational medicinal product" at both places where it occurs, insert "or EAMS medicinal product", and

(ii) after "clinical trials" insert "or as part of the Early Access to Medicines Scheme";

(d) in paragraph 10, after "investigational medicinal product" insert "or EAMS medicinal product";

(e) in paragraph 11, after "investigational medicinal product", at each place where it occurs, insert "or EAMS medicinal product";

(f) in paragraph 12, after "investigational medicinal product", at both places where it occurs, insert "or EAMS medicinal product";

(g) in paragraph 13(**24**), after sub-paragraph (a) insert—

"(aa) amending the conditions attached to or revoking an EAMS scientific opinion;";

(h) in paragraph 14, for "regulation 43(2)" substitute "regulation 43(1A) or (2)"; and

(i) after paragraph 14 insert—

"**14A.** The holder of the authorisation shall only manufacture or assemble EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(3) In Part 3 (provisions which may be incorporated in an authorisation relating to the importation of investigational medicinal products)—

(a) in paragraph 1, after "investigational medicinal products", at each place where it occurs, insert "or EAMS medicinal products";

(b) in paragraph 3, after "investigational medicinal products" insert "or EAMS medicinal products";

(c) in paragraph 6(**25**)—

(i) after "investigational medicinal product", at both places where it occurs, insert "or EAMS medicinal product", and

(ii) after "in clinical trials" insert "or as part of the Early Access to Medicines Scheme";

(d) in paragraph 8, after sub-paragraph (a) insert—

"(aa) amending the conditions attached to or revoking an EAMS scientific opinion;";

(e) in paragraph 9, for "regulation 43(2)" substitute "regulation 43(1A) or (2)"; and

(**23**) Amended by S.I. 2012/1916.
(**24**) Amended by S.I. 2012/1916.
(**25**) Amended by S.I. 2012/1916.

(f) after paragraph 9 insert—

"**9A.** The holder of the authorisation shall only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

Transitional and saving provisions

19.—(1) In any case where, prior to the coming into force of these Regulations, the licensing authority has issued an EAMS scientific opinion (under the pre-existing non-statutory arrangements) in respect of a medicinal product, the amendments to the Human Medicines Regulations 2012 made by these Regulations do not apply in respect of the sale or supply of, or the pharmacovigilance arrangements for, that product.

(2) Paragraph (1) ceases to apply in respect of the sale or supply of, or the pharmacovigilance arrangements for, that product once that EAMS scientific opinion is renewed (which the licensing authority may bring forward) or it ceases to have effect.

(3) Consent as mentioned in regulation 167H of the Human Medicines Regulations 2012 may be consent obtained prior to these Regulations coming into force.

Signed by authority of the Secretary of State for Health and Social Care

Name
Address — Minister of State
Date — Department of Health and Social Care

Sealed with the Official Seal of the Department of Health in Northern Ireland [date]

Name
A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations"), which govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use, and the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the 2004 Regulations"), which govern the conduct of clinical trials of medicinal products for human use. The amendments make provision for the establishment and operation of the statutory version of the Early Access to Medicine Scheme (EAMS) – there has previously been a non-statutory version of the Scheme. The EAMS has the purpose of giving patients with life threatening or seriously debilitating conditions access to medicinal products that are either not authorised or not authorised for that use.

Subject to various exceptions, medicines for human use may only be sold or supplied if they have been granted a marketing authorisation by the licensing authority (which is either, or both, of the Secretary of State and the Minister of Health in Northern Ireland). These Regulations add to those exceptions dedicated arrangements that allow unlicensed medicines to be placed on the market in the United Kingdom if they are supplied as part of the EAMS. The core functions of the licensing authority in relation to the EAMS are set out in the new regulation 167C of the 2012 Regulations, and include a licensing authority power to issue EAMS scientific opinions in respect of medicinal products. This opinion allows the EAMS scientific opinion holder to supply the product within the United Kingdom without a marketing authorisation, subject to the conditions that may be attached by the licensing authority to the opinion, as well as to the statutory conditions set out in the new regulations 167E to 167G. The new regulation 167D of the 2012 Regulations makes provision in respect of EAMS scientific opinions ceasing to have effect.

The new regulation 167E of the 2012 Regulations contains the statutory conditions with regard to the ordering, manufacture and distribution of unlicensed EAMS medicinal products, whilst also providing for licensed medicinal products to be supplied as part of the EAMS where this is done to ensure the ongoing availability of products, with the agreement of the licensing authority. The requirements in respect of unlicensed medicinal products are similar in effect to those included in regulation 167 of the 2012 Regulations in relation to special medicinal products, and similarly take as their starting point Article 5(1) of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**26**). The new regulation 167F of the 2012 Regulations prohibits the advertisement of EAMS medicinal products, although this does not preclude promotion of the Scheme itself – and the new regulation 167G of the 2012 Regulations thereafter sets out pharmacovigilance obligations in respect of EAMS medicinal products, such as the reporting by the EAMS scientific opinion holder of changes to the risk-benefit balance of the product. The new regulation 167H of the 2012 Regulations deals with data collection, but also makes clear that patient consent to data collection is not, and must not be made, a requirement of access to an EAMS medicinal product as part of the EAMS (regulation 8).

A number of consequential changes are made to the 2012 Regulations and the 2004 Regulations. In particular, requirements relating to the manufacture, importation and distribution of EAMS medicinal products are integrated within the existing framework of requirements for the manufacture, import and distribution of medicinal products under the 2012 Regulations and the 2004 Regulations, so that holders of authorisations for the purposes of those Regulations will be able to carry out the activities that they are authorised to perform in relation to licensing medicinal products,

(**26**) OJ L 311, 28.11.2001, p.67, to which there have been amendments which are not relevant.

special medicinal products and investigational products in relation to EAMS medicinal products as well – and the conditions for their licences or authorisations to manufacture, import or distribute are modified to support this (regulations 5 to 7, 13, 17 and 18). There are also consequential changes to licensing authority functions (regulations 3, 10 and 11), in relation to classification of EAMS medicinal products (regulation 12), to definitions provisions (regulations 4 and 16), and to sanctions provisions (regulation 9). There is also a transitional provision which provides that EAMS medicinal products that were the subject of EAMS scientific opinions issued before these Regulations came into force are to be regulated as if the arrangements with regard to the sale or supply of, or the pharmacovigilance for, EAMS medicinal products set out in these Regulations had not been made – pending the renewal of that scientific opinion or it ceasing to have effect (regulation 19).

A Regulatory Triage Assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be proportionate. These Regulations are not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.