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

2024 No. 000

MEDICINES

The Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2024

Made - - - - ***

Coming into force in accordance with regulation 1(2)

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, ("the appropriate authority"), make the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(a), (d), (e), (h) to (j), 5(1)(b), (d) and (e) and 43(2)(a), (b) and (d) of the Medicines and Medical Devices Act 2021(**1**) ("the Act").

The appropriate authority has carried out a public consultation in accordance with section 45(1) of the Act.

In accordance with section 2(2) to (4) of the Act, the appropriate authority's overarching objective in making these Regulations is safeguarding public health, and the appropriate authority has had regard to the matters specified in section 2(3) of the Act and considers that, where these Regulations may have an impact on the safety of human medicines, the benefits of making these Regulations outweigh the risks.

In accordance with section 47(3) and (6)(c) of the 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.

(**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". Section 2(6) of that Act contains the definition of "appropriate authority" that is relevant to the powers being exercised. Section 43 was amended by section 101(5)(a) of the Health and Care Act 2022 (c. 31).

PART 1

General

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2024.

(2) These Regulations come into force six months after the date 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 Part 2.

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

3. The Medicines for Human Use (Clinical Trials) Regulations 2004(**3**) are amended in accordance with Part 3.

PART 2

Amendment of the Human Medicines Regulations 2012

Amendment of regulation 8

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

""manufacturer's licence (MM)" means a manufacturer's licence that relates to the manufacture or assembly of MM medicinal products specified in that licence;";

""manufacturer's licence (POC)" means a manufacturer's licence that relates to the manufacture or assembly of POC medicinal products specified in that licence;";

""MM" means modular manufacture;";

""MM control site" means the premises at which the holder of a manufacturer's licence (MM) supervises and controls the manufacture or assembly of MM medicinal products;";

""MM master file" means a detailed description of the arrangements for the manufacture or assembly of an MM medicinal product;";

""MM medicinal product" means a medicinal product that, for reasons relating to deployment, the licensing authority determines it necessary or expedient to be manufactured or assembled in a modular unit;";

""modular unit" means a relocatable manufacturing unit;";

""POC" means point of care;";

""POC control site" means the premises at which the holder of a manufacturer's licence (POC) supervises and controls the manufacture or assembly of POC medicinal products;";

""POC master file" means a detailed description of the arrangements for the manufacture or assembly of a POC medicinal product;";

(**2**) S.I. 2012/1916.
(**3**) S.I. 2004/1031.
(**4**) There are amendments but none is relevant.

""POC medicinal product" means a medicinal product that, for reasons relating to method of manufacture, shelf life, constituents or method or route of administration, can only be manufactured at or near the place where the product is to be used or administered;"; and

""POC site" means a site at which the manufacture or assembly of a POC medicinal product takes place;".

Amendment of regulation 17

5.—(1) Regulation 17 (manufacturing of medicinal products)(**5**) is amended as follows.

(2) In paragraph (1), after "a licence" insert "of the appropriate type".

(3) After paragraph (1) insert—

"(1A) For the purposes of paragraph (1), the appropriate type of manufacturer's licence is a licence that relates to whichever, or whichever combination, of the following that is appropriate—

(a) manufacture and assembly of medicinal products, except for advanced therapy medicinal products, MM medicinal products, POC medicinal products or special medicinal products;

(b) import of medicinal products, except for special medicinal products, MM medicinal products or POC medicinal products;

(c) manufacture and assembly of advanced therapy medicinal products;

(d) manufacture and assembly of MM medicinal products;

(e) manufacture and assembly of POC medicinal products;

(f) manufacture and assembly of special medicinal products;

(g) import of special medicinal products."

(4) After paragraph (9) insert—

"(10) Regulation 17A sets out additional requirements in relation to the manufacture or assembly of MM medicinal products.

(11) Regulation 17B sets out additional requirements in relation to the manufacture or assembly of POC medicinal products.".

Insertion of new regulations 17A and 17B (manufacturing of MM and POC medicinal products)

6. After regulation 17 (manufacturing of medicinal products) insert—

"**Manufacturing of MM medicinal products**

17A. A person may not manufacture or assemble an MM medicinal product unless—

(a) it is specified in a manufacturer's licence (MM); and

(b) there is an MM master file relating to that product and it is manufactured or assembled in accordance with that master file.

Manufacturing of POC medicinal products

17B. A person may not manufacture or assemble a POC medicinal product unless—

(a) it is specified in a manufacturer's licence (POC); and

(**5**) Amended by S.I. 2019/775 and 2023/437.

(b) there is a POC master file relating to that product and it is manufactured or assembled in accordance with that master file.".

Amendment of regulation 20

7. In regulation 20(2) (mixing of medicines)(**6**), for "the combining of two or more medicinal products together" substitute "the combining together of two or more medicinal products, none of which are MM medicinal products nor POC medicinal products".

Amendment of regulation 22

8. After regulation 22(1) (factors relevant to determination of application for manufacturer's or wholesale dealer's licence) insert—

"(1A) In dealing with an application for a manufacturer's licence (MM) the licensing authority must, in addition to the matters specified in paragraph (1), take into consideration the arrangements made, or to be made, for—

(a) supervising and controlling operations at a modular unit specified in the application; and

(b) ensuring that manufacture or assembly is under appropriate control so that the MM medicinal product consistently meets the requirements in the MM master file when manufactured at that modular unit.

(1B) In dealing with an application for a manufacturer's licence (POC) the licensing authority must, in addition to the matters specified in paragraph (1), take into consideration the arrangements made, or to be made, for—

(a) supervising and controlling operations at a POC site specified in the application; and

(b) ensuring that manufacture or assembly is under appropriate control so that the POC medicinal product consistently satisfies the requirements in the POC master file when manufactured at that POC site.".

Amendment of regulation 26

9. In regulation 26(2) (general power to suspend, revoke or vary licences)(**7**)—

(a) in sub-paragraph (b), omit "or" in the second place where it occurs; and

(b) after sub-paragraph (c) insert—

"(d) in the case of a manufacturer's licence (MM), limited to modular units specified in the MM master file associated with the licence; or

(e) in the case of a manufacturer's licence (POC), limited to POC sites specified in the POC master file associated with the licence.".

Insertion of new regulation 27A (effect of suspension or variation relating to modular unit or POC site)

10. After regulation 27 (procedure where licensing authority proposes to suspend, revoke or vary licence) insert—

(**6**) There are amendments but none is relevant.
(**7**) There are amendments but none is relevant.

"**Effect of suspension or variation relating to modular unit or POC site**

27A.—(1) If the licensing authority suspends or varies a manufacturer's licence (MM) in accordance with regulation 26(2)(d) so that manufacturing or assembly is suspended, or no longer authorised, at a modular unit, the licence holder may not approve that unit for the purpose of manufacturing or assembly of the MM medicinal product other than by way of an application under regulation 29.

(2) If the licensing authority suspends or varies a manufacturer's licence (POC) in accordance with regulation 26(2)(e) so that manufacturing or assembly is suspended, or no longer authorised, at a POC site, the licence holder may not approve that site for the purpose of manufacturing or assembly of the POC medicinal product other than by way of an application under regulation 29.".

Amendment of regulation 29

11. After regulation 29(2) (variation of licence on the application of the holder)(**8**) insert—

"(2A) In the case of an application of a type specified in paragraph (2C), the information to be provided under paragraph (2)(d) must include the information specified in paragraph 1A(2) of Schedule 3.

(2B) In the case of an application of a type specified in paragraph (2D), the information to be provided under paragraph (2)(d) must include the information specified in paragraph 1B(2) of Schedule 3.

(2C) The following types of application are specified for the purpose of paragraph (2A) and (2E)—

(a) an application to vary the licence so that it relates to the manufacture or assembly of MM medicinal products;

(b) an application to vary a manufacturer's licence (MM) to add a new MM medicinal product.

(2D) The following types of application are specified for the purpose of paragraphs (2B) and (2F)—

(a) an application to vary the licence so that it relates to the manufacture or assembly of POC medicinal products;

(b) an application to vary a manufacturer's licence (POC) to add a new POC medicinal product.

(2E) In dealing with an application of a type specified in paragraph (2C), the licensing authority must take into consideration the arrangements made or to be made for—

(a) supervising and controlling operations at a modular unit specified in the application; and

(b) ensuring that manufacture or assembly is under appropriate control so that the MM medicinal product consistently satisfies the requirements in the MM master file when manufactured at that modular unit.

(2F) In dealing with an application of a type specified in paragraph (2D), the licensing authority must take into consideration the arrangements made or to be made for—

(a) supervising and controlling operations at a POC site specified in the application; and

(**8**) There are amendments but none is relevant.

(b) ensuring that manufacturing or assembly is under appropriate control so that the POC medicinal product consistently satisfies the requirements in the POC master file when manufactured at that POC site.".

Insertion of new regulations 29A and 29B (variation of MM and POC master files)

12. After regulation 29 (variation of licence on the application of the holder) insert—

"**Variation of MM master file**

29A. Except where regulation 27A(1) applies, the holder of a manufacturer's licence (MM) may amend the information in the MM master file provided in accordance with paragraph 1A(2)(a), (c) and (h) to (k) of Schedule 3 without applying to the licensing authority for a variation under regulation 29.

Variation of POC master file

29B. Except where regulation 27A(2) applies, the holder of a manufacturer's licence (POC) may amend the information in the POC master file provided in accordance with paragraph 1B(2)(a), (b) and (g) to (j) of Schedule 3 without applying to the licensing authority for a variation under regulation 29.".

Amendment of regulation 37

13.—(1) Regulation 37 (manufacturing and assembly)(**9**) is amended as follows.

(2) In paragraph (6)—

(a) at the end of sub-paragraph (aa), delete "and"; and

(b) after sub-paragraph (aa) insert—

"(ab) in the case of an MM medicinal product, the MM master file;

(ac) in the case of a POC medicinal product, the POC master file; and".

(3) In paragraph (8), at the beginning insert "Except in the case of an MM medicinal product or a POC medicinal product,".

Insertion of new regulations 37A and 37B (manufacturing and assembly of MM and POC medicinal products: additional requirements)

14. After regulation 37 (manufacturing and assembly) insert—

"**Manufacturing and assembly of MM medicinal products: additional requirements**

37A. In addition to the requirements in regulation 37, the holder of a manufacturer's licence (MM) must ensure that—

(a) the requirements in regulation 37(2) to (7), (9) and (11) are complied with in relation to manufacturing or assembly carried out at the modular units specified in the MM master file; and

(b) only the MM medicinal products specified in the licence are manufactured or assembled at the modular units specified in the MM master file.

(**9**) Regulation 37 was substituted by S.I. 2013/1855 and amended by S.I. 2019/775, 2021/1452 and 2022/352.

Manufacturing and assembly of POC medicinal products: additional requirements

37B. In addition to the requirements in regulation 37, the holder of a manufacturer's licence (POC) must ensure that—

(a) the requirements in regulation 37(2) to (7), (9) and (11) are complied with in relation to manufacturing or assembly carried out at the POC sites specified in the POC master file;

(b) only the POC medicinal products specified in the licence are manufactured or assembled at the POC sites specified in the POC master file; and

(c) a POC medicinal product specified in the licence is only manufactured at a POC site specified in the POC master file.".

Amendment of regulation 39

15.—(1) Regulation 39 (further requirements for manufacturer's licence)(**10**) is amended as follows.

(2) In paragraphs (4) and (5), at the beginning insert "Except in the case of an MM medicinal product or a POC medicinal product,".

(3) After paragraph (5) insert—

"(5A) The holder of a manufacturer's licence (MM) must ensure that the medicinal products specified in the licence are not handled, controlled, stored or distributed on any premises other than the MM control site and the modular units specified in the MM master file.

(5B) The holder of a manufacturer's licence (MM) must inform the licensing authority before making a material alteration to the premises or facilities at the MM control site, or to any modular unit specified in the MM master file, or to the purposes for which those premises or facilities are used.

(5C) The holder of a manufacturer's licence (POC) must ensure that the medicinal products specified in the licence are not handled, controlled, stored or distributed on any premises other than the POC control site and those specified in the POC master file.

(5D) The holder of a manufacturer's licence (POC) must inform the licensing authority before making a material alteration to the premises or facilities at the POC control site, or to the purposes for which those premises or facilities are used.

(5E) Paragraphs (5A) and (5C) do not apply to anything done in the course of the business of a hospital that consists of dealing with a medicine or making it ready for use for the purposes of its final supply or administration to a patient.".

Amendment of regulation 50

16.—(1) Regulation 50 (accompanying material)(**11**) is amended as follows.

(2) In paragraph (5), at the beginning insert "Subject to paragraphs (5AA) and (5AB),".

(3) After paragraph (5), insert—

"(5AA) In addition to the information referred to in Part 1, paragraph 1.2, fourth paragraph of Annex 1 to the 2001 Directive, an applicant for the grant of a UK marketing authorisation for an MM medicinal product must also provide a copy of the MM master file for that product.

(**10**) There is an amendment to this regulation but it is not relevant.
(**11**) Regulation 50 was amended by S.I. 2014/1878 and 2019/775.

(5AB) In addition to the information referred to in Part 1, paragraph 1.2, fourth paragraph of Annex 1 to the Directive, an applicant for the grant of a UK marketing authorisation for a POC medicinal product must also provide a copy of the POC master file for that product.".

Insertion of new regulation 50K (applications relating to POC medicinal products)

17. After regulation 50J (applications in relation to medicinal products containing or consisting of genetically modified organisms)(**12**) insert—

"**Applications relating to POC medicinal products**

50K.—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product that is a POC medicinal product.

(2) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority information about the measures the applicant envisages putting in place to ensure the follow up of the efficacy of the product and of any adverse reactions to it.".

Insertion of new regulations 74A and 74B (obligations to provide information relating to methods of manufacture and control)

18. After regulation 74 (obligation to take account of scientific and technical progress) insert—

"**Obligation to provide information relating to methods of manufacture and control: MM medicinal products**

74A. The holder of a UK marketing authorisation relating to an MM medicinal product must provide the holder of the manufacturer's licence (MM) relating to that product with information in order to enable the licence holder to ensure that the manufacturer's licence (MM) and MM master file relating to the product are consistent with the marketing authorisation at all times.

Obligation to provide information relating to methods of manufacture and control: POC medicinal products

74B. The holder of a UK marketing authorisation relating to a POC medicinal product must provide the holder of the manufacturer's licence (POC) relating to that product with information in order to enable the licence holder to ensure that the manufacturer's licence (POC) and POC master file relating to the product are consistent with the marketing authorisation at all times.".

Amendment of regulation 167

19.—(1) Regulation 167 (supply to fulfil special patient needs)(**13**) is amended as follows.

(2) In paragraph (6), at the beginning insert "Except in the case of an MM medicinal product or a POC medicinal product,".

(3) After paragraph (6) insert—

"(6A) In the case of an MM medicinal product, condition E is that the product is manufactured or assembled by the holder of a manufacturer's licence (MM) that relates

(**12**) Inserted by S.I. 2019/775.
(**13**) Regulation 167 was amended by S.I. 2019/775. There are other amending instruments but none is relevant.

specifically to the manufacture or assembly of special medicinal products and in accordance with the MM master file relating to the product.

(6B) In the case of a POC medicinal product, condition E is that the product is manufactured or assembled by the holder of a manufacturer's licence (POC) that relates specifically to the manufacture or assembly of special medicinal products and in accordance with the POC master file relating to the product.".

(4) In paragraph (7), delete "a country other than".

Amendment of regulation 167G

20.—(1) Regulation 167G (EAMS medicinal products: pharmacovigilance)(**14**) is amended as follows.

(2) In paragraph (1)—

(a) at the beginning insert "Subject to paragraphs (1A) and (1B),"; and

(b) in sub-paragraph (c), at the end insert "and, in the case of an MM medicinal product or a POC medicinal product, include the product's batch number or other product identifier if no batch number is available".

(3) After paragraph (1) insert—

"(1A) In the case of an MM medicinal product, the periods of 15 and 90 days referred to in paragraph (1)(c) begin on the day following the day on which the holder of the scientific opinion gained knowledge of the reaction.

(1B) In the case of a POC medicinal product, the periods of 15 and 90 days referred to in paragraph (1)(c) begin on the day following the day on which the holder of the scientific opinion gained knowledge of the reaction.".

Amendment of regulation 169

21. Before regulation 169(1) (mixing of general sales medicinal products)(**15**) insert—

"(A1) This regulation does not apply to an MM medicinal product or a POC medicinal product.".

Amendment of regulation 170

22. Before regulation 170(1) (record-keeping requirements) insert—

"(A1) This regulation does not apply to an MM medicinal product or a POC medicinal product.".

Insertion of new regulations 170A and 170B (pharmacovigilance requirements: MM and POC medicinal products)

23. After regulation 170 (record-keeping requirements) insert—

"**MM medicinal products: pharmacovigilance requirements**

170A.—(1) Where the sale or supply of an MM medicinal product relies on the exemption in regulation 167, the person who sells or supplies the product must maintain a record of the information specified in paragraph (2) from the date that sale or supply first

(**14**) Regulation 167G was inserted by S.I. 2022/352.
(**15**) There are amendments but none is relevant.

takes place until a date that is at least five years from the date on which supply of the product is discontinued.

(2) The following information is specified for the purpose of paragraph (1)—

(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 product's batch number from which the sale or supply was made, or other product identifier if no batch number is available; 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.

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

(4) The person must submit electronically to the licensing authority—

(a) a report on all serious suspected adverse reactions to the product that occur within 15 days of the day following the day on which the person gained knowledge of the reaction, and

(b) a report on all non-serious suspected adverse reactions to the product that occur in the United Kingdom within 90 days of the day following the day on which the person gained knowledge of the reaction.

(5) The person must ensure that the reports referred to in paragraph (4)—

(a) are in the format and have the content specified in Part 6 of Schedule 12A; and

(b) include the product's batch number, or other product identifier if no batch number is available.

(6) The person must, at the written request of the licensing authority, set up a risk management system designed to identify, characterise, prevent or minimise risks relating to the product.

POC medicinal products: pharmacovigilance requirements

170B.—(1) Where the sale or supply of a POC medicinal product relies on the exemption in regulation 167, the person who sells or supplies the product must maintain a record of the information specified in paragraph (2) from the date that sale or supply first takes place until a date that is at least five years from the date on which supply of the product is discontinued.

(2) The following information is specified for the purpose of paragraph (1)—

(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 product's batch number from which the sale or supply was made, or other product identifier if no batch number is available; 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.

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

(4) The person must submit electronically to the licensing authority—

(a) a report on all serious suspected adverse reactions to the product that occur within 15 days of the day following the day on which the person gained knowledge of the reaction, and

(b) a report on all non-serious suspected adverse reactions to the product that occur in the United Kingdom within 90 days of the day following the day on which the person gained knowledge of the reaction.

(5) The person must ensure that the reports referred to in paragraph (4)—

(a) are in the format and have the content specified in Part 6 of Schedule 12A; and

(b) include the product's batch number, or other product identifier if no batch number is available.

(6) The person must, at the written request of the licensing authority, set up a risk management system designed to identify, characterise, prevent or minimise risks relating to the product.".

Amendment of regulation 171

24. Before regulation 171(1) (exempt advanced therapy medicinal products)(**16**) insert—

"(A1) This regulation does not apply to an MM medicinal product or a POC medicinal product.".

Amendment of regulation 175

25.—(1) Regulation 175 (offences relating to exceptions)(**17**) is amended as follows.

(2) In paragraph (3)—

(a) in sub-paragraph (a), replace "or 170(1) (records in connection with special medicinal products etc)" with ", 170(1) (records in connection with special medicinal products etc), 170A(1) (MM medicinal products: pharmacovigilance requirements), or 170B(1) (POC medicinal products: pharmacovigilance requirements)";

(b) in sub-paragraph (b), replace "or 170(2)" with ", 170(2), 170A(3) or 170B(3)"; and

(c) in sub-paragraph (c), after "170(3)" insert ", 170A(4) or 170B(4)".

Amendment of regulation 178

26. In regulation 178(e) (general obligations of the licensing authority), replace "(including name and batch number)" with ", MM medicinal product and POC medicinal product (including name and batch number or other product identifier if no batch number is available)".

Amendment of regulation 188

27.—(1) Regulation 188 (recording obligations on holders)(**18**) is amended as follows.

(2) In paragraph (1)—

(a) at the beginning insert "Subject to paragraphs (1B) and (1C),"; and

(b) after sub-paragraph (c) insert—

(**16**) Regulation 171 was amended but none is relevant.
(**17**) Regulation 175 was amended by S.I. 2022/352.
(**18**) Regulation 188(1) was amended by S.I. 2019/775 and 2021/1452. Paragraph (1A) was inserted by S.I. 2019/775. There are other amendments but none is relevant.

"(ca) in the case of an MM medicinal product or a POC medicinal product, ensure that all appropriate measures are taken to identify the product by batch number, or other product identifier if no batch number is available;".

(3) In paragraph (1A)—

(a) at the beginning insert "Subject to paragraphs (1B) and (1C),"; and

(b) after sub-paragraph (b) insert—

"(ba) in the case of an MM medicinal product or a POC medicinal product, ensure that all appropriate measures are taken to identify the product by batch number, or other product identifier if no batch number is available; ".

(4) After paragraph (1A) insert—

"(1B) In the case of an MM medicinal product, the periods of 15 and 90 days referred to in in paragraphs (1) and (1A) begin on the day following the day on which the holder of the marketing authorisation gained knowledge of the reaction.

(1C) In the case of a POC medicinal product, the periods of 15 and 90 days referred to in paragraphs (1) and (1A) begin on the day following the day on which the holder of the marketing authorisation gained knowledge of the reaction.".

Amendment of regulation 202A

28. After regulation 202A(2)(c) (licensing authority power in relation to medicinal products subject to additional monitoring)(**19**) insert—

"(d) any MM medicinal product;

(e) any POC medicinal product.".

Amendment of regulation 257

29. After regulation 257(9) (packaging requirements: general)(**20**) insert—

"(10) Nothing in this regulation applies to a POC medicinal product that is the subject of a UKMA(UK)(Category 1).".

Amendment of regulation 257C

30. After regulation 257C(4) (packaging requirements: advance therapy medicinal products)(**21**) insert—

"(5) Nothing in this regulation applies to an advanced therapy medicinal product that is a POC medicinal product, if the entirety of the product is to be administered immediately after manufacture.".

Insertion of new regulation 257CA (packaging requirements: POC medicinal products)

31. After regulation 257C (packaging requirements: advanced therapy medicinal products) insert—

(**19**) Regulation 202A was inserted by S.I. 2019/775.
(**20**) Regulation 257(9) was inserted by S.I. 2024/832.
(**21**) Regulation 257C was inserted by S.I. 2019/775.

"**Packaging requirements: POC medicinal products**

257CA.—(1) This regulation applies to a POC medicinal product that is the subject of a UKMA(UK)(Category 1) and not—

(a) an advanced therapy medicinal product; and

(b) to be administered in its entirety immediately after manufacture.

(2) The information specified in Part 6 of Schedule 24 must appear—

(a) on the outer packaging of a POC medicinal product to which this regulation applies; and

(b) on the immediate packaging of that product, unless paragraph (3) or (4) applies to the packaging.

(3) This paragraph applies to the immediate packaging if the packaging is in the form of a blister pack and is placed in outer packaging which complies with the requirements of Part 6 of Schedule 24.

(4) This paragraph applies to the immediate packaging if the packaging is too small to display the information required by Part 6 of Schedule 24.

(5) The information specified in Part 7 of Schedule 24 must appear on the immediate packaging to which paragraph (3) or (4) applies.".

Amendment of regulation 258

32. After regulation 258(8) (packaging requirements: specific provisions) insert—

"(9) Nothing in this regulation or Schedule 25 applies to a POC medicinal product.".

Amendment of regulation 346

33.—(1) Regulation 346 (review)(**22**) is amended as follows.

(2) In paragraph (2)(c)—

(a) before paragraph (i) insert—

"(ai) 17A,

(bi) 17B,";

(b) after paragraph (ii) insert—

"(iiza) 27A,

(iizb) 29A,

(iizc) 29B";

(c) after paragraph (iii) insert—

"(iiiza) 37A,

(iiizb) 37B,";

(d) after paragraph (v) insert—

"(va) 50K,";

(e) after paragraph (xiva) insert—

"(xivb) 74A,

(xivc) 74B,";

(**22**) Regulation 346 was amended by S.I. [to follow].

(f) after paragraph (xxviiiaza) insert—

"(xxviiiazb) 170A,

(xxviiiazc) 170B,"; and

(g) after paragraph (xxviiij) insert—

"(xxviiik) 257CA,".

Amendment of Schedule 3

34.—(1) Schedule 3 (applications for licences under Part 3)(**23**) is amended as follows.

(2) In paragraph 1(2)—

(a) in sub-paragraph (c), at the beginning insert "except where the operations will relate to an MM medicinal product or a POC medicinal product,";

(b) after sub-paragraph (c) insert—

"(ca) where the application relates to an MM medicinal product, the address of the MM control site;

(cb) where the application relates to a POC medicinal product, the address of the POC control site;"; and

(c) in sub-paragraph (d), after "paragraph (c)" insert ", (ca) or (cb)".

(3) In paragraph 1(3), after sub-paragraph (b) insert—

"(ba) a statement of whether any of the medicinal products to be manufactured or assembled are MM medicinal products or POC medicinal products;".

(4) After paragraph 1 insert—

"**Manufacturer's licences (MM)**

1A.—(1) This paragraph applies to an application for a manufacturer's licence relating to MM medicinal products.

(2) In addition to the requirements in paragraph 1, the application must be accompanied by a dossier for each MM medicinal product to which the application relates, which includes, as a minimum, the following—

(a) a description and means of identification of each modular unit at which manufacture or assembly of the MM medicinal product is to take place;

(b) the location of each unit at which manufacturing or assembly of the MM medicinal product is to take place;

(c) the location of each site at which operations related to the manufacture or assembly of the MM medicinal product are to take place;

(d) a description of the process by which the licence holder will approve new modular units;

(e) a description of the processes by which the licence holder will initiate, suspend and cease manufacturing or assembly of the product at a modular unit;

(f) a description of the manufacturing, assembly and product release processes to take place at each modular unit;

(g) a description of the arrangements for supervision and control by the licence holder of the manufacture or assembly operations at each modular unit;

(**23**) There are amendments but none is relevant.

(h) a description of the arrangements for reporting of suspected adverse reactions from modular units to the MM control site;

(i) the name and contact details of the person at the MM control site who is to be contacted in respect of manufacturing or assembly operations under the licence;

(j) the name and contact details of the person to be contacted in respect of manufacturing or assembly operations at each modular unit;

(k) the name and contact details of the person at the MM control site who is to be contacted in respect of quality operations under the licence;

(l) the name and contact details of the person to be contacted in respect of quality operations at each modular unit; and

(m) a description of the processes by which the licence holder will review and amend the MM master file for the product.

Manufacturer's licence (POC)

1B.—(1) This paragraph applies to an application for a manufacturer's licence relating to POC medicinal products.

(2) In addition to the requirements in paragraph 1, the application must be accompanied by a dossier for each POC medicinal product to which the application relates, which includes, as a minimum, the following—

(a) the location of each site at which manufacturing or assembly of the POC medicinal product is to take place;

(b) the location of each site at which operations related to the manufacture or assembly of the POC medicinal product are to take place;

(c) a description of the process by which the licence holder will approve new POC sites;

(d) a description of the processes by which the licence holder will suspend and cease manufacturing or assembly of the POC medicinal product at a POC site;

(e) a description of the manufacturing, assembly and product release processes to take place at each POC site;

(f) a description of the arrangements for supervision and control by the licence holder of the manufacture or assembly operations at each POC site;

(g) a description of the arrangements for reporting of suspected adverse reactions from POC sites to the POC control site;

(h) the name and contact details of the person at the POC control site who is to be contacted in respect of manufacturing or assembly operations under the licence;

(i) the name and contact details of the person to be contacted in respect of manufacturing or assembly operations at each POC site;

(j) the name and contact details of the person at the POC control site who is to be contacted in respect of quality operations under the licence;

(k) the name and contact details of the person who is to be contacted in respect of quality operations at each POC site; and

(l) a description of the processes by which the licence holder will review and amend the POC master file for the product.".

Amendment of Schedule 4

35. In Schedule 4 (standard provisions of licences under Part 3), after paragraph 14B(**24**) insert—

"**Part 1A Manufacturer's licence (MM)**

14C. The provisions of paragraphs 14D to 14K are incorporated as additional standard provisions of a manufacturer's licence (MM).

14D. The licence holder must maintain an MM master file for each MM medicinal product specified in the licence.

14E. An MM master file may relate to one MM medicinal product only.

14F. An MM master file must contain, as a minimum, the following information—

(a) the information specified in paragraph 1A(2) of Schedule 3; and

(b) the location and identification of any modular unit at which manufacturing or assembly of the MM medicinal product has commenced, has been suspended or has ceased, the date on which manufacturing or assembly commenced or ceased, and the dates on which it was suspended.

14G. The licence holder must ensure that the information contained in the MM master file is kept up to date, and consistent with any UK marketing authorisation for the product, at all times.

14H. The licence holder must make the MM master file available to the licensing authority at all times on request.

14I. The licence holder must submit to the licensing authority, at annual intervals, an update of any changes to the MM master file made in the previous 12 month period, the first update being required to be submitted no later than the date that is 12 months from the date on which the manufacturer's licence (MM) was granted.

14J. The licence holder must keep under review the arrangements for supervision and control of the manufacture or assembly operations at each modular unit and, if the arrangements are found to be inadequate, ensure that appropriate remedial action is taken as soon as reasonably practicable.

14K.—(1) The licence holder must record all suspected adverse reactions to the MM medicinal product which are brought to the licence holder's attention.

(2) The licence holder must not refuse to consider reports of suspected adverse reactions to the product received electronically or by any other appropriate means from patients or from health care professionals.

(3) The licence holder must report suspected adverse reactions identified under sub-paragraph (1) to the holder of the UK marketing authorisation, or the EAMS scientific opinion holder (as applicable), relating to the MM medicinal product as soon as reasonably practicable after the licence holder gains knowledge of the reaction.

Part 1B Manufacturer's Licence (POC)

14L. The provisions of paragraphs 14M to 14T are incorporated as additional standard provisions of a manufacturer's licence (POC).

14M. The licence holder must maintain a POC master file for each POC medicinal product specified in the licence.

(**24**) Paragraph 14A of Part 1 was inserted by S.I. 2019/775 and paragraph 14B was inserted by S.I. 2022/352.

14N. A POC master file may relate to one POC medicinal product only.

14O. A POC master file must contain, as a minimum, the following information:

(a) the information specified in paragraph 1B(2) of Schedule 3; and

(b) the location of any POC sites at which manufacturing or assembly of the POC medicinal product has commenced, has been suspended or has ceased, the date on which manufacturing or assembly commenced or ceased, and the dates on which it was suspended.

14P. The licence holder must ensure that the information contained in the POC master file is kept up to date, and consistent with any UK marketing authorisation for the product, at all times.

14Q. The licence holder must make the POC master file available to the licensing authority at all times on request.

14R. The licence holder must submit to the licensing authority, at annual intervals, an update of any changes to the POC master file made in the previous 12 month period, the first update being required to be submitted no later than the date that is 12 months from the date on which the manufacturer's licence (POC) was granted.

14S. The licence holder must keep under review the arrangements for supervision and control of the manufacture or assembly operations at each POC site and, if the arrangements are found to be inadequate, ensure that appropriate remedial action is taken as soon as reasonably practicable.

14T.—(1) The licence holder must record all suspected adverse reactions to the POC medicinal product which are brought to the licence holder's attention.

(2) The licence holder must not refuse to consider reports of suspected adverse reactions to the product received electronically or by any other appropriate means from patients or from health care professionals.

(3) The licence holder must report suspected adverse reactions identified under sub-paragraph (1) to the holder of any UK marketing authorisation, or the EAMS scientific opinion holder (as applicable), relating to the POC medicinal product as soon as reasonably practicable after the licence holder gains knowledge of the reaction.".

Amendment of Schedule 7

36. In Schedule 7 (qualified persons)(**25**), after paragraph 12A insert—

"**12B.** In the case of an MM medicinal product or a POC medicinal product, the obligations in paragraphs 12(1)(a) and 12A(1)(a) may be satisfied by securing that each product has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation relating to the product.".

Amendment of Schedule 8

37.—(1) Schedule 8 (material to accompany an application for a UK marketing authorisation)(**26**) is amended as follows.

(2) In paragraph 9A, at the beginning insert "Except in the case of an active substance that contains human cells or tissues, or that is part of a medicinal product which is (or is in a form which means a dose or part of it is) to be administered immediately after manufacture,".

(3) For paragraph 16 substitute the following—

(**25**) Paragraph 12A was inserted by S.I. 2019/775. There are other amendments but none is relevant.
(**26**) Paragraph 9A was inserted by S.I. 2013/1855. There are other amendments but none is relevant.

"**16.**—(1) Subject to sub-paragraph (2), a mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.

(2) Sub-paragraph (1)(a) and (b) does not apply to an application for a marketing authorisation for a POC medicinal product which is (or is in a form which means a dose or part of it is) to be administered immediately after manufacture.".

Amendment of Schedule 24

38. In Schedule 24 (packaging information requirements)(**27**), after Part 5 insert—

"**Part 6 Outer and Immediate Packaging: POC Medicinal Products for sale or supply in Great Britain only**

54. The name of the medicinal product.

55. The strength and pharmaceutical form of the product.

56. Where appropriate, whether the product is intended for babies, children or adults.

57. The expiry date, including the year and month and, if applicable, the day or time in hours and minutes.

58. Where the product contains up to three active substances, the common name of each active substance.

59. A statement of the active substances in the product, expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names.

60. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.

61. A list of—

(a) where the product is injectable or is a topical or eye preparation, all excipients; or

(b) in any other case, those excipients known to have a recognised action or effect and included in the guidance published under regulation 257D that is applicable to such products.

62. The method of administration of the product and if necessary the route of administration.

63. Where appropriate, space for the prescribed dose to be indicated.

64. A warning that the product must be stored out of the reach and sight of children.

65. Any special warning applicable to the product.

66. Any special precautions relating to the disposal of an unused product or part of a product, or waste derived from the product, and reference to any appropriate collection system in place.

67. The name and address of the holder of the UK marketing authorisation relating to the product and, where applicable, the name of the holder's representative.

68. The number of the UK marketing authorisation for placing the product on the market.

(**27**) Part 5 of Schedule 24 was inserted by S.I. 2019/775.

69. The manufacturer's batch number or other product identifier.

70. The patient's name and unique patient identifier.

Part 7 Immediate Packaging: Blister Packs and Small Packaging (POC Medicinal Products for sale or supply in Great Britain only)

71. The name of the medicinal product.

72. The strength and pharmaceutical form of the product.

73. Where appropriate, whether the product is intended for babies, children or adults.

74. The expiry date, including the year and month and, if applicable, the day or time in hours and minutes.

75. Where the product contains up to three active substances, the common name of each active substance.

76. The method of administration of the product and if necessary the route of administration.

77. The name of the holder of the UK marketing authorisation relating to the product.

78. The manufacturer's batch number or other product identifier.

79. The contents of the packaging by weight, by volume or by unit.

80. The patient's name and unique patient identifier.".

PART 3

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

Amendment of regulation 2

39. In regulation 2(1) (interpretation)(**28**), at the appropriate places insert—

""manufacturer's licence (MM)" has the meaning given in regulation 8(1) of the 2012 Regulations;";

""manufacturer's licence (POC)" has the meaning given in regulation 8(1) of the 2012 Regulations; ";

""manufacturing authorisation (MM)" means a manufacturing authorisation that authorises the manufacture or assembly of MM investigational medicinal products;";

""manufacturing authorisation (POC)" means a manufacturing authorisation that authorises the manufacture or assembly of POC investigational medicinal products;";

""MM" means modular manufacture;";

""MM (IMP) control site" means the premises at which the holder of a manufacturing authorisation (MM) supervises and controls the manufacture or assembly of MM investigational medicinal products;";

""MM (IMP) master file" means a detailed description of the arrangements for manufacture or assembly of an MM investigational medicinal product;";

(**28**) Amended by S.I. 2019/744. There are other amendments but none is relevant.

""MM investigational medicinal product" means an investigational medicinal product that, for reasons relating to deployment, the licensing authority determines it necessary or expedient to be manufactured or assembled in a modular unit;";

""modular unit" means a relocatable manufacturing unit;";

""POC" means point of care;";

""POC (IMP) control site" means the premises at which the holder of a manufacturing authorisation (POC) supervises and controls the manufacture or assembly of POC investigational medicinal products;";

""POC (IMP) master file" means a detailed description of the arrangements for the manufacture or assembly of a POC investigational medicinal product;";

""POC (IMP) site" means a site at which the manufacture or assembly of a POC investigational medicinal product takes place;";

""POC investigational medicinal product" means an investigational medicinal product that, for reasons relating to method of manufacture, shelf life, constituents or method or route of administration, can only be manufactured at or near the place where the product is to be used or administered;".

Amendment of regulation 13

40.—(1) Regulation 13 (supply of investigational medicinal products for the purpose of clinical trials)(**29**) is amended as follows.

(2) In paragraph (2)(b)(i), after "United Kingdom" insert "except for an MM investigational medicinal product or a POC investigational medicinal product".

(3) After paragraph (2)(b)(i) insert—

"(ia) an MM investigational medicinal product manufactured or assembled in the United Kingdom, the product has been manufactured or assembled in accordance with the terms of a manufacturing authorisation (MM) or assembled under the exemption in regulation 37;

(ib) a POC investigational medicinal product manufactured or assembled in the United Kingdom, the product has been manufactured or assembled in accordance with the terms of a manufacturing authorisation (POC) or assembled under the exemption in regulation 37;".

Amendment of regulation 36

41.—(1) Regulation 36 (requirement for authorisation to manufacture or import investigational medicinal products)(**30**) is amended as follows.

(2) In paragraph (1), after "an authorisation" insert "of the appropriate type".

(3) After paragraph (1) insert—

"(1A) For the purposes of paragraph (1), the appropriate type of authorisation is an authorisation that relates to whichever, or whichever combination, of the following that is appropriate—

(a) manufacture or assembly of investigational medicinal products, except for MM investigational medicinal products and POC investigational medicinal products;

(b) import of investigational medicinal products, except for MM investigational medicinal products and POC investigational medicinal products;

(c) manufacture or assembly of MM investigational medicinal products;

(**29**) Paragraph (2)(b) was substituted by S.I. 2019/775. There are other amendments but none is relevant.
(**30**) There are amendments but none is relevant.

(d) manufacture or assembly of POC investigational medicinal products.".

(4) After paragraph (2) insert—

"(3) Regulation 36A sets out additional requirements in relation to the manufacture and assembly of MM investigational medicinal products.

(4) Regulation 36B sets out additional requirements in relation to the manufacture and assembly of POC investigational medicinal products.".

Insertion of new regulations 36A and 36B (manufacture of MM and POC investigational medicinal products)

42. After regulation 36 (requirement for authorisation to manufacture or import investigational medicinal products) insert—

"**Manufacture of MM investigational medicinal products**

36A.—(1) No person shall manufacture or assemble an MM investigational medicinal product unless—

(a) the activity and product type is specified in a manufacturing authorisation (MM); and

(b) there is an MM (IMP) master file relating to the product and the product is manufactured and assembled in accordance with that master file.

(2) Paragraph (1) does not apply to the manufacture or assembly of an MM investigational medicinal product to the extent that the manufacture or assembly is in accordance with the terms and conditions of a UK marketing authorisation or a marketing authorisation issued by the competent authority of an EEA State in accordance with Directive 2001/83/EC relating to that product.

Manufacture of POC investigational medicinal products

36B.—(1) No person shall manufacture or assemble a POC investigational medicinal product unless—

(a) the activity and product type is specified in a manufacturing authorisation (POC); and

(b) there is a POC (IMP) master file relating to the product and the product is manufactured and assembled in accordance with that master file.

(2) Paragraph (1) does not apply to the manufacture or assembly of a POC investigational medicinal product to the extent that the manufacture or assembly is in accordance with the terms and conditions of a UK marketing authorisation or a marketing authorisation issued by the competent authority of an EEA State in accordance with Directive 2001/83/EC relating to that product.".

Amendment of regulation 39

43. After regulation 39(4) (consideration of application for manufacturing authorisation) insert—

"(4A) If the application for a manufacturing authorisation relates (wholly or partially) to an MM investigational medicinal product, the licensing authority shall take into consideration the arrangements for—

(a) supervising and controlling operations at a modular unit specified in the application; and

(b) ensuring that manufacture or assembly is under appropriate control so that the MM investigational medicinal product consistently meets the requirements in the MM (IMP) master file when manufactured at that modular unit.

(4B) If the application for a manufacturing authorisation relates (wholly or partially) to a POC investigational medicinal product, the licensing authority shall take into consideration the arrangements for—

(a) supervising and controlling operations at any POC (IMP) site specified in the application; and

(b) ensuring that manufacture or assembly is under appropriate control so that the POC investigational medicinal product consistently meets the requirements in the POC (IMP) master file when manufactured at that site.".

Amendment of regulation 41

44. In regulation 41(c) (application and effect of manufacturing authorisation), before "the premises," insert "except in the case of an MM investigational medicinal product or a POC investigational medicinal product,".

Amendment of regulation 44

45. After regulation 44(8) (variation of manufacturing authorisation)(**31**) insert—

"(9) In the case of an application of a type specified in paragraph (11), the information to be provided under sub-paragraph (d) in the definition of "valid application" in paragraph (8) shall include the information specified in paragraph 10 of Schedule 6.

(10) In the case of an application of a type specified in paragraph (12), the information to be provided under sub-paragraph (d) in the definition of "valid application" in paragraph (8) shall include the information specified in paragraph 11 of Schedule 6.

(11) The following types of application are specified for the purpose of paragraph (9)—

(a) an application to vary the licence so that it relates to the manufacture or assembly of MM investigational medicinal products;

(b) an application to vary a manufacturing authorisation (MM) to add a new MM investigational medicinal product.

(12) The following types of application are specified for the purpose of paragraph (10)—

(a) an application to vary the licence so that it relates to the manufacture or assembly of POC investigational medicinal products;

(b) an application to vary a manufacturing authorisation (POC) to add a new POC investigational medicinal product.

(13) In dealing with an application of a type specified in paragraph (11), the licensing authority shall take into consideration the arrangements made or to be made for—

(a) supervising and controlling operations at a modular unit; and

(b) ensuring that manufacturing or assembly is under appropriate control so that the MM investigational medicinal product consistently satisfies the requirements in the MM (IMP) master file when manufactured at a modular unit.

(14) In dealing with an application of a type specified in paragraph (12), the licensing authority shall take into consideration the arrangements made or to be made for—

(**31**) Regulation 44(8) was substituted by S.I. 2006/1928.

(a) supervision and controlling operations at a POC (IMP) site specified in the application; and

(b) ensuring that manufacturing or assembly is under appropriate control so that the POC investigational medicinal product consistently satisfies the requirements in the POC (IMP) master file when manufactured at that POC (IMP) site.".

Insertion of new regulations 44A and 44B (variation of master files)

46. After regulation 44 (variation of manufacturing authorisation) insert—

"**Variation of MM (IMP) master file**

44A. Subject to regulation 45(5), the holder of a manufacturing authorisation (MM) may amend the information in the MM (IMP) master file provided in accordance with paragraph 10(a), (c) and (h) to (k) of Schedule 6 and paragraph 14E(a) of Schedule 7 without applying to the licensing authority for a variation under regulation 44.

Variation of POC (IMP) master file

44B. Subject to regulation 45(6), the holder of a manufacturing authorisation (POC) may amend the information in the POC (IMP) master file provided in accordance with paragraph 11(a), (b) and (g) to (i) of Schedule 6 and paragraph 14M(a) of Schedule 7 without applying to the licensing authority for a variation under regulation 44.".

Amendment of regulation 45

47.—(1) Regulation 45 (suspension and revocation of manufacturing authorisation)(**32**) is amended as follows.

(2) In paragraph (2)—

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

(b) after sub-paragraph (b) insert—

"(c) in the case of a manufacturing authorisation (MM), limited to modular units specified in an MM (IMP) master file associated with the authorisation; or

(d) in the case of a manufacturing authorisation (POC), limited to POC (IMP) sites specified in a POC (IMP) master file associated with the authorisation.".

(3) After paragraph (4) insert—

"(5) If the licensing authority suspends or revokes a manufacturing authorisation (MM) in accordance with paragraph (2)(c) so that manufacturing or assembly is suspended, or no longer authorised, at a modular unit, the holder of the authorisation may not approve that unit for the purpose of manufacturing or assembly of the MM investigational medicinal product other than by way of an application under regulation 44.

(6) If the licensing authority suspends or revokes a manufacturing authorisation (POC) in accordance with paragraph (2)(d) so that manufacturing or assembly is suspended, or no longer authorised, at a POC (IMP) site, the holder of the authorisation may not approve that site for the purpose of manufacturing or assembly of the POC investigational medicinal product other than by way of an application under regulation 44.".

(**32**) There are amendments but none is relevant.

Amendment of regulation 46

48. After regulation 46(2) (labelling of investigational medicinal products)(**33**) insert—

"(3) Paragraph (1) does not apply to a POC investigational medicinal product that is to be administered in its entirety immediately after manufacture.".

Amendment of regulation 48

49. In regulation 48(4) (infringement notices)(**34**), for "31A and 32 to 35" substitute "31A, 32 to 35, 36A and 36B".

Amendment of regulation 49

50. In regulation 49(1) (offences)(**35**), after sub-paragraph (k) insert—

"(ka) regulation 36A;

(kb) regulation 36B;".

Amendment of Schedule 6

51.—(1) Schedule 6 (particulars that must accompany an application for a manufacturing authorisation)(**36**) is amended as follows.

(2) In paragraph 2, after "forms" insert "and whether any of them is an MM investigational medicinal product or a POC investigational medicinal product".

(3) In paragraph 3—

(a) in sub-paragraph (a), after "products" insert ", including specifically MM investigational medicinal products or POC investigational medicinal products";

(b) in sub-paragraph (b), after "products" insert ", including specifically MM investigational medicinal products or POC investigational medicinal products"; and

(c) in sub-paragraph (c), after "products" insert "except for MM investigational medicinal products and POC investigational medicinal products".

(4) In paragraph 4—

(a) in sub-paragraph (1), at the beginning insert "Except where the application relates to an MM investigational medicinal product or a POC investigational medicinal product,";

(b) after sub-paragraph (1) insert—

"(1A) Where the application relates to an MM investigational medicinal product, the address of the MM (IMP) control site and the location of any testing associated with manufacture or assembly that is, or is to be, carried out.

(1B) Where the application relates to a POC investigational medicinal product, the address of the POC (IMP) control site and the location of any testing associated with manufacture or assembly that is, or is to be, carried out.";

(c) after sub-paragraph (2) insert—

"(2A) Where the application relates to an MM investigational medicinal product, the address of each of the premises other than the MM (IMP) control site where the proposed holder of the manufacturing authorisation (MM) proposes to store components or equipment to be used in the manufacturing process.

(**33**) There are amendments but none is relevant.
(**34**) Regulation 48 has been amended by S.I. 2006/1928. There are other amendments but none is relevant.
(**35**) Regulation 49 has been amended by S.I. 2006/1928. There are other amendments but none is relevant.
(**36**) Paragraph 2 was substituted by S.I. 2006/1928. There are other amendments but none is relevant.

(2B) Where the application relates to a POC investigational medicinal product, the address of each of the premises other than the POC (IMP) control site where the proposed holder of the manufacturing authorisation (POC) proposes to store components or equipment to be used in the manufacturing process.”; and

(d) in sub-paragraphs (3), (4) and (5), for “(1) and (2)” substitute “(1) to (2B) (as applicable)”.

(5) After paragraph 9 insert—

“**10.** Where the application relates to an MM investigational medicinal product, the application for each product must be accompanied by a dossier which includes, as a minimum, the following:

(a) a description and means of identification of each modular unit at which manufacture or assembly of the MM investigational medicinal product is to take place;

(b) the location of each unit at which manufacturing or assembly of the MM investigational medicinal product is to take place;

(c) the location of each site at which operations related to the manufacture or assembly of the MM investigational medicinal product are to take place;

(d) a description of the process by which the proposed holder of the authorisation will approve new modular units;

(e) a description of the processes by which the proposed holder of the authorisation will initiate, suspend and cease manufacturing or assembly of the product at a modular unit;

(f) a description of the manufacturing, assembly and product release processes to take place at each modular unit;

(g) a description of the arrangements for supervision and control by the proposed holder of the authorisation of the manufacture or assembly operations at each modular unit;

(h) a description of the arrangements for reporting of suspected adverse reactions from modular units to the MM (IMP) control site;

(i) the name and contact details of the person at the MM (IMP) control site who is to be contacted in respect of manufacturing or assembly operations under the authorisation;

(j) the name and contact details of the person to be contacted in respect of manufacturing or assembly operations at each modular unit;

(k) the name and contact details of the person at the MM (IMP) control site who is to be contacted in respect of quality operations under the authorisation;

(l) the name and contact details of the person to be contacted in respect of quality operations at each modular unit; and

(m) a description of the processes by which the proposed holder of the authorisation will review and amend the MM (IMP) master file for the product.

11. Where the application relates to a POC investigational medicinal product, the application for each product must be accompanied by a dossier which includes, as a minimum, the following:

(a) the location of each site at which manufacturing or assembly of the POC investigational medicinal product is to take place;

(b) the location of each site at which operations related to the manufacture or assembly of the POC investigational medicinal product are to take place;

(c) a description of the process by which the proposed holder of the authorisation will approve new POC (IMP) sites;

(d) a description of the processes by which the proposed holder of the authorisation will suspend and cease manufacturing or assembly of the POC investigational medicinal product at a POC (IMP) site;

(e) a description of the manufacturing, assembly and product release processes to take place at each POC (IMP) site;

(f) a description of the arrangements for supervision and control by the proposed holder of the authorisation of the manufacture or assembly operations at each POC (IMP) site;

(g) a description of the arrangements for reporting of suspected adverse reactions from POC (IMP) sites to the POC (IMP) control site;

(h) the name and contact details of the person at the POC (IMP) control site who is to be contacted in respect of manufacturing or assembly operations under the authorisation;

(i) the name and contact details of the person to be contacted in respect of manufacturing or assembly operations at each POC (IMP) site;

(j) the name and contact details of the person at the POC (IMP) control site who is to be contacted in respect of quality operations under the authorisation;

(k) the name and contact details of the person to be contacted in respect of quality operations at each POC (IMP) site; and

(l) a description of the processes by which the proposed holder of the authorisation will review and amend the POC (IMP) master file for the product.".

Amendment of Schedule 7

52.—(1) Part 2 of Schedule 7 (standard provisions for manufacturing authorisation) (**37**) is amended as follows.

(2) In paragraph 1—

(a) for sub-paragraph (a) substitute the following—

"(a) provide and maintain such staff, premises and plant (including technical equipment) as are necessary for the carrying out of such stages of the manufacture and assembly of the investigational medicinal products or EAMs medicinal products as are undertaken by the holder, in accordance with the following—

(i) the holder's authorisation;

(ii) the product specification;

(iii) the MM (IMP) master file, in the case of an MM investigational medicinal product; and

(iv) the POC (IMP) master file, in the case of a POC investigational medicinal product; " and

(b) in sub-paragraph (b), at the beginning insert "except in the case of an MM investigational medicinal product and a POC investigational medicinal product,".

(3) In paragraph 2(b), after "authorisation" insert "or, in the case of an MM investigational medicinal product, the MM (IMP) master file and in the case of a POC investigational medicinal product, the POC (IMP) master file,".

(4) After paragraph 2 insert—

"**2A.** The holder of a manufacturing authorisation (MM) shall not use premises other than the MM (IMP) control site and the modular units specified in the MM (IMP) master file for the purposes specified in paragraph 2(a).

(**37**) Paragraphs 1 and 2 were amended by S.I. 2022/352. There are other amendments but none is relevant.

2B. The holder of a manufacturing authorisation (POC) shall not use premises other than the POC (IMP) control site and the sites specified in the POC (IMP) master file for the purposes specified in paragraph 2(a).".

(5) In paragraph 6(a), at the beginning insert "except in the case of an MM investigational medicinal product or a POC investigational medicinal product,".

(6) After paragraph 6 insert—

"**6A.** The holder of the authorisation shall inform the licensing authority before making a material alteration to the premises or plant used at the MM (IMP) control site or to any modular unit specified in the MM (IMP) master file, or to the operations for which they are used.

6B. The holder of the authorisation shall inform the licensing authority before making a material alteration to the premises or plant used at the POC (IMP) control site, or to the operations for which they are used.".

(7) After paragraph 14A insert—

"**Part 2A Manufacturing authorisation (MM)**

14B. The provisions of paragraphs 14C to 14I are incorporated as additional standard provisions of a manufacturing authorisation (MM).

14C. The holder of the authorisation shall maintain and make available on request of the licensing authority an MM (IMP) master file for each MM investigational medicinal product to which the authorisation relates.

14D. Each master file may relate to one MM investigational medicinal product only.

14E. An MM (IMP) master file shall contain, as a minimum, the following information:

(a) the information specified in paragraph 10 of Schedule 6; and

(b) the location of any modular units at which manufacturing or assembly of the MM investigational medicinal product has commenced, has been suspended or has ceased, and the date on which manufacturing or assembly commenced, the dates on which it is suspended, or the date from which it has ceased.

14F. The holder of the authorisation shall ensure that the information in the MM (IMP) master file is kept up to date at all times.

14G. The holder of the authorisation shall submit to the licensing authority at annual intervals an update of any changes to the MM (IMP) master file made in the previous 12 month period, the first update being required to be submitted no later than the date that is 12 months from the date on which the manufacturing authorisation (MM) was granted.

14H. The holder of the authorisation shall conduct regular reviews of the arrangements for supervision and control of the manufacture or assembly operations at each modular unit and ensure that, where appropriate, remedial action is taken as soon as reasonably practicable.

14I. The holder of a manufacturing authorisation (MM) shall ensure that—

(a) the requirements of paragraphs 1 to 14 and 14C to 14H are complied with in relation to manufacturing carried out at the modular units specified in the MM (IMP) master file;

(b) only the MM investigational medicinal products specified in the MM (IMP) master file are manufactured or assembled at those modular units; and

(c) an MM investigational medicinal product specified in the MM (IMP) master file is only manufactured on premises specified in the MM (IMP) master file.

Part 2B manufacturing authorisation (POC)

14J. The provisions of paragraphs 14K to 14Q are incorporated as additional standard provisions of a manufacturing authorisation (POC).

14K. The holder of the authorisation shall maintain and make available on request of the licensing authority a POC (IMP) master file for each POC investigational medicinal product to which the authorisation relates.

14L. Each master file may relate to one POC investigational medicinal product only.

14M. A POC (IMP) master file shall contain, as a minimum, the following information:

(a) the information specified in paragraph 11 of Schedule 6; and

(b) the location of any POC (IMP) sites at which manufacturing or assembly of the POC investigational medicinal product has commenced, has been suspended or has ceased, and the date on which manufacturing or assembly commenced, the dates on which it is suspended, or the date from which it has ceased.

14N. The holder of the authorisation shall ensure that the information in the POC (IMP) master file is kept up to date at all times.

14O. The holder of the authorisation shall submit to the licensing authority at annual intervals an update of any changes to the POC (IMP) master file made in the previous 12 month period, the first update being required to be submitted no later than the date that is 12 months from the date on which the manufacturing authorisation (POC) was granted.

14P. The holder of the authorisation shall conduct regular reviews of the arrangements for supervision and control of the manufacture or assembly operations at each POC (IMP) site and ensure that, where appropriate, remedial action is taken as soon as reasonably practicable.

14Q. The holder of a manufacturing authorisation (POC) shall ensure that—

(a) the requirements of paragraphs 1 to 14 and 14K to 14P are complied with in relation to manufacturing carried out at the POC (IMP) sites specified in the POC (IMP) master file;

(b) only the POC investigational medicinal products specified in the authorisation are manufactured or assembled at those sites; and

(c) a POC investigational medicinal product specified in the authorisation is only manufactured at a POC (IMP) site specified in the POC (IMP) master file.”.

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

Name

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 (S.I. 2012/1916) ("HMRs") and the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) ("CTRs"). These Regulations make provision for medicinal products that are manufactured in a modular unit, to enable deployment from that site. This is known as modular manufacture ("MM") and the products are referred to as "MM medicinal products". The Regulations also make provision in relation to the manufacture and supply of medicines that are innovative and have particular characteristics such as a very short shelf life, or that are highly personalised to the recipient. These characteristics mean that the medicines have to be manufactured very close to the place where they are administered. The type of manufacture is known as point of care ("POC") and the products are referred to in the Regulations as "POC medicinal products".

POC medicinal products cannot be manufactured in advance in conventional, factory-based sites and distributed to supply sites from there. They have to be manufactured in small amounts in close proximity to the patient at sites that are likely to be healthcare facilities such as pharmacies, operating theatres and clinics. The number of sites at which a product is manufactured may be comparatively high, and sites may be added or removed depending on circumstances. The regulatory framework that currently applies to medicines manufacturing, whereby each site is named on the licence and individually inspected and authorised, requires adjustment to allow for this new manufacturing structure. These Regulations make the necessary amendments to the HMRs so that the manufacture of POC medicinal products is regulated by way of an authorisation and a master file that relates to the product. Similarly, the current regulatory framework is not appropriate for manufacture in units that may be relocated, so the Regulations make equivalent amendments, where necessary, in relation to modular manufacture.

The amendments in these Regulations comprise firstly of changes to the requirements that apply to manufacturers of MM medicinal products and POC medicinal products. These are set out in regulations 5 to 15 and 34 to 36. There are also some amendments to the process of applying for a marketing authorisation for such a product. These are contained in regulations 16 to 18 and 37. The HMRs provide for certain exemptions from the requirement for a marketing authorisation. Regulations 19 to 25 amend those provisions with regard to MM and POC medicinal products. The HMRs also set out requirements with regard to the post-marketing stage of a medicinal product. Regulations 26 to 28 amend those provisions. And regulations 29 to 32 and 38 make provision with regard to the labelling and packaging of POC medicinal products.

Regulations 39 to 52 make equivalent amendments to the CTRs.

An impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published alongside this instrument at www.legislation.gov.uk.