SCHEDULES

SCHEDULE 1

Regulation 3

Amendment of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

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1. In regulation 3 (amendment of regulation 2 (interpretation))—

(a) in paragraph (2), for the substituted definition of " Commission Directive 2003/94/EC " substitute—

""Commission Directive 2003/94/EC", other than in Parts 2 and 3 of Schedule 7, means—

(a) in the case of an investigational medicinal product manufactured or assembled in, or imported into, Great Britain—

(i) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use, as modified by Schedule 2A to the 2012 Regulations, or

(ii) if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations, and have come into force, those Regulations;

(b) in the case of an investigational medicinal product manufactured or assembled in, or imported into, Northern Ireland, Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use;";

(b) in paragraph (6), for the substituted definition of " import " substitute—

""import", except in regulation 13 and Schedule 13, means import, or attempt to import—

(a) into Great Britain other than from Northern Ireland, or

(b) into Northern Ireland from a country other than an EEA State,

whether by land, sea or air and "imported" is to be construed accordingly;;";

(c) omit paragraph (7);

(d) in paragraph (8), for the substituted definition of " marketing authorization " substitute—

""marketing authorization" means—

(a) a UK marketing authorization,

(b) an EU marketing authorisation (as defined in the 2012 Regulations), or

(c) an authorization granted by a regulatory body responsible for licensing medicinal products in a country that is included in the list referred to in regulation 2A(1);";

(e) omit paragraph (9);

(f) in paragraph (11), for the inserted definition of "UK marketing authorization" substitute—

""UK marketing authorization"—

(a) has the same meaning as "UK marketing authorisation" in the 2012 Regulations (and references to "UKMA(UK)", "UKMA(GB)" and "UKMA(NI)" in these Regulations should be construed in accordance with that definition); and

(b) includes a product licence granted by the licensing authority for the purposes of section 7 of the Medicines Act 1968;".

Commencement Information

I1 Sch. 1 para. 1 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

2. In regulation 7 (amendment of regulation 13 (supply of investigational medicinal products for the purpose of clinical trials))—

(a) in paragraph (2), for the inserted sub-paragraph (b), substitute—

"(b) in the case of—

(i) an investigational medicinal product manufactured or assembled in the United Kingdom, the product has been manufactured or assembled—

(aa) in accordance with the terms of a manufacturing authorisation, or

(bb) in the case of assembly only, under the exemption in regulation 37;

(ii) an investigational medicinal product imported into Northern Ireland from an EEA State—

(aa) the product has been manufactured, assembled or imported into an EEA State in accordance with the terms of an authorisation referred to in Article 13 of the Directive granted by a competent authority of an EEA State, and

(bb) the production batch of investigational medicinal products of which the product is a part has been checked and certified by a qualified person pursuant to Article 13(3) and (4) of the Directive;

(iii) an investigational medicinal product imported into Northern Ireland from a country other than an EEA State, the product has been imported into Northern Ireland in accordance with the terms of a manufacturing authorisation;

(iv) an investigational medicinal product imported into Great Britain other than from Northern Ireland, the product has been imported in accordance with the terms of a manufacturing authorisation.";

(b) in paragraph (3), in the inserted paragraph (2A)—

(i) omit "UK";

(ii) after "marketing authorization" insert " or marketing authorisation issued by the competent authority of an EEA State in accordance with Directive 2001/83/EC ";

(c) for paragraph (5) substitute—

"(5) For paragraph (4) substitute—

"(4) The restriction in paragraph (1) shall not apply to—

(a) the sale or supply of a medicinal product in Great Britain in accordance with the terms of a UKMA(GB) or UKMA(UK), and

(b) the sale or supply of a medicinal product in Northern Ireland in accordance with—

(i) the terms of a UKMA(NI) or UKMA(UK), or

(ii) an EU marketing authorisation (as defined in the 2012 Regulations).".".

Commencement Information

I2 Sch. 1 para. 2 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

3. For regulation 17 (amendment of regulation 36 (requirement for authorisation to manufacture or import investigational medicinal products)) substitute—

"**17.** In regulation 36(2), after "marketing authorization" insert " or marketing authorisation issued by the competent authority of an EEA State in accordance with Directive 2001/83/EC ".".

Commencement Information

I3 Sch. 1 para. 3 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

4. For regulation 18 (amendment of regulation 43 (qualified persons)) substitute—

"**18.** In regulation 43—

(a) for paragraphs (1) and (2) substitute—

"(1) Subject to paragraphs (4) and (5), the holder of a manufacturing authorisation must have at his disposal the services of at least one qualified person—

(a) where the manufacturing authorisation relates wholly to the import of an investigational medicinal product into Great Britain from an approved country for import, who must operate and be ordinarily resident in either the United Kingdom or an approved country for import, or

(b) in any other case, who must operate and be ordinarily resident in the United Kingdom, and

who is responsible for carrying out the duties referred to in paragraph 2.

(2) Subject to paragraphs (2A) and (2C), the qualified person is responsible for ensuring that—

(a) in the case of an investigational medicinal product manufactured in Northern Ireland, each production batch has been manufactured and checked in compliance with—

(i) the requirements of these Regulations;

(ii) the principles and guidelines of good manufacturing practice;

(iii) the product specification, as defined in Part 1 of Schedule 7; and

(iv) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(b) in the case of an investigational medicinal product manufactured in Great Britain, each production batch has been manufactured and checked in compliance with—

(i) the requirements of these Regulations;

(ii) the principles and guidelines of good manufacturing practice, as modified by Schedule 2A to the 2012 Regulations or any regulations made under the power in regulation B17(1) of those Regulations;

(iii) the product specification, as defined in Part 1 of Schedule 7; and

(iv) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(c) in the case of an investigational medicinal product imported into Northern Ireland from a country other than an EEA State, each production batch has been manufactured and checked in compliance with—

(i) standards of good manufacturing practice at least equivalent to the principles and guidelines of good manufacturing practice;

(ii) the product specification, as defined in Part 1 of Schedule 7; and

(iii) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(d) in the case of an investigational medicinal product imported into Great Britain other than from Northern Ireland, each production batch has been manufactured and checked in compliance with—

(i) standards of good manufacturing practice at least equivalent to the principles and guidelines of good manufacturing practice, as modified by Schedule 2A to the 2012 Regulations or any regulations made under the power in regulation B17(1) of those Regulations;

(ii) the product specification, as defined in Part 1 of Schedule 7; and

(iii) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used.

(2A) The qualified person is not responsible for carrying out the controls in paragraph (2) where—

(a) the product is imported into Great Britain from a country that is included on the list referred to in regulation 43A ("approved country for import"); and

(b) the qualified person ensures that there is appropriate evidence to confirm that each production batch has been certified as provided for in Article 13 of the Directive, or such equivalent certification procedure as applies in the approved country for import.

(2B) The licensing authority must publish guidance on the evidence that it considers to be appropriate for the purposes of paragraph (2A)(b).

(2C) The qualified person is not responsible for carrying out the controls in paragraph (2) where—

(a) an investigational medicinal product—

(i) which has a marketing authorization other than a UKMA(GB), is imported into Northern Ireland as a comparator product; or

(ii) which has a marketing authorization, or has been approved for marketing in another country, is imported into Great Britain as a comparator product; and

(b) documentation cannot be obtained certifying that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 2003/94/EC.

(2D) Where paragraph (2) does not apply by virtue of paragraph (2C), the qualified person is responsible for ensuring that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the request, particulars and documents submitted to the licensing authority under regulation 17.

(2E) The qualified person is responsible for ensuring, in relation to an investigational medicinal product, that documentary evidence is produced that each batch of the product satisfies the provisions of paragraph (2), (2A) or (2D) (as the case may be).

(2F) The documentary evidence referred to in paragraph (2E) must be—

(a) kept up to date as operations are carried out; and

(b) available for inspection by the licensing authority for a period of at least five years beginning with the date on which the documentary evidence is produced.";

(b) for paragraph (5) substitute—

"(5) For the purposes of this paragraph, but without prejudice to paragraph (6) below, the holder of the authorisation may regard a person as satisfying the provisions of the said Article 49 or 50, as respects formal qualifications if—

(a) in relation to the obligation in paragraph (1)(a), he is already named as a qualified person in respect of an authorisation issued in an approved country for import; or

(b) he produces evidence that—

(i) he is a member of—

(aa) the Institute of Biology,

(bb) the Pharmaceutical Society,

(cc) the Royal Society of Chemistry, or

(dd) such other body as may appear to the licensing authority to be an appropriate body for the purpose of this paragraph; and

(ii) he is regarded by the body of which he is a member as so satisfying those provisions.".".

Commencement Information

I4 Sch. 1 para. 4 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

5. In regulation 19 (insertion of regulation 43A (approved country for import)), in the inserted regulation 43A, for "the United Kingdom" in both places it occurs substitute " Great Britain ".

Commencement Information

I5 Sch. 1 para. 5 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

6. In regulation 20 (amendment of regulation 45 (suspension and revocation of manufacturing authorisation)), for "omit "or any equivalent provisions in any EEA State other than the United Kingdom"." substitute "for "or any equivalent provisions in any EEA State other than the United Kingdom" substitute " or, in the case of an investigational medicinal product manufactured or assembled in Northern Ireland, any equivalent provisions in any EEA State ".".

Commencement Information

I6 Sch. 1 para. 6 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

7. In regulation 23 (insertion of regulation 57 (functions in relation to good clinical practice)), in the inserted regulation 57—

(a) in paragraph (1), after "Regulations may" insert " , in respect of Great Britain ";

(b) for paragraphs (2) and (3) substitute—

"(2) Any power to make regulations under paragraph (1)—

(a) is exercisable by the Secretary of State by statutory instrument;

(b) includes power to make—

(i) different provision for different purposes or different areas;

(ii) consequential, supplementary, incidental, transitional, transitory or saving provisions, including consequential amendments to these Regulations.

(3) Regulations under paragraph (1) are subject to annulment in pursuance of a resolution of either House of Parliament.".

Commencement Information

I7 Sch. 1 para. 7 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

8. In regulation 24 (amendment of Schedule 3 (particulars and documents that must accompany an application for an ethics committee opinion, a request for authorisation, a notice of amendment and a notification of the conclusion of a trial))—

(a) for paragraph (3)(c) substitute—

"(c) in paragraph 7, after "details of any" insert " manufacturing authorisation or any ";";

(b) for paragraph (3)(d)(i) substitute—

"(i) in sub-paragraph (1), after "in accordance with" insert " regulation 43(2) or ";";

(c) for paragraph (3)(d)(ii) substitute—

"(ii) for sub-paragraph (2) substitute—

"(2) If an investigational medicinal product to be used in the clinical trial has been, or is to be—

(a) imported into Great Britain from a country other than Northern Ireland or imported into Northern Ireland from a country other than an EEA State, a statement from the qualified person at the disposal of the person holding the manufacturing authorisation in relation to that importation specifying—

(i) the address of any premises outside the United Kingdom at which the product was manufactured or assembled; and

(ii) the manufacturing or assembling operations performed at those premises;

(b) imported into Northern Ireland from an EEA State, a statement from the qualified person at the disposal of the person holding the authorisation referred to in Article 13 of the Directive in relation to that importation specifying—

(i) the address of any premises outside the European Economic Area at which the product was manufactured or assembled; and

(ii) the manufacturing or assembling operations performed at those premises.".".

Commencement Information

I8 Sch. 1 para. 8 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

9. For regulation 25 (amendment of Schedule 7 (standard provisions for manufacturing authorisations)) substitute—

"**25.** In Part 1 of Schedule 7—

(a) for "In this Schedule," substitute " In this Schedule— ";

(b) the definition of "product specification" becomes part of a list of definitions;

(c) before the definition of "product specification" insert—

""Commission Directive 2003/94/EC", in relation to the holder of an authorisation means—

(a) in the case of a holder in Great Britain—

(i) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use, as modified by Schedule 2A to the 2012 Regulations, or

(ii) if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations, and have come into force, those Regulations;

(b) in the case of a holder in Northern Ireland, Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use;";

(d) in the definition of "product specification", for paragraph (a) substitute—

"(a) in the case of an investigational medicinal product manufactured before a request for authorisation to conduct the clinical trial involving those products has been made—

(i) in the case of an investigational medicinal product manufactured or assembled in Great Britain, in accordance with regulation 17, or

(ii) in the case of an investigational medicinal product manufactured or assembled in Northern Ireland, in accordance with regulation 17 or any equivalent provisions in any EEA State,

the specification for that product provided by the person who is to act as the sponsor of the proposed clinical trial,".".

Commencement Information

I9 Sch. 1 para. 9 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

10. In regulation 26 (insertion of Schedule 13 (transitional provisions in relation to EU Exit)), in the inserted Schedule 13—

(a) for "exit day" in each place it occurs substitute " IP completion day ";

(b) in paragraph 3—

(i) in the heading to the paragraph, after "medicinal products" insert " into Great Britain ";

(ii) in sub-paragraph (1), after "that is imported" insert " into Great Britain ".

Commencement Information

I10 Sch. 1 para. 10 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, SCHEDULE 1.