

## SCHEDULES

### SCHEDULE 1

Regulation 3

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

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

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;”.
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).”.”.

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](#)”.”.

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.”.

**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”.

**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”.”.

**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.”.
- 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.”.
- 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.”.
- 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”.

## SCHEDULE 2

Regulation 4

### Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

## PART 1

### Amendment of Part 2 (amendment of Part 1 (General))

- 1.** In regulation 4 (definitions in relation to advanced therapy medicinal products), in the inserted regulation 2A, in paragraphs (1) and (10), after “In these Regulations,” insert “in their application to products for sale or supply in Great Britain only.”.
- 2.** In regulation 5 (amendment of regulation 3 (scope of Regulations: special provisions))—
- (a) for paragraph (2)(b) and (c) substitute—
    - “(b) after paragraph (i) insert—
      - “(ia) the EU marketing authorisation.”.

- (b) for paragraph (3)(b) and (c) substitute—
  - “(b) after paragraph (i) insert—
    - “(aa) an EU marketing authorisation;”.
- 3. In regulation 6 (amendment of regulation 4 (special provision for pharmacies etc) substitute—
  - “6. In regulation 4—
    - (a) in paragraph (4)(d)—
      - (i) in paragraph (i) insert “UK” before “marketing authorisation”;
      - (ii) after paragraph (i) insert—
        - “(ia) the EU marketing authorisation;”;
    - (b) in paragraph (6) for “269 (offences relating to packaging and package leaflets: other persons)” substitute “269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)”.
- 4. In regulation 7 (amendment of regulation 5 (classification of medicinal products))—
  - (a) for paragraph (2) substitute—
    - “(2) In paragraph (1)(b), before “a product that” insert “in the case of a medicinal product for sale or supply in Northern Ireland,”.
  - (b) in paragraph (3)—
    - (i) omit sub-paragraph (a);
    - (ii) for sub-paragraph (b) substitute—
      - “(b) in sub-paragraph (d), before “an Article 126a” insert “in the case of a medicinal product for sale or supply in Northern Ireland,”.
  - (c) in paragraph (4)—
    - (i) for sub-paragraph (a) substitute—
      - “(a) in sub-paragraph (b), before “a medicinal product” insert “in the case of a medicinal product for sale or supply in Northern Ireland,”.
    - (ii) omit sub-paragraph (b);
  - (d) in paragraph (5) for “omit sub-paragraph (b)” to the end substitute “in sub-paragraph (b), before “an Article” insert “in the case of a medicinal product for sale or supply in Northern Ireland,”. and
  - (e) in paragraph (6)—
    - (i) for sub-paragraph (a) substitute—
      - “(a) in sub-paragraph (b), before “a product that” insert “in the case of a medicinal product for sale or supply in Northern Ireland,”. and”; and
    - (ii) omit sub-paragraph (b).
- 5. For regulation 8 (amendment of Schedule 1 (further provisions for classification of medicinal products)) substitute—
  - “8. In Schedule 1—
    - (a) in paragraph 1—
      - (i) in sub-paragraph (b), insert “UK” before “marketing authorisation”;



- (ii) in sub-paragraphs (e)(i), (f)(i) and (g)(i), for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence”; and
  - (b) in paragraph 4, for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation, Article 126a authorisation, parallel import licence”.
- 6. Omit regulation 9 (amendment of regulation 6 (the licensing authority and the Ministers)).
- 7. In regulation 10 (amendment of regulation 8 (general interpretation))—
  - (a) in paragraph (2)—
    - (i) in the definition of—
      - (aa) “Annex I to the 2001 Directive”, after “means” insert “, in relation to UKMA(GB),”;
      - (bb) “conditional marketing authorisation”, for “UK marketing authorisation” substitute “UKMA(GB)”;
    - (ii) at the appropriate place in the list of definitions to be inserted, insert—
      - ““EU agreed paediatric investigation plan” means a paediatric investigation plan agreed in accordance with the Paediatric Regulation;”
      - ““nursing home” has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(1);”;
      - ““parallel import licence” has the meaning given in regulation 48(2);”;
      - ““qualifying Northern Ireland goods” has the same meaning that it has in the European Union (Withdrawal) Act 2018, including any meaning defined for the purposes of that Act from time to time by regulations made under the power conferred by section 8C(6) of that Act;”;
      - ““under the unfettered access route” means an application for—
        - (a) a UKMA(GB) under reduced or alternative requirements specified in Part 5 (as referred to in regulation 49(1A));
        - (b) a COR(GB) under reduced or alternative requirements specified in Part 6 (as referred to in regulation 103(1A));
        - (c) a THR(GB) under reduced or alternative requirements specified in Part 7 (as referred to in regulation 127(1A));”;
      - ““withdrawal agreement” has the meaning given in section 39 of the European Union (Withdrawal Agreement) Act 2020;”;
  - (b) in paragraph (3)—
    - (i) before sub-paragraph (a) insert—
      - “(za) in the definition of “advanced therapy medicinal product”, after “means” insert “, in the case of a medicinal product for sale or supply by the holder of a UKMA(NI) or UKMA(UK),”;
      - (zb) in the definition of “certificate of registration”, after “these Regulations” insert—
        - “and—

- (a) “COR(UK)” means such a certificate in force in the whole United Kingdom;
  - (b) “COR(GB)” means such a certificate in force in Great Britain only;
  - (c) “COR(NI)” means such a certificate in force in Northern Ireland only;”;
- (ii) for sub-paragraph (a) substitute—
- “(a) for the definition of “the Good Manufacturing Practice Directive” substitute—
- ““the Good Manufacturing Practice Directive” means—
- (a) in the case of a 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, or
    - (ii) if Regulations have been made under the powers in regulation B17(1), and have come into force, those Regulations;
  - (b) in the case of a 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;”;
- (iii) in sub-paragraph (b) (amendment of definition of “homoeopathic medicinal product”) for “substitute “the British Pharmacopoeia” to the end substitute—
- “substitute—
- “(i) in relation to a certificate of registration or marketing authorisation for a national homoeopathic product in force in Great Britain only, the British Pharmacopoeia, or in an pharmacopoeia used officially in an country that is included in a list published by the licensing authority for this purpose;
  - (ii) in relation to a certificate of registration or marketing authorisation for a national homoeopathic product in force in the whole United Kingdom or in Northern Ireland only, in the British Pharmacopoeia or in any pharmacopoeia used officially in an EEA State;”;
- (iv) omit sub-paragraph (d) (amendment of definition of “name”);
- (v) in sub-paragraph (e) (amendment of definitions of “pharmacovigilance system”, “pharmacovigilance system master file” and “post-authorisation safety study”) for “for “marketing authorisation, traditional” to the end substitute “for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation””;
- (vi) for sub-paragraph (j) (amendment of definition of “the summary of the product characteristics”) substitute—
- “(j) in the definition of “traditional herbal registration”, after “these Regulations” insert—

- “and—
- (a) “THR(UK)” means such a registration in force in the whole United Kingdom;
  - (b) “THR(GB)” means such a registration in force in Great Britain only;
  - (c) “THR(NI)” means such a registration in force in Northern Ireland only.”;”;
- (vii) for sub-paragraph (k) (amendment of definition of “UK marketing authorisation”) substitute—
- “(k) for the definition of “UK marketing authorisation” substitute—
- ““UK marketing authorisation” means a marketing authorisation granted by the licensing authority under Part 5 of these Regulations or Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure) and—
- (a) “UKMA(UK)” means such an authorisation in force in the whole United Kingdom;
  - (b) “UKMA(GB)” means such an authorisation in force in Great Britain only;
  - (c) “UKMA(NI)” means such an authorisation in force in Northern Ireland only.”;”;
- (c) in paragraph (4) omit subparagraphs (i), (ii), (iv), (vii), (viii), (ix), (x), (xi) and (xii);
- (d) after paragraph (7) insert—
- “(8) After paragraph (8) insert—
- “(9) Unless otherwise provided, any provision of an EU Regulation made applicable to a UKMA(NI), COR(NI) or THR(NI) by virtue of Article 5(4) of, and Annex 2 to, the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement applies equally in respect of a UKMA(UK), COR(UK) or THR(UK).”.”.

## PART 2

### Amendment of Part 3 (amendment of Part 3 (manufacture and distribution of medicinal products and active substances))

- 8.** In regulation 13 (new regulation B17 and C17 (good manufacturing practice and good distribution practice))—
- (a) in the inserted regulation B17—
    - (i) in paragraph (1)—
      - (aa) for “Ministers” substitute “Secretary of State”;
      - (bb) after “by regulations” insert “in respect of Great Britain”;
    - (ii) in paragraph (2)(b) after “UK marketing authorisation” insert “or EU marketing authorisation”;
    - (iii) in paragraph (3)—
      - (aa) after “have effect” insert “in Great Britain”;
      - (bb) for “exit day” in both places it occurs substitute “IP completion day”;

- (iv) in paragraph (4)—
  - (aa) for “Ministers” substitute “Secretary of State”;
  - (bb) after “by regulations” insert “in respect of Great Britain”;
- (b) in the inserted regulation C17—
  - (i) in paragraph (1), after “may publish” insert “in relation to the manufacture or assembly of a medicinal product in, or import to, Great Britain”;
  - (ii) in paragraph (3) for “exit day” in both places it occurs substitute “IP completion day”.
- 9. In regulation 14 (amendment of regulation 17 (manufacturing of medicinal products))—
  - (a) for paragraph (2) substitute—
    - “(2) For paragraph (1) substitute—
      - “(1) A person may not except in accordance with a licence (a “manufacturer’s licence”)—
        - (a) manufacture a medicinal product,
        - (b) assemble a medicinal product,
        - (c) import a medicinal product into Great Britain from a country other than—
          - (i) Northern Ireland, or
          - (ii) an approved country for import,
        - (d) import a medicinal product into Northern Ireland from a country other than an EEA State, or
        - (e) possess a medicinal product for the purpose of any activity in sub-paragraphs (a) to (d).”.”;
  - (b) omit paragraph (3);
  - (c) for paragraph (4) substitute—
    - “(4) In paragraph (4), after sub-paragraph (a) insert—
      - “(aa) a UK marketing authorisation; or”.”;
  - (d) for paragraph (5) substitute—
    - “(5) In paragraph (5) omit “from a state other than an EEA State”.”;
  - (e) after paragraph (5) insert—
    - “(6) After paragraph (6) insert—
      - “(7) Paragraph (1) does not apply to imports into Northern Ireland from Great Britain of—
        - (a) special medicinal products, and
        - (b) medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.
      - (8) For the purposes of paragraph (7) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.”.”.

**10.** In regulation 15 (amendment of regulation 18 (wholesale dealing in medicinal products))—

(a) in paragraph (2)(c), in the inserted sub-paragraph (c)—

(i) after “medicinal product” insert “into Great Britain”;

(ii) omit “for either purpose”;

(b) after paragraph (2) insert—

“(2A) After paragraph (2) insert—

“(2A) Paragraph (1)(c) does not apply to imports into Great Britain from an EEA State of medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(2B) For the purposes of paragraph (2A) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.”;

(c) for paragraph (3) substitute—

“(3) For paragraph (6) substitute—

“(6) A wholesale dealer’s licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession of a medicinal product for the purpose of such distribution, unless—

(a) in the case of a product for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration is in force in respect of the product, or

(b) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product,

but this is subject to the exceptions in regulation 43(6).”;

(d) for paragraph (4) substitute—

“(4) In paragraph (7) for “paragraph (6)” substitute “paragraph (6)(b)”. ”.

**11.** In regulation 17 (amendment of regulation 19 (exemptions from requirement for wholesale dealer’s licence))—

(a) for paragraph (2) substitute—

“(2) For paragraph (1)(a) substitute—

“(a) the holder of—

(i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an “authorisation”) which relates to the product, or

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an “authorisation”) which relates to the product,

including a holder of an authorisation who manufactured or assembled the product; or”;

(b) after paragraph (3) insert—

“(4) At the end insert—

“(6) Regulation 18 does not apply to a person (“P”) who imports a medicinal product into Great Britain from an approved country for import for administration to P or to any other person who is a member of P’s household.””.

**12.** In regulation 18 (amendment of Schedule 3 (applications for licences under Part 3))—

(a) for paragraph (2) substitute—

“(2) For paragraph 1(2)(g) substitute—

“(g) the name, address, qualifications and experience of the person with responsibility for quality control in relation to the medicinal products to be manufactured or assembled under the licence (and, if that responsibility is to be carried out by the holder of—

(i) in the case of a product for sale or supply in Great Britain, the UK marketing authorisation, certificate of registration or traditional herbal registration relating to the products, or

(ii) in the case of a product for sale or supply in Northern Ireland, the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to the products,

a statement of that fact);””;

(b) for paragraph (3) substitute—

“(3) For paragraph 2(1) substitute—

“2.—(1) This paragraph applies to an application for a manufacturer’s licence relating to the import from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State,

of medicinal products.””;

(c) in paragraph (4)(b)—

(i) for sub-paragraph (i) substitute—

“(i) for paragraph (i) substitute—

“(i) in the case of a product for sale or supply in Great Britain, a UK marketing authorisation,

(ia) in the case of a product for sale or supply in Northern Ireland, a marketing authorisation,””;

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

“(ii) in paragraph (iv) before “an Article” insert “in the case of a product for sale or supply in Northern Ireland,” and”;

(d) in paragraph (4)(c)(iii), in the inserted paragraph (iii), after “export” insert “from Great Britain”.

**13.** After regulation 19 (amendment of regulation 23 (grant or refusal of licence)) insert—

**“Amendment of regulation 24 (standard provisions of licences)**

**19A.** In regulation 24, after paragraph (2) insert—

“(3) In Schedule 4, in relation to a licence holder in Great Britain, references to the principles and guidelines set out in the Good Manufacturing Practice Directive are to those principles and guidelines as they apply under or by virtue of regulation B17.”.

**14.** In regulation 20 (amendment of Schedule 4 (standard provisions of licences under Part 3))—

(a) for paragraph (2) substitute—

“(2) For paragraph 13(b) substitute—

“(b) in the case of a product for sale or supply—

(i) in Great Britain, a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in Northern Ireland, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

contains provisions relating to them.”;

(b) after paragraph (2) insert—

“(2A) After paragraph 14 insert—

“**14A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.”;

(c) for paragraph (3) substitute—

“(3) In the heading of Part 2, after “State Other Than an EEA State” insert “/ Country other than an Approved Country for Import”.”;

(d) for paragraph (4) substitute—

“(4) In paragraph 15, for “from a state other than an EEA State” substitute—

“from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State”.

(4A) In paragraphs 22(1) and 23, for “a state other than an EEA State” substitute “, in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State”.

(4B) After paragraph 23, insert—

“**23A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.”;

(e) for paragraph (6) substitute—

“(6) In paragraph 33, for “another EEA State” substitute “, in the case of an import into Great Britain, an approved country for import and in the case of an import into Northern Ireland, an EEA State”.”;

(f) after paragraph (6) insert—

“(7) After paragraph 41 insert—

“**41A.** A licence holder—

- (a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and
- (b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.”.”.

**15.** For regulation 21 (amendment of regulation 26 (general power to suspend, revoke or vary licences)) substitute—

“**21.** For regulation 26(5)(a) substitute—

“(a) that the holder of the manufacturer’s licence has manufactured or assembled medicinal products to the order of a person who holds—

- (i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an “authorisation”), or
- (ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI) or a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an “authorisation”),

and has habitually failed to comply with the provisions of that authorisation; or”.”.

**16.** In regulation 24 (amendment of regulation 31 (certification of manufacturer’s licence)) for paragraph (3) substitute—

“(3) In paragraphs (3)(b), (5)(a) and (5)(b) for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation, Article 126a authorisation”.”.

**17.** In regulation 27 (amendment of regulation 36 (conditions for manufacturer’s licence)) for “, omit paragraphs (4) to (7)” substitute—

“—

(a) in paragraph (4)—

- (i) for “The requirements” substitute “Where a manufacturer’s licence relates to the manufacture or assembly of a medicinal product in, or import of a medicinal product into, Northern Ireland, the requirements”;
- (ii) for “provisions of a manufacturer’s” substitute “provisions of that”;

(b) in paragraph (6), after “by way of wholesale dealing” insert “in Northern Ireland”.”.

**18.** In regulation 28 (amendment of regulation 37 (manufacturing and assembly))—

(a) after paragraph (1) insert—

“(1A) In paragraph (2), after “Good Manufacturing Practice Directive” insert “which apply under or by virtue of regulation B17”.”.

(b) for paragraph (2) substitute—



“(2) For paragraph (4)(b) substitute—

“(b) that unless the active substance is imported into Great Britain from a country other than an approved country for import or into Northern Ireland from a country other than an EEA State from a third country, any manufacturers, importers or distributors supplying active substances to the licence holder—

(i) in the case of a product imported into Great Britain, are registered with the appropriate authority for the registration of such persons in the approved country for import, and

(ii) in the case of a product imported into Northern Ireland, are registered with the competent authority of a member State in which they are established; and”.

(c) for paragraph (3) substitute—

“(3) In paragraph (5)(b), after “as described” insert “in the case of a product for sale or supply in Great Britain, in the guidelines which apply under or by virtue of regulation C17 and, in the case of a product for sale or supply in Northern Ireland,”;

(d) for paragraph (4) substitute—

“(4) For paragraph (6)(b) substitute—

“(b) in the case of a product for sale or supply—

(i) in Great Britain, the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK), or

(ii) in Northern Ireland, the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisations or Article 126a authorisations,

applying to the medicinal products.”.

**19.** In regulation 29 (amendment of regulation 38 (imports))—

(a) for paragraph (2) substitute—

“(2) In the heading, after “states other than EEA states” insert “/ countries other than approved countries for import”.

(b) for paragraph (3) substitute—

“(3) In paragraph (2) for “from a state other than an EEA State” substitute—

“from—

(a) in the case of an import into Great Britain, a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State”.

(c) after paragraph (3) insert—

“(4) In paragraph (3)(b) for “a state other than an EEA State” substitute “, in the case of an import into Great Britain, a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State”.

**20.** In regulation 30 (amendment of regulation 39 (further requirements for manufacturer’s licence))—

(a) “omit “, 43A”” becomes paragraph (a);

(b) after paragraph (a) insert—

“and

- (b) after “and (6)” insert “and, where the product is being distributed in Northern Ireland, regulation 43A,”.”.

**21.** In regulation 31 (amendment of regulation 42 (conditions for wholesale dealer’s licence))—

- (a) for paragraph (2) substitute—

“(2) In paragraph (1), after “45” insert “(in the case of a wholesale dealer’s licence held in Northern Ireland) or regulations 43 to 45AA (in the case of a wholesale dealer’s licence held in Great Britain)”.”;

- (b) for paragraph (3) substitute—

“(3) In paragraph (4)—

- (a) for “The requirements” substitute “Where a wholesale dealer’s licence relates to wholesale dealings in Northern Ireland, the requirements”; and

- (b) for “provisions of a wholesale dealer’s” substitute “provisions of that”.”.

**22.** In regulation 32 (amendment of Schedule 7 (qualified persons))—

- (a) after paragraph (3)(a)(i) insert—

“(ia) for “The qualified person” substitute “In Great Britain, the qualified person”.”;

- (b) in paragraph (3)(a)(ii), before sub-paragraph (aa), insert—

“(zaa) for “the United Kingdom” substitute “Great Britain”.”;

- (c) in paragraph (3)(a)(iii)(aa) after “medicinal products imported from” insert “a country other than Northern Ireland or”;

- (d) after paragraph (3)(a) insert—

“(aa) after paragraph 12 insert—

“**12A.**—(1) In Northern Ireland, the qualified person is responsible for securing—

- (a) that each batch of medicinal products manufactured in Northern Ireland has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

- (b) in the case of medicinal products imported from a country other than an EEA State, irrespective of whether the products have been manufactured in Northern Ireland or an EEA State, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

- (c) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive and not intended to be exported to a country other than an

EEA State, that the features specified in paragraph 18A of Schedule 24 have been affixed on the packaging.”.”;

(e) for paragraph (3)(b) substitute—

“(b) in paragraph 13—

(i) in sub-paragraph (1) after “This paragraph applies” insert “in Northern Ireland”;

(ii) in sub-paragraph (1)(a) for “paragraph 12 in another member State is imported to the United Kingdom” substitute “paragraph 12A in a member State is imported to Northern Ireland”;

(iii) in sub-paragraph (2) for “12” substitute “12A”.”;

(f) in paragraph (3)(c)—

(i) for paragraph (i) substitute—

“(i) in sub-paragraph (1)(a) after “are imported” insert “into Great Britain from a country other than an approved country for import or into Northern Ireland.”;

(ii) for paragraph (ii) substitute—

“(ii) for sub-paragraph (1)(b) substitute—

“(b) appropriate arrangements have been made, in the case of import into Great Britain by the licensing authority with the country from which those products are imported and, in the case of a product for import into Northern Ireland by the European Union with that country, to ensure that—

(i) the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down—

(aa) in the case of a product for sale or supply in Great Britain, in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17, and

(bb) in the case of a product for sale or supply in Northern Ireland, by the European Union;

(ii) the controls referred to in paragraph 12(b) or 12A(b) (as appropriate) have been carried out in that country.”.”;

(iii) after paragraph (ii) insert—

“(iia) in paragraph (2) after “paragraph 12” insert “or 12A”.”.

**23.** In regulation 33 (amendment of regulation 43 (obligations of licence holder))—

(a) for paragraph (2) substitute—

“(2) For paragraph (1), substitute—

“**43.**—(1) The licence holder must comply with the guidelines on good distribution practice—

(a) in the case of a licence holder in Great Britain, published under, or that apply by virtue of, regulation C17;

- (b) in the case of a licence holder in Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive.”.”;
- (b) for paragraph (3) substitute—
  - “(3) For paragraph (5)(a) substitute—
    - “(a) in the case of a product for sale or supply—
      - (i) in Great Britain, there is a UKMA(GB), UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an “authorisation”), or
      - (ii) in Northern Ireland, there is a UKMA(NI), UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), and EU marketing authorisation or an Article 126a authorisation (an “authorisation”),
    - in force in relation to the product; and”.”;
- (c) after paragraph (4)(a) insert—
  - “(aa) in sub-paragraph (b), after “the export” insert “from Northern Ireland”.”;
- (d) in paragraph (4)(b)—
  - (i) for “for sub-paragraph (b), substitute” substitute “after sub-paragraph (b), insert”;
  - (ii) in the text inserted by that paragraph—
    - (aa) renumber the paragraph to be inserted as “(ba)”;
    - (bb) after “the export” insert “from Great Britain”;
- (e) after paragraph (4)(b) insert—
  - “(c) for sub-paragraph (d) substitute—
    - “(d) the wholesale distribution of medicinal products—
      - (i) from Northern Ireland to a person in a country other than Great Britain or a country other than an EEA State; or
      - (ii) from Great Britain to a person in a country other than Northern Ireland or a country other than an approved country for import.”.”;
- (f) in paragraph (5)(a)—
  - (i) for paragraph (i) substitute—
    - “(i) for sub-paragraph (i) substitute—
      - “(i) ordered by the licensing authority or—
        - (aa) in the case of a licence holder in Great Britain, by an appropriate authority for the licensing of medicinal products in an approved country for import;
        - (bb) in the case of a licence holder in Northern Ireland, by the competent authority of any EEA State, or”.”;
    - (ii) for paragraph (ii) substitute—
      - “(ii) for sub-paragraph (ii) substitute—
        - “(ii) carried out in co-operation with the manufacturer of, or the holder of—
          - (aa) in the case of a product for sale or supply in Great Britain, the UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration, or

- (bb) in the case of a product for sale or supply in Northern Ireland, the UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,  
for, the product; and”;
  - (g) for paragraph (5)(b) substitute—
    - “(b) in sub-paragraph (c)(vii), before “the batch number” insert “where the receipt, dispatch or brokering of medicinal products takes places in Northern Ireland.”;
  - (h) after paragraph (5) insert—
    - “(5A) In paragraph (8)—
      - (a) after “A licence holder” insert “in Northern Ireland”;
      - (b) for “third country” substitute ““country other than an EEA State”.”;
  - (i) in paragraph (6)—
    - (i) for “For paragraph (8) substitute” substitute “After paragraph (8) insert”;
    - (ii) renumber the paragraphs to be inserted as (8A) and (8B) respectively;
    - (iii) in the newly renumbered paragraph (8A)—
      - (aa) for “Paragraph (8A)” substitute “Paragraph (8B)”;
      - (bb) in sub-paragraph (a), after “imports” insert “into Great Britain”;
  - (j) for paragraph (7) substitute—
    - “(7) In paragraph (10), after “The holder” insert “of a licence relating to wholesale dealings in Northern Ireland”.”;
  - (k) for paragraph (8) substitute—
    - “(8) In paragraph (13), for “marketing authorisation holder” substitute “UK marketing authorisation holder or EU marketing authorisation holder”.”;
  - (l) for paragraph (9) substitute—
    - “(9) For paragraph (14) substitute—
      - “(14) Where the medicinal product is obtained through brokering—
        - (a) a licence holder in Great Britain must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b);
        - (b) a licence holder in Northern Ireland must verify that the broker involved is validly registered with the licensing authority or the competent authority of an EEA State.”.
    - (10) In paragraph (15), after “In this regulation” insert “as it applies in the case of a product for sale or supply in Northern Ireland”.”.
- 24.** For regulation 34 (omission of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)) substitute—

**“Amendment of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)**

- 34.** In regulation 43A—
- (a) in paragraph (2) for “in the United Kingdom” substitute “in Northern Ireland”;  
and
  - (b) in paragraph (3)—

(i) in sub-paragraph (g) omit “a police force in England, Wales or Scotland or”; and

(ii) in sub-paragraph (l) for “care” substitute “nursing”.

**25.** In regulation 35 (amendment of regulation 44 (requirement for wholesale dealers to deal only with specified persons))—

(a) in paragraph (2)—

(i) for sub-paragraph (a) substitute—

“(a) in sub-paragraph (b), for “another EEA State” substitute “an approved country for import (in the case of a licence holder in Great Britain) or by an EEA State (in the case of a licence holder in Northern Ireland)”; and”;

(ii) for sub-paragraph (b) substitute—

“(b) for sub-paragraph (c) substitute—

“(c) where the medicinal product is directly received—

(i) in the case of a licence holder in Great Britain, from a country that is not an approved country for import (“A”), for export to a country that is not an approved country for import (“B”), and

(ii) in the case of a licence holder in Northern Ireland, from a country other than an EEA State (“A”) for export to another country other than an EEA State (“B”),

the supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.”;

(b) for paragraph (3) substitute—

“(3) For paragraph (5)(b) substitute—

“(b) the holder of an authorisation granted by—

(i) in the case of a licence holder in Great Britain, the appropriate authority of an approved country for import;

(ii) in the case of a licence holder in Northern Ireland, the competent authority of an EEA State,

that is responsible for authorising the supply of those products by way of wholesale dealing;”;

(c) for paragraph (4) substitute—

“(4) For paragraph (5)(e) substitute—

“(e) in relation to supply—

(i) in the case of a licence holder in Great Britain to persons in countries other than approved countries for import, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country to which the product is supplied;

(ii) in the case of a licence holder in Northern Ireland to persons in a country other than an EEA State, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in

accordance with the applicable legal and administrative provisions of the country other than an EEA State concerned.”.”;

(d) for paragraph (5)(b) substitute—

“(b) in sub-paragraph (e) after “of the 2001 Directive” insert “, in the case of a licence holder in Northern Ireland.”.”;

(e) after paragraph (5) insert—

“(6) After paragraph (7) insert—

“(8) A licence holder in Great Britain may only obtain a medicinal product in respect of which a UKMA(GB) was granted under the unfettered access route if the product satisfies the definition of qualifying Northern Ireland goods.

(9) Paragraph (2)(c) does not apply to—

- (a) in the case of a licence holder in Great Britain, products received from Northern Ireland, and
- (b) in the case of a licence holder in Northern Ireland, products received from Great Britain.

(10) Paragraph (5)(e) does not apply to—

- (a) in the case of a licence holder in Great Britain, products supplied to Northern Ireland, and
- (b) in the case of a licence holder in Northern Ireland, products supplied to Great Britain.”.”.

**26.** In regulation 36 (amendment of regulation 45 (requirement as to responsible persons))—

(a) for paragraph (2) substitute—

“(2) After paragraph (1) insert—

“(1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.”.”;

(b) for paragraph (3) substitute—

“(3) For paragraph (2)(b) substitute—

“(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of—

- (i) in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations, and
- (ii) in the case of a licence holder in Northern Ireland, the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products.”.”.

**27.** In regulation 37 (insertion of new regulations 45AA and 45AB (responsible persons: import)), in the inserted regulation 45AA—

(a) in paragraph (1), after “this regulation applies” insert “to a licence holder in Great Britain”;

(b) omit “and” at the end of paragraph (4)(a);

(c) at the end of paragraph (4)(b) insert—

“; and

- (c) ensure that each production batch of a medicinal product that is subject to the batch testing condition and that is imported into Great Britain from an approved country for import has been certified as being in conformity with the approved specifications in the UK marketing authorisation by—
  - (i) the appropriate authority, or
  - (ii) where the batch testing exemption applies, a laboratory in a country that has an agreement with the United Kingdom to the effect that the appropriate authority will recognise that certificate in place of the appropriate authority’s own examination.”.

**28.** In regulation 38 (amendment of regulation 45A (brokering in medicinal products))—

- (a) for paragraph (2) substitute—

“(2) For paragraph (1) substitute—

“(1) A person may not broker a medicinal product in Great Britain unless—

- (a) the product is covered by an authorisation granted—

- (i) by the licensing authority, or
- (ii) by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, and

- (b) that person—

- (i) is validly registered as a broker with the licensing authority,
- (ii) has a permanent address in the United Kingdom, and
- (iii) complies with the guidelines on good distribution practice which apply under, or by virtue of, regulation C17 insofar as those guidelines apply to brokers.

(1A) A person may not broker a medicinal product in Northern Ireland unless—

- (a) the product is covered by an authorisation granted—

- (i) under Regulation (EC) No 726/2004,
- (ii) by the licensing authority, or
- (iii) by a competent authority of a member State, and

- (b) that person—

- (i) is validly registered as a broker with the licensing authority or a competent authority of a member State,
- (ii) except where the person is validly registered with the competent authority of an EEA State, has a permanent address in the United Kingdom, and
- (iii) complies with the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive insofar as those guidelines apply to brokers.”.”;

- (b) for paragraph (3) substitute—

“(3) In paragraph (2)—

- (a) after “paragraph (1)(b)” insert “or (1A)(b)”;
- (b) in sub-paragraphs (a) and (c), after “competent authority of a member State” insert “or the licensing authority (as appropriate)”.”.



- 29.** In regulation 40 (amendment of regulation 45E (criteria of broker’s registration))—
- (a) for paragraph (a) substitute—
    - “(a) for sub-paragraph (b)(i) substitute—
      - “(i) ordered by—
        - (aa) in the case of a broker in Great Britain, the licensing authority or by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or
        - (bb) in the case of a broker in Northern Ireland, the licensing authority or by the competent authority of any EEA State, or”;
  - (b) for paragraph (b) substitute—
    - “(b) in sub-paragraph (d)(iii), before “the batch number” insert “where the sale or supply of the medicinal product is in Northern Ireland,”.”
- 30.** In regulation 41 (amendment of regulation 45F (provision of information)), for the inserted sub-paragraph (b) substitute—
- “(b) in the case of a broker in—
    - (i) Great Britain, either—
      - (aa) the UK marketing authorisation holder, or
      - (bb) where applicable, the holder of the licence or authorisation granted by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or
    - (ii) Northern Ireland, either—
      - (aa) the UK marketing authorisation holder, or
      - (bb) where applicable, the EU marketing authorisation holder,”.
- 31.** In regulation 42 (amendment of regulation 45M (criteria for importation, manufacture or distribution of an active substance)) for paragraph (2) substitute—
- “(2) For paragraph (2)(a) substitute—
    - “(a) if—
      - (i) in the case of a product for sale or supply in Great Britain, the product has a UK marketing authorisation, certificate of registration or traditional herbal registration, or
      - (ii) in the case of a product for sale or supply in Northern Ireland, the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration, and”;
- 32.** In regulation 44 (amendment of regulation 45O (requirements for registration as an importer, manufacturer or distributor of an active substance))—
- (a) for paragraph (2) substitute—
    - “(2) For paragraph (1) substitute—
      - “(1) Where principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance manufactured in Great Britain, a manufacturer in Great Britain must comply with the principles and guidelines of good manufacturing practice for active substances.
      - (1A) Where the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the

2001 Directive which applies to an active substance manufactured in Northern Ireland, a manufacturer in Northern Ireland must comply with the principles and guidelines of good manufacturing practice for active substances.”.”;

(b) for paragraph (3) substitute—

“(3) For paragraph (2) substitute—

“(2) Where principles and guidelines of good distribution practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance distributed in Great Britain, a distributor in Great Britain must comply with the principles and guidelines of good distribution practice for active substances.

(2A) Where the Commission has adopted principles and guidelines of good distribution practice under the fourth paragraph of Article 47 of the 2001 Directive which applies to an active substance distributed in the Northern Ireland, a distributor in Northern Ireland must comply with the principles and guidelines of good distribution practice for active substances.”.”;

(c) for paragraph (4) substitute—

“(4) In paragraph (3)—

- (a) for “the UK” substitute “Northern Ireland”;
- (b) for “from a third country” substitute “into Northern Ireland from a country other than an EEA State”;
- (c) for “exporting third country” in both places it occurs substitute “exporting country”;
- (d) in sub-paragraph (c)(ii), for “the Union” substitute “Northern Ireland”.”;

(d) after paragraph (4) insert—

“(4A) After paragraph (3) insert—

“(3A) Without prejudice to regulation 37(4) and paragraph 9A of Schedule 8, where principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance imported into Great Britain other than from Northern Ireland and where an active substance is so imported—

- (a) the importer must comply with good manufacturing practice and good distribution practice in relation to the active substance,
- (b) the active substances must have been manufactured in accordance with standards which are at least equivalent to good manufacturing practice, and
- (c) the active substances must be accompanied by a written confirmation from the competent authority of the exporting country of the following—
  - (i) the standards of manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to good manufacturing practice,
  - (ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of standards of manufacturing practice at least equivalent to good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in Great Britain, and

- (iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting country to the licensing authority without any delay.”.”;
- (e) for paragraph (5) substitute—
  - “(5) In paragraph (4)—
    - (a) for “(3)(c) does” substitute “(3)(c) and (3A)(c) do”;
    - (b) in sub-paragraph (a), after “Article 111b of the 2001 Directive” insert “(in the case of an import into Northern Ireland) or paragraph (6) (in the case of an import into Great Britain)”;
    - (c) in sub-paragraph (b)(i), after “competent authority of a member State” insert “or licensing authority (in the case of an import into Northern Ireland) or licensing authority or an appropriate authority responsible for the licensing of medicinal products in a country included in a list under paragraph (6) (in the case of an import into Great Britain)”.”;
- (f) in paragraph (6), in the inserted paragraph (6), for “the United Kingdom” in both places substitute “Great Britain”.

## PART 3

### Amendment of Part 4 (amendment of Part 4 (requirement for authorisation))

- 33. In regulation 45 (amendment of regulation 46 (requirement for authorisation))—
  - (a) for paragraph (2)(b) and (c) substitute—
    - “(b) after sub-paragraph (a) insert—
      - “(aa) an EU marketing authorisation;”.”;
  - (b) for paragraphs (4)(a) to (c) substitute—
    - “(a) after “in force for the product” insert “in the country in which the product is intended to be sold or supplied, or offered for sale or supply”;
    - (b) in sub-paragraph (a), before “marketing authorisation”, insert “UK”; and
    - (c) after sub-paragraph (a) insert—
      - “(aa) an EU marketing authorisation;”.”;
  - (c) omit paragraph (5).
- 34. In regulation 46 (amendment of regulation 47 (breach of requirement)), omit paragraph (3).

## PART 4

### Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

- 35. In regulation 47 (amendment of regulation 48 (application of Part 5))—
  - (a) in paragraph (2)(a)—
    - (i) for the definition of “EU reference medicinal product”, substitute—
      - ““EU reference medicinal product” means a medicinal product which falls within paragraph (b)(ii) or (iii) of the definition of “reference medicinal product”.”;

- (i) after the definition of “EU reference medicinal product”, insert—
- ““excluded reference product” means—
- (a) a medicinal product authorised on the basis that it was a generic medicinal product;
  - (b) a medicinal product authorised on the basis that one or more of the circumstances listed in Article 10(3) of the 2001 Directive or regulation 52(1)(b) applied; or
  - (c) a biological medicinal product authorised on the basis that it did not meet a condition for being a generic medicinal product for any of the reasons described in Article 10(4) of the 2001 Directive or regulation 53A(1);”;
- (b) in paragraph (2)(b), for the definition of “generic medicinal product”, substitute—
- ““generic medicinal product”, in relation to a reference medicinal product for an application for—
- (a) a UKMA(NI) or UKMA(UK), has the meaning given in Article 10(2)(b) of the 2001 Directive;
  - (b) a UKMA(GB), means a medicinal product—
    - (i) that has the same qualitative and quantitative composition in active substances as the reference medicinal product;
    - (ii) that has the same pharmaceutical form as the reference medicinal product; and
    - (iii) whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies;”;
- (c) in paragraph (2)(d), for the definition of “reference medicinal product” substitute—
- ““reference medicinal product” means—
- (a) in relation to an application for a UKMA(NI), a medicinal product—
    - (i) authorised for sale or supply in Northern Ireland under regulation 49(1)(a), in accordance with the provisions of regulation 50; or
    - (ii) in relation to which an EU marketing authorisation or a marketing authorisation granted by a member State pursuant to the 2001 Directive is or has been in force,but which is not an excluded reference product;
  - (b) in relation to an application for a UKMA(GB), a medicinal product—
    - (i) authorised under regulation 49(1)(a), in accordance with the provisions of regulation 50;
    - (ii) in relation to which an EU marketing authorisation was in force on IP completion day, but in relation to which no UK marketing authorisation is in force because the holder of the EU marketing authorisation notified the licensing authority in accordance with paragraph 6(3) of Schedule 33A that it did not wish to be the holder of a converted EU marketing authorisation; or
    - (iii) in relation to which an EU marketing authorisation had ceased to be in force before IP completion day for reasons not related to safety, quality or efficacy,but which is not an excluded reference product;
  - (c) in relation to an application for a UKMA(UK), a medicinal product—

- (i) authorised under regulation 49(1)(a) for sale or supply in the whole of the United Kingdom, whether by virtue of one or more UK marketing authorisations, in accordance with the provisions of regulation 50; or
  - (ii) in relation to which an EU marketing authorisation or a marketing authorisation granted by a member State pursuant to the 2001 Directive is or has been in force,but which is not an excluded reference product;”;
- (d) in paragraph (3)—
  - (i) in the inserted paragraph (6)(b), for “regulations 51 to 53” substitute “regulations 51 to 53B”;
  - (ii) in the inserted paragraph (7), for “regulation 51(1) and (8)” substitute “regulation 51A(1) and (6)”;
  - (iii) in the inserted paragraph (8)(b), for “regulations 51 to 53” substitute “regulations 51 to 53B”;
  - (iv) in the inserted paragraph (9), for “regulation 51(1) and (8)” substitute “regulation 51A(1) and (6)”.

**36.** In regulation 48 (amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence))—

- (a) in paragraph (3)—
  - (i) renumber the inserted paragraph (1A) as paragraph (1B);
  - (ii) before newly renumbered paragraph (1B) insert—

“(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part (“under the unfettered access route”) and grant a UKMA(GB) only where—

    - (a) there is already in place, or will be at the time the UKMA(GB) is granted, a marketing authorisation in respect of the product authorising sale or supply in Northern Ireland,
    - (b) the applicant complies with the requirements in regulation 50(1A), and
    - (c) the medicinal product satisfies the definition of qualifying Northern Ireland goods.”;
  - (iii) after newly renumbered paragraph (1B) insert—

“(1C) A marketing authorisation or parallel import licence must state whether it is in force in—

    - (a) the whole United Kingdom;
    - (b) Great Britain only; or
    - (c) Northern Ireland only,and in these Regulations the meaning of a reference to that authorisation or licence being “in force” is limited to that territory.”;
- (b) for paragraph (4) substitute—

“(4) For paragraph (3) substitute—

“(3) The applicant, where it is applying for—

  - (a) a UKMA(NI)—
    - (i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

- (ii) on any other basis, must be established in the United Kingdom;
  - (b) a UKMA(GB)—
    - (i) under the unfettered access route, must be established in Northern Ireland;
    - (ii) other than under the unfettered access route, must be established in the United Kingdom;
  - (c) a UKMA(UK), must be established in the United Kingdom.”.”;
- (c) in paragraph (6), in the text to be inserted—
  - (i) renumber paragraph (9) as paragraph (10);
  - (ii) before newly renumbered paragraph (10) insert—
    - “(9) The application must include a statement indicating whether the authorisation or licence sought is for sale or supply of the product in—
      - (a) the whole United Kingdom;
      - (b) Great Britain only; or
      - (c) Northern Ireland only.”.
- 37. In regulation 49 (amendment of regulation 50 (accompanying material))—
  - (a) after paragraph (1) insert—
    - “(1A) After paragraph (1) insert—
      - “(1A) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide—
        - (a) in the case of an application under the unfettered access route—
          - (i) the material specified in Schedule 8C, and
          - (ii) any material specified in Schedule 8 which is not included in the material specified in Schedule 8C, and
        - (b) in all other cases, the material specified in Schedule 8, in relation to the product.”;
      - (1B) After paragraph (3) insert—
        - “(3A) Paragraph (4) does not apply in respect of an application under the unfettered access route.”.”;
    - (b) for paragraph (2) substitute—
      - “(2) For paragraph (4) substitute—
        - “(4) If any of the medicinal products to which the application for a UK marketing authorisation relates—
          - (a) in the case of a UKMA(NI) or a UKMA(UK), is liable to be imported from a country other than an EEA State, or
          - (b) in the case of a UKMA(GB), is liable to be imported,
    - (c) in paragraph (3)—
      - (i) for the inserted paragraph (5A) substitute—

- “(5A) The Secretary of State may by regulations in respect of Great Britain amend Schedule 8B (modifications of Annex I) in relation to a UKMA(GB) for the purpose of further modifying Annex I to the 2001 Directive in order to take account of scientific and technical progress.”;
- (ii) in the inserted paragraph (5C), for “exit day” substitute “IP completion day”;
- (d) after paragraph (4) insert—
- “(4A) In paragraph (6)—
- (a) for sub-paragraph (a), substitute—
- “(a) regulation 51 (application for UKMA(NI) relating to generic medicinal products)
- (aa) regulation 51A (application for UKMA(GB) relating to generic medicinal products);
- (ab) regulation 51B (application for UKMA(UK) relating to generic medicinal products);”;
- (b) for sub-paragraph (b), substitute—
- “(b) regulation 52 (application for UKMA(NI) relating to certain medicinal products that do not qualify as generic etc)
- (ba) regulation 52A (application for UKMA(GB) relating to certain medicinal products that do not qualify as generic etc);
- (bb) regulation 52B (application for UKMA(UK) relating to certain medicinal products that do not qualify as generic etc);”;
- (c) for sub-paragraph (c), substitute—
- “(c) regulation 53 (application for UKMA(NI) relating to similar biological medicinal products)
- (ca) regulation 53A (application for UKMA(GB) relating to similar biological medicinal products);
- (cb) regulation 53B (application for UKMA(UK) relating to similar biological medicinal products);”.
- 38.** In regulation 50 (amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation))—
- (a) in paragraph (2)—
- (i) in paragraph (a), after “in the United Kingdom” insert “or a member State”;
- (ii) for paragraph (b) substitute—
- “(b) for sub-paragraph (b) substitute—
- “(b) the country (which must be either the United Kingdom or a member State) in which the appropriately qualified person resides and carries out his or her tasks;”;
- (iii) for paragraph (c) substitute—
- “(c) for paragraph (e) substitute—
- “(e) a reference to the physical location where the pharmacovigilance system master file for the medicinal product can be accessed electronically, which must be in the United Kingdom.”;
- (b) in paragraph (3), for the inserted paragraph 18, substitute—

**“18. Where—**

- (a) in the case of a UKMA(NI) or a UKMA(UK), an application for authorisation for the medicinal product to be placed on the market is under consideration in one or more member States—
  - (i) a list of the member State or States concerned, and
  - (ii) in relation to each such application, a copy of the summary of the product characteristics, and the package leaflet, proposed by the applicant;
- (b) in the case of a medicinal product for sale or supply in Great Britain, an application for authorisation for the medicinal product to be placed on the market is under consideration in a country other than the United Kingdom, or by the EMA, notification of that fact.”;
- (c) for paragraph (4) substitute—
 

“(4) In paragraph 19, for “a member State or by a third country” substitute “, in the case of a medicinal product for sale or supply in Northern Ireland, a member State or by a country other than an EEA State, or in the case of a medicinal product for sale or supply in Great Britain, by a country other than the United Kingdom or by the European Commission”.”;
- (d) for paragraph (5) substitute—
 

“(5) In paragraph 20, after “Where” insert “, in the case of a medicinal product for sale or supply in Northern Ireland,”.”;
- (e) for paragraph (6) substitute—
 

“(6) For paragraph 21 substitute—

**“21. Where an authorisation for the medicinal product to be placed on the market has been refused—**

  - (a) in the case of a medicinal product for sale or supply in Northern Ireland, by a member State or by a country other than an EEA State, or
  - (b) in the case of a medicinal product for sale or supply in Great Britain, by a country other than the United Kingdom,

details of that decision and of the reasons for it.”.”;
- (f) for paragraph (7) substitute—
 

“(7) In paragraph 22 for “A copy of any” substitute “In the case of a medicinal product for sale or supply in Northern Ireland, a copy of any”.”;
- (g) for paragraph (8) substitute—
 

“(8) For paragraph 23 substitute—

**“23. For medicinal products included on the list referred to—**

  - (a) in the case of a medicinal product for sale or supply in Northern Ireland, in Article 23 of Regulation (EC) No 726/2004, the symbol and statement “▼ This medicinal product is subject to additional monitoring”, or
  - (b) in the case of a medicinal product for sale or supply in Great Britain, in regulation 202A, the symbol and statement “▼ This medicinal product is subject to additional monitoring”.”.”;
- (h) in paragraph (9), in the inserted paragraph 25A, after “advanced therapy medicinal product” insert “for sale or supply in Great Britain”;



- (i) in paragraph (10), in the inserted paragraph 36, after “advanced therapy medicinal product” insert “for sale or supply in Great Britain”.

39. After regulation 51 (amendment of Schedule 8A (material to accompany an application for a parallel import licence)) insert—

**“Insertion of new Schedule 8C in relation to material to accompany unfettered access applications**

51A. Schedule 2A inserts a new Schedule 8C after Schedule 8B.”.

40. In regulation 53 (new regulation 50A to 50J (applications in relation to particular medicinal products))—

- (a) in the inserted regulation 50A (requirement for certain applications to include results of paediatric investigation plan)—

- (i) in paragraph (1)(a) and (b) for “UK marketing authorisation” substitute “UKMA(GB) or UKMA(UK)”; and

- (ii) after paragraph (6) insert—

- “(7) In the case of an application for a UKMA(GB) under the unfettered access route, an agreed paediatric investigation plan in respect of the product’s marketing authorisation in Northern Ireland applies also to that application as regards the UK marketing authorisation.

- (8) This regulation does not remove, in respect of an application for a UKMA(UK), the obligation also to comply with the requirements of the Paediatric Regulation in connection with the agreement of, and compliance with, an EU agreed paediatric investigation plan in relation to Northern Ireland.”;

- (b) in the inserted regulation 50B(1) (agreement and modification of paediatric investigation plan), after “paediatric investigation plan” insert “for the purposes of an application to which regulation 50A applies”;

- (c) in the inserted regulation 50E (application for paediatric use marketing authorisation)—

- (i) in paragraph (1) for “UK marketing authorisation” substitute “UKMA(GB) or UKMA(UK)”; and

- (ii) after paragraph (4) insert—

- “(5) This regulation does not remove, in respect of an application for a UKMA(UK), the obligation also to comply with the requirements of the Paediatric Regulation in connection with the agreement of, and compliance with, an EU agreed paediatric investigation plan in relation to Northern Ireland.”;

- (d) in the inserted regulation 50F(1)(a) and (b) (other applications including paediatric indications), for “UK marketing authorisation” substitute “UKMA(GB)”; and

- (e) in the inserted regulation 50G (applications relating to orphan medicinal products)—

- (i) for paragraph (1) substitute—

- “(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product—

- (a) in relation to which the applicant intends to demonstrate that the orphan criteria are met, and

- (b) which, in the case of an application for a UKMA(NI) or a UKMA(UK), is not a medicinal product designated as an orphan medicinal product in accordance with the Orphan Regulation.”;

- (ii) in paragraph (2)(b)(i) and (c) for “the United Kingdom” substitute “Great Britain”;
- (f) in the inserted regulation 50H(1) and (3) (applications relating to advanced therapy medicinal products), for “UK marketing authorisation” substitute “UKMA(GB)”;
- (g) in the inserted regulation 50I (applications relating to conditional marketing authorisations)—
  - (i) in the heading, at the end insert “for sale or supply in Great Britain only”;
  - (ii) in paragraph (1), for “UK marketing authorisation” substitute “UKMA(GB)”.

**41.** For regulation 56 (substitution of regulation 51 (applications relating to generic medicinal products)) substitute—

**“Substitution of regulation 51 (applications relating to generic medicinal products)**

**56.** For regulation 51 substitute—

**“Application for UKMA(NI) relating to generic medicinal products**

**51.—**(1) An applicant for a UKMA(NI) for a relevant medicinal product that is a generic medicinal product may provide information in relation to the application in accordance with Article 10(1), (5) and (6) of the 2001 Directive.

(2) If the licensing authority grants a UKMA(NI) for the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in Northern Ireland before the time at which it may be placed on the market in accordance with Article 10(1) of the 2001 Directive as modified by paragraph (3).

(3) The second subparagraph of Article 10(1) of the 2001 Directive has effect with the exception described in paragraph (4).

(4) Where—

- (a) ten years have elapsed since a UK marketing authorisation was granted otherwise than under Chapter 4 of Title III to the 2001 Directive in relation to the reference medicinal product;
- (b) in relation to that product there is—
  - (i) an EU marketing authorisation, or
  - (ii) a UKMA(NI) which was granted under that Chapter; and
- (c) a period of ten years has not elapsed since the authorisation mentioned in sub-paragraph (b) for sale or supply of that product in the European Union,

the product may not be made available for sale or supply in Northern Ireland until the period mentioned in sub-paragraph (c) has elapsed.

**Application for UKMA(GB) relating to generic medicinal products**

**51A.—**(1) An applicant for a UKMA(GB) for a generic medicinal product may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials if the applicant can demonstrate that the medicinal product is a generic of a reference medicinal product authorised for sale or supply in Great Britain which is or has been authorised for not less than eight years—

- (a) under regulation 49(1)(a); or

(b) if the product is an EU reference medicinal product, under Regulation (EC) No 726/2004.

(2) In the case of an application under this regulation in relation to a salt, ester, ether, isomer, mixture of isomers, complex or derivative of an authorised active substance which differs significantly in properties with regard to safety or efficacy from the active substance in the reference medicinal product, the applicant must supply additional information providing proof of the safety or efficacy of the salt, ester, ether, isomer, mixture of isomers, complex or derivative.

(3) The applicant may omit bioavailability studies from an application under this regulation if the applicant can demonstrate that the generic medicinal product meets the relevant criteria as specified in the guidelines referred to in paragraph (4).

(4) The licensing authority may publish guidelines specifying the criteria to be met by generic medicinal products for the purpose of omitting bioavailability studies from an application in accordance with paragraph (3).

(5) Until replaced by guidelines published under paragraph (4), the guidelines published by the EMA under Article 10(2)(b) of the 2001 Directive<sup>(2)</sup> continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under paragraph (4)).

(6) If the licensing authority grants a UKMA(GB) in relation to the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in Great Britain before the expiry of ten years beginning with the date on which the marketing authorisation for the reference medicinal product entered into force.

(7) Paragraph (8) applies where an EU reference medicinal product which falls within paragraph (b)(ii) of the definition of “reference medicinal product” is used as a reference medicinal product for the purposes of this regulation.

(8) Where this paragraph applies, the terms of the marketing authorisation of the EU reference medicinal product are treated as being the terms of the product’s EU marketing authorisation as they stood immediately before IP completion day.

(9) Paragraph (10) applies if—

(a) during the first eight of the ten years referred to in paragraph (6) the marketing authorisation holder for the reference medicinal product obtained a UKMA(GB) or a UKMA(UK) for one or more new therapeutic indications; and

(b) during the scientific evaluation prior to their authorisation, the licensing authority considers the new indications bring a significant clinical benefit in comparison with existing therapies.

(10) Where this paragraph applies, the period of ten years referred to in paragraph (6) is extended to eleven years.

(11) Paragraph (12) applies where—

(a) an application for the grant or variation of a UKMA(GB) is made in relation to a new indication for a well-established substance; and

(b) significant pre-clinical or clinical studies were carried out in relation to the new indication.

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(2) The guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

(12) Where this paragraph applies, the applicant for a UKMA(GB) under paragraph (1) or regulation 52A or 53A may not refer in its application to the studies mentioned in paragraph (11)(b) for the period of one year beginning on the date on which the licensing authority grants or varies a UKMA(GB) in relation to the new indication.

### **Application for UKMA(UK) relating to generic medicinal products**

**51B.**—(1) This regulation applies in relation to an application for a UKMA(UK) for a generic medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

- (a) a UKMA(UK), the provisions of regulation 51(1) and (2) apply in respect of the application;
- (b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) The applicant may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials only after the expiry of both—

- (a) the period referenced in the applicable Article referred to in regulation 51(1), in relation to the UKMA(NI) for the reference medicinal product; and
- (b) the period specified in regulation 51A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) In the case of an application under paragraph (3) in relation to a salt, ester, ether, isomer, mixture of isomers, complex or derivative of an authorised active substance which differs significantly in properties with regard to safety or efficacy from the active substance in the reference medicinal product, the applicant must supply additional information providing proof of the safety or efficacy of the salt, ester, ether, isomer, mixture of isomers, complex or derivative.

(5) If the licensing authority grants a UK marketing authorisation in relation to the generic medicinal product in accordance with paragraph (3), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in the United Kingdom before the expiry of both—

- (a) the period specified in regulation 51(2), in relation to the UKMA(NI) for the reference medicinal product; and
- (b) the period specified in regulation 51A(6) or (where applicable) 51A(10), in relation to the UKMA(GB) for the reference medicinal product.

(6) Paragraph (7) applies where—

- (a) an application for the grant or variation of a UKMA(UK) is made in relation to a new indication for a well-established substance; and
- (b) significant pre-clinical or clinical studies were carried out in relation to the new indication.

(7) Where this paragraph applies, the applicant for a UKMA(UK) under paragraph (1) or regulation 52B or 53B may not refer in its application to the studies mentioned in paragraph (6)(b) for the period of one year beginning on the date on which the licensing authority grants or varies a UKMA(UK) in relation to the new indication.”.”.

42. For regulation 57 (amendment of regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc)) substitute—

**“Substitution of regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc)**

57. For regulation 52 substitute—

**“Application for UKMA(NI) relating to certain medicinal products that do not qualify as generic etc**

52.—(1) This regulation applies where—

- (a) an application is made for a UKMA(NI) by reference to another medicinal product as reference medicinal product; and
- (b) one or more of the circumstances listed in Article 10(3) of the 2001 Directive applies in respect of the application.

(2) The applicant must provide information in accordance with Article 10(3) and (6) of the 2001 Directive.

(3) Paragraphs (2) to (4) of regulation 51 apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

**Application for UKMA(GB) relating to certain medicinal products that do not qualify as generic etc**

52A.—(1) This regulation applies where—

- (a) an application is made for a UKMA(GB) in respect of a product by reference to another medicinal product as reference medicinal product which is or has been authorised for sale or supply in Great Britain for not less than eight years—
  - (i) under regulation 49(1)(a); or
  - (ii) if the product is an EU reference medicinal product, under Regulation (EC) No 726/2004; and
- (b) one or more of the following circumstances applies in respect of the application—

- (i) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,
- (ii) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or
- (iii) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration.

(2) The applicant—

- (a) may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials relating to the reference medicinal product; but
- (b) must provide the results of the appropriate pre-clinical tests or clinical trials relating to the applicable circumstance in paragraph (1)(b).

(3) Paragraphs (2) to (10) of regulation 51A apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

**Application for UKMA(UK) relating to certain medicinal products that do not qualify as generic etc**

**52B.**—(1) This regulation applies in relation to an application for a UKMA(UK) in respect of a product by reference to another medicinal product as reference medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

- (a) a UKMA(UK), the provisions of regulation 52(1) and (2) apply in respect of the application;
- (b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) Subject to paragraph (4), the applicant may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials only after the expiry of both—

- (a) the period referenced in the applicable Article referred to regulation 52(1), in relation to the UKMA(NI) for the reference medicinal product; and
- (b) the period specified in regulation 52A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) Where one or more of the following circumstances applies in respect of the application—

- (a) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,
- (b) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or
- (c) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration,

the applicant must provide the results of the appropriate pre-clinical tests or clinical trials relating to the applicable circumstance.

(5) Paragraphs (4) and (5) of regulation 51B apply to the application as they apply in relation to an application made in accordance with paragraph (3) of that regulation.”.”.

**43.** For regulation 58 (amendment of regulation 53 (applications relating to similar biological medicinal products) substitute—

**“Substitution of regulation 53 (applications relating to similar biological medicinal products)**

**58.** For regulation 53 substitute—

### **“Application for UKMA(NI) relating to similar biological medicinal products**

**53.**—(1) This regulation applies if an applicant for a UKMA(NI) for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of any of the reasons described in Article 10(4) of the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10(4) and (6) of the 2001 Directive.

(3) Paragraphs (2) to (4) of regulation 51 apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

### **Application for UKMA(GB) relating to similar biological medicinal products**

**53A.**—(1) This regulation applies if an applicant for a UKMA(GB) for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product.

(2) The applicant—

(a) may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials relating to a reference medicinal product which is or has been authorised for not less than eight years—

(i) under regulation 49(1)(a), or

(ii) if the reference medicinal product is an EU reference medicinal product, under Regulation (EC) No 726/2004; but

(b) must provide the results of appropriate pre-clinical tests or clinical trials relating to the differences referred to in paragraph (1).

(3) The type and quantity of supplementary data to be provided by the applicant under paragraph (2)(b) must comply with the relevant criteria in Annex I to the 2001 Directive and in the related detailed guidelines published by the licensing authority under paragraph (4), or (as the case may be) as mentioned in paragraph (5).

(4) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (2) (b).

(5) Unless replaced by guidelines published under paragraph (4), the guidelines published by the EMA under Article 10(4) of the 2001 Directive<sup>(3)</sup> continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

(6) Paragraphs (4) to (12) of regulation 51A apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

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(3) The guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

### **Application for UKMA(UK) relating to similar biological medicinal products**

**53B.**—(1) This regulation applies in relation to an application for a UKMA(UK) for a biological medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

(a) a UKMA(UK), the provisions of regulation 53 apply in respect of the application;

(b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) Subject to paragraph (4), the applicant may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials only after the expiry of both—

(a) the period referenced in the applicable Article referred to regulation 53(1), in relation to the UKMA(NI) for the reference medicinal product; and

(b) the period specified in regulation 53A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) Where the applicant for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product, the applicant must provide the results of the appropriate pre-clinical tests or clinical trials relating to the differences.

(5) The type and quantity of supplementary data to be provided by the applicant under paragraph (4) must comply with the relevant criteria in Annex I to the 2001 Directive and in the related detailed guidelines published by the licensing authority under paragraph (6), or (as the case may be) as mentioned in paragraph (7).

(6) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (4).

(7) Unless replaced by guidelines published under paragraph (6), the guidelines published by the EMA under Article 10(4) of the 2001 Directive<sup>(4)</sup> continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

(8) Paragraphs (4) and (5) of regulation 51B apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.”.”.

**44.** For regulation 60 (amendment of regulation 55 (applications relating to new combinations of active substances)) substitute—

### **“Substitution of regulation 55 (applications relating to new combinations of active substances)**

**60.** For regulation 55 substitute—

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(4) The guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.



“55.—(1) This regulation applies to an application for a UK marketing authorisation for a relevant medicinal product that contains active substances, provided those active substances—

- (a) have not been used in that combination for therapeutic purposes; and
- (b) where the application is for—
  - (i) a UKMA(NI), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations, the 2001 Directive or Regulation (EC) No 726/2004;
  - (ii) a UKMA(GB), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations; or
  - (iii) a UKMA(UK), have been used in medicinal products that have been the subject of—
    - (aa) a UKMA(UK) under these Regulations; or
    - (bb) a relevant Northern Ireland authorisation.

(2) The applicant must provide the results of new pre-clinical tests or new clinical trials relating to that combination in accordance with paragraph 10 of Schedule 8, but does not need to provide scientific references relating to each individual active substance.

(3) In paragraph (1), “relevant Northern Ireland authorisation” means—

- (a) a UKMA(NI) under these Regulations;
- (b) a marketing authorisation under the 2001 Directive; or
- (c) an EU marketing authorisation,

which authorises the sale or supply of a medicinal product in Northern Ireland.”.”.

**45.** In regulation 62 (amendment of regulation 58 (consideration of application))—

(a) in paragraph (2), for the inserted paragraphs (4A) and (4B) substitute—

“(4A) When considering an application for a UK marketing authorisation, the licensing authority may, if it considers it appropriate, have regard to—

- (a) an opinion of the Committee for Medicinal Products for Human Use; or
- (b) the results of an assessment of an application for a marketing authorisation by the appropriate authority for the licensing of medicinal products of a country other than the United Kingdom,

in respect of the medicinal product to which the application relates.

(4B) The licensing authority may under paragraph (4A)—

- (a) decide to have regard to the opinions and assessments described in that paragraph in relation to certain types of medicinal products only;
- (b) determine and publish a list of the countries other than the United Kingdom whose assessments of applications for a marketing authorisation are relevant for the purposes of paragraph (4A)(b); and
- (c) decide to have regard to the assessments described in paragraph (4A)(b) in relation to medicinal products that have been authorised by way of certain procedures only.

(4C) When considering an application for a UK marketing authorisation (other than an application under the unfettered access route), the licensing authority may, if it considers it appropriate and without undertaking further consideration, rely on a decision by the

European Commission to authorise the medicinal product to which the application relates to establish that any or all of the conditions in paragraph (4)(a), (b) or (d) have been met.”;

(b) for paragraph (3) substitute—

“(4) After paragraph (7) insert—

“(8) In the case of an application under the unfettered access route, the licensing authority may grant a UKMA(GB) (notwithstanding paragraph (4)) where the licensing authority—

(a) has considered the application under the unfettered access route and the accompanying material,

(b) is satisfied that the applicant has complied with the application requirements, and

(c) is satisfied that the conditions in regulation 50 will continue to be met.

(9) The licencing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.”.

**46.** In regulation 63 (amendment of Schedule 11 (advice and representations))—

(a) for paragraph (2)(c) substitute—

“(c) for sub-paragraph (2) substitute—

“(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.”;

(b) for paragraph (4) substitute—

“(4) In paragraph 14(a) (application of Part 2), after “veterinary medicinal products” insert “or paragraph 1 of Schedule 10A”.”;

(c) for paragraph (7) substitute—

“(7) For paragraph 17 substitute—

“**17.** In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.”;

(d) for paragraph (8)(b)(ii) substitute—

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

“(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.”; and”;

(e) for paragraph (9) substitute—

“(9) In Part 4 (exceptions to Schedule) omit paragraphs 31, 34, 35, 37 and 38.”.

**47.** In regulation 64 (insertion of provisions concerning consideration of certain applications for UK marketing authorisations)—

(a) in the inserted regulation 58A (paediatric rewards)—

(i) for paragraph (1) substitute—

“(1) Paragraph (2) applies if—

(a) an application—

(i) to which regulation 50A (requirement for certain applications to include the results of a paediatric investigation plan) applies, and in relation to which there is an agreed paediatric investigation plan; or

- (ii) to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan, is granted by the licensing authority; and
- (b) the licensing authority is satisfied that the material provided by the applicant pursuant to—
  - (i) regulation 50A(3), where paragraph (1)(a)(i) applies; or
  - (ii) Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,demonstrates compliance with the agreed paediatric investigation plan.”;
- (ii) for paragraph (3) substitute—
  - “(3) Where—
    - (a) paragraph (2) applies; or
    - (b) an application to which Article 7 or 8 of the Paediatric Regulation applies—
      - (i) includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or
      - (ii) confirms completion of an EU agreed paediatric investigation plan which failed to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, the package leaflet of the medicinal product,the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).”;
- (iii) for paragraph (4)(b) substitute—
  - “(b) the holder of the UK marketing authorisation is entitled to a one year extension of the ten year period referred to in regulation 51A(6), under regulation 51A(12).”;
- (iv) after paragraph (4) insert—
  - “(4A) Paragraph (3) does not apply where—
    - (a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does not cover the whole of the United Kingdom; and
    - (b) the UK marketing authorisation in which the statement of compliance is included is not in force in the same part of the United Kingdom as the supplementary protection certificate.
  - (4B) Where—
    - (a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does cover the whole of the United Kingdom; and
    - (b) the UK marketing authorisation in which the statement of compliance is included is in force in in Great Britain only or in Northern Ireland only,

the extension provided for in paragraph (3) only applies in relation to Great Britain only or Northern Ireland only (as appropriate).”;

(v) in paragraph (8), for “regulation 51(1) and (8)” substitute “regulation 51A(1) and (6)”;

(b) in the inserted regulation 58B (publication of information relating to paediatric marketing authorisations), in paragraph (1)(a) for “agreed investigation paediatric plan” substitute “agreed paediatric investigation plan”;

(c) in the inserted regulation 58C (consideration of applications relating to orphan medicinal products), in paragraph (1), after “application for a UK marketing authorisation” insert “(including an application under the unfettered access route)”;

(d) in the inserted regulation 58D (orphan rewards), omit paragraphs (2) and (3);

(e) in the inserted regulation 58F(1)(b) (consideration of applications relating to conditional marketing authorisations), for “UK marketing authorisation” substitute “UKMA(GB)”.

**48.** In regulation 65 (amendment of regulation 59 (conditions of UK marketing authorisation or parallel import licence: general)—

(a) after paragraph (1) insert—

“(1A) In paragraph (3) for “An obligation” substitute “In relation to a UKMA(NI) or UKMA(UK), an obligation”.”;

(b) omit paragraph (2);

(c) for paragraph (3) substitute—

“(3) After paragraph (3), insert—

“(3A) In relation to a UKMA(GB), an obligation to conduct such studies as are referred to in paragraph (2)(f) must—

(a) be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive; and

(b) take into account the scientific guidance that applies under regulation 205B in relation to post-authorisation efficacy studies.

(3B) The Secretary of State may by regulations make provision in respect of Great Britain specifying the situations in which post-authorisation efficacy studies may be required by virtue of the condition referred to in paragraph (2)(f).

(3C) Paragraph (3A)(a) ceases to apply on the coming into force of regulations made under paragraph (3B).”.”;

(d) for paragraph (6) substitute—

“(6) In paragraph (5) for “marketing authorisation” substitute “UKMA(NI) or UKMA(UK).”.

**49.** For regulation 66 (amendment of regulation 60 (conditions of UK marketing authorisation: exceptional circumstances)) substitute—

“**66.** In regulation 60—

(a) after “UK marketing authorisation” in each place it occurs (including the heading to the regulation) insert “or parallel import licence”;

(b) after “the authorisation” in each place it occurs insert “or licence”;

(c) in paragraph (3), after “an authorisation” insert “or licence”;

(d) for paragraph (9) substitute—

“(9) The licensing authority must notify the EMA of any UKMA(NI) or UKMA(UK) that it has granted subject to a condition included in accordance with this regulation.”;

(e) in paragraph (10), after “a marketing authorisation” insert “or licence”.

**50.** In regulation 67 (insertion of new regulations 60A (condition as to the submitting of samples and other information to the appropriate authority))—

(a) in the heading to the regulation, at the end insert “and 60B (submitting of samples and other information: EU marketing authorisations)”

(b) in the inserted regulation 60A—

(i) in paragraph (1), for the definition of “the batch testing exemption” substitute—

““the batch testing exemption” means that—

(a) in the case of a medicinal product for sale or supply in Northern Ireland only—

(i) a certificate has been issued by a laboratory in an EEA State, and

(ii) in relation to a product of a kind listed in Article 114(1) of the 2001 Directive, the certificate was issued in the same EEA State as that in which the batch was manufactured, or

(b) (i) a certificate has been issued by a laboratory in a country other than the United Kingdom,

(ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country, a group of countries or an organisation of which that country is a part), and

(iii) that agreement is to the effect that the appropriate authority will recognise that certificate in respect of the batch of the medicinal product, in place of the appropriate authority’s own examination of a sample from the batch, the appropriate documentation or both.”;

(ii) in paragraph (2)(b), omit “medicinal”;

(iii) in paragraph (5) after “paragraph (6)” insert “and regulation 60B(5)”;

(iv) in paragraphs (9)(a) and (b), after “batch testing exemption” insert “under this regulation or regulation 60B”;

(v) after paragraph (13) insert—

“(14) The appropriate authority may, in any particular case, apply this regulation to a medicinal product imported into the United Kingdom pursuant to a parallel import licence and accordingly any reference in this regulation to—

(a) a UK marketing authorisation should be read as a reference to a parallel import licence for a medicinal product,

(b) the holder of a UK marketing authorisation should be read as a reference to the holder of a parallel import licence, and

(c) the approved specifications in a UK marketing authorisation should be read as a reference to the approved specifications in the UK reference product specified for the purposes of the parallel import licence in accordance with paragraph 4 of Schedule 8A.

(15) Where, pursuant to paragraph (14), this regulation is applied to a medicinal product imported into the United Kingdom pursuant to a parallel import licence, subparagraph (a) of the definition of “the batch testing exemption” does not apply.

(16) In the application of this regulation to a medicinal product for sale or supply in Northern Ireland only to which Article 114 of the 2001 Directive applies, a reference in this regulation to a laboratory is to an Official Medicines Control Laboratory or a laboratory referred to in that Article.”;

(c) after the inserted regulation 60A insert—

**“Submitting of samples and other information: EU marketing authorisations**

**60B.**—(1) In this regulation—

“the appropriate authority” is to be construed in accordance with section 57(7) of the Health and Social Care Act 2012<sup>(5)</sup>;

“appropriate documentation”, in relation to a sample of a batch submitted to the appropriate authority in accordance with the batch testing requirement or pursuant to a notification under paragraph (8), means such documentation as the appropriate authority notifies the holder of the EU marketing authorisation to which the sample relates that it requires;

“approved country list for batch testing and certification of biological medicinal products” means the list described in regulation 60A(5), and “approved country for batch testing and certification of biological medicinal products” means a country included in that list;

“the batch testing exemption” means that—

- (a) (i) a certificate has been issued by a laboratory in an EEA State, and
  - (ii) in relation to a product of a kind listed in Article 114(1) of the 2001 Directive, the certificate was issued in the same EEA State as that in which the batch was manufactured, or
- (b) (i) a certificate has been issued by a laboratory in a country other than the United Kingdom,
  - (ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country, a group of countries or an organisation of which that country is a part), and
  - (iii) that agreement is to the effect that the appropriate authority will recognise that certificate in respect of the batch of the medicinal product, in place of the appropriate authority’s own examination of a sample from the batch, the appropriate documentation or both;

“the batch testing requirement”, in respect of an EU marketing authorisation, is a requirement that, unless the batch testing exemption applies, the holder of the EU marketing authorisation—

- (a) must submit a sample from each batch of the medicinal product that is the subject of that authorisation to the appropriate authority, together with appropriate documentation; and
- (b) must not sell or supply, or offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

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(5) 2012 c.7.

- (i) the sample from that batch,
- (ii) the appropriate documentation, or
- (iii) both that sample and that documentation,

and confirmed that it is satisfied that the batch is in conformity with the approved specifications in the EU marketing authorisation.

(2) The licensing authority may impose the batch testing requirement on the holder of an EU marketing authorisation for a medicinal product—

- (a) that is—
  - (i) a live vaccine;
  - (ii) an immunological product used in the primary immunisation of infants or other groups at risk;
  - (iii) an immunological product used in public health immunisation programmes;
  - (iv) subject to paragraph (3), a new immunological product manufactured using new or altered kinds of technology or new for a particular manufacturer; or
  - (v) derived from human blood or human plasma, and
- (b) which is intended for sale or supply in Northern Ireland.

(3) If the licensing authority imposes the batch testing requirement in respect of an EU marketing authorisation for a medicinal product of a kind mentioned in paragraph (2)(a)(iv), it must, in imposing that requirement, specify a period of time for the duration of the requirement.

(4) The appropriate authority must complete its examination of the sample for testing, the appropriate documentation or both (as the case may be) within the period of 60 days, beginning with the date on which the appropriate authority is in receipt of both the sample for testing, and the appropriate documentation.

(5) Where a holder of an EU marketing authorisation, in order to comply with the batch testing requirement, submits appropriate documentation that includes a certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products in respect of the batch, the appropriate authority must, in addition to any other factors it considers relevant, take that into account in determining whether the appropriate authority needs to undertake any further testing of the medicinal product submitted to it.

(6) Where a holder of an EU marketing authorisation relies on the batch testing exemption in relation to a batch of a medicinal product, that holder must submit the certificate in respect of that batch to the licensing authority and the appropriate authority, and such other documentation as those authorities may notify that holder they require, before it sells or supplies, or offers to sell or supply, a medicinal product that forms part of that batch in Northern Ireland.

(7) Paragraph (8) applies where the appropriate authority considers that there are public health concerns in respect of a batch of a medicinal product (“the relevant batch”) in relation to which the batch testing exemption would otherwise apply.

(8) Where this paragraph applies, the appropriate authority must, subject to paragraph (9), notify the holder of the EU marketing authorisation in respect of the relevant batch that it nevertheless requires that holder—

- (a) to submit a sample from the relevant batch to the appropriate authority, together with appropriate documentation; and
- (b) not to sell or supply, or to offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—
  - (i) the sample from that batch,
  - (ii) the appropriate documentation, or
  - (iii) both that sample and that documentation,

and confirmed that it is satisfied that the relevant batch is in conformity with the approved specifications in the EU marketing authorisation.

(9) The appropriate authority may only exercise its powers under paragraph (8) if the agreement made between the country in which the certificate was issued, and the United Kingdom (whether the agreement is solely with that country, a group of countries or an organisation of which that country is a part) provides for the relevant batch to be re-examined by the appropriate authority in the circumstances described in paragraph (7).

(10) A reference in this regulation to a laboratory (other than in paragraph (b) of the definition of “the batch testing exemption” in paragraph (1)) is to an Official Medicines Control Laboratory or a laboratory referred to in Article 114 of the 2001 Directive.”.

**51.** In regulation 68 (amendment of regulation 61 (conditions of UK marketing authorisation))—

- (a) in paragraph (2), in the inserted paragraph (4)(b), before “to comply” insert “in relation to a UKMA(GB),”;
- (b) after paragraph (2) insert—
  - “(2A) In paragraph (6), after “one medicinal product” insert “authorised by a UKMA(NI) or UKMA(UK)”.”;
- (c) for paragraph (3) substitute—
  - “(3) After paragraph (6) insert—
    - “(6A) If concerns as described in paragraph (2) apply to more than one medicinal product authorised by a UKMA(GB), the licensing authority—
      - (a) must, where the obligation is to conduct a post-authorisation safety study, encourage the UK marketing authorisation holders concerned to conduct a joint study, and
      - (b) may, where the obligation is to comply with any other conditions or restrictions, encourage the UK marketing authorisation holders concerned to take co-ordinated action to comply with the conditions or restrictions.”.”;
- (d) after paragraph (3) insert—
  - “(3A) In paragraph (7) for “The obligation under paragraph (5) shall” substitute “In relation to a UKMA(NI) or UKMA(UK), the obligation under paragraph (5) must”.”;
- (e) for paragraph (4) substitute—
  - “(4) After paragraph (7) insert—
    - “(7A) In relation to a UKMA(GB), the obligation under paragraph (5) must—
      - (a) be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive; and
      - (b) take into account the scientific guidance that applies under regulation 205B in relation to post-authorisation efficacy studies.



(7B) The Secretary of State may by regulations make provision in respect of Great Britain specifying the situations in which post-authorisation efficacy studies may be required by virtue of the obligation under paragraph (5).

(7C) Paragraph (7A)(a) ceases to apply on the coming into force of regulations made under paragraph (7B).”.”;

(f) for paragraph (5) substitute—

“(5) In paragraph (13), after “notify the EMA” insert “, in relation to a UKMA(NI) or UKMA(UK),”.”.

**52.** For regulation 69 (amendment of regulation 64 (duties of licensing authority in connection with determination)) substitute—

“**69.** For regulation 64(4)(d) substitute—

“(d) any conditions—

(i) in the case of a UKMA(NI) or UKMA(UK), established in accordance with Articles 21a, 22 and 22a of the 2001 Directive;

(ii) in the case of UKMA(GB), imposed under regulations 59 to 61; and”.”.

**53.** In regulation 70 (obligation of licensing authority in case of change of classification), in the inserted regulation 64A, for paragraph (2)(a) substitute—

“(a) the licensing authority grants or varies—

(i) a UK marketing authorisation;

(ii) an Article 126a authorisation;

(iii) a traditional herbal registration; or

(iv) a certificate of registration of a homoeopathic medicinal product;”.

**54.** In regulation 72 (validity of conditional marketing authorisation and variation of a UK marketing authorisation), in the inserted regulation 65C—

(a) in the heading to the regulation, for “UK marketing authorisation” substitute “UKMA(GB)”;

(b) in paragraphs (1) and (3), for “UK marketing authorisation” substitute “UKMA(GB)”;

(c) in paragraph (6), for “exit day” in each place it occurs substitute “IP completion day”.

**55.** In regulation 74 (amendment of regulation 66 (application for renewal of authorisation)) for “66(2)” to the end substitute—

“66, for paragraph (2) substitute—

“(2) The applicant, where it is applying for renewal of—

(a) a UKMA(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a UKMA(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a UKMA(UK), must be established in the United Kingdom.”.”;

56. After regulation 76 (renewal of conditional marketing authorisation) insert—

**“Amendment of regulation 67 (failure to place on the market etc.)**

**76A.**—(1) Regulation 67 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after “in the United Kingdom” insert “(or, in the case of a UKMA(GB) granted after an application under the unfettered access route, in Great Britain)”.

(3) In paragraph (2) after “in the United Kingdom” insert “(or, in the case of a UKMA(GB) granted after an application under the unfettered access route, in Great Britain)”.

57. In regulation 77 (amendment of regulation 68 (revocation, variation and suspension of UK marketing authorisation or parallel import licence))—

(a) in paragraph (3), for sub-paragraph (b) substitute—

“(b) for “established in the European Union” substitute—

“established in—

(a) the United Kingdom; or

(b) in relation to a UKMA(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.”;

(b) for paragraph (5) substitute—

“(5) In paragraph (9)(a) omit “other than the United Kingdom”;

(c) in paragraph (8)—

(i) in the inserted paragraph (11E), for “exit day” in both places it occurs substitute “IP completion day”;

(ii) after the inserted paragraph (11F), insert—

“(11G) Condition P is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.”.

58. In regulation 80(2) (amendment of regulation 71 (withdrawal of medicinal product from the market)) for sub-paragraph (b) substitute—

“(b) for sub-paragraph (b) substitute—

“(b) under—

(i) regulation 69 the licensing authority suspends the use, sale, supply or offer for sale or supply within Great Britain of a product to which a UKMA(GB) relates; or

(ii) regulation 69 or Article 20(4) of Regulation (EC) No 726/2004 the licensing authority suspends the use, sale, supply or offer for sale or supply within Northern Ireland of a product to which a UKMA(NI) or UKMA(UK) relates.”.

59. For regulation 81 (amendment of regulation 72 (sale etc of suspended medicinal product)) substitute—

“**81.** In regulation 72(1), for “regulation 69 or 70(2) or Article 20(4) of Regulation (EC) No 726/2004” substitute—

“—

- (a) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), regulation 69;
- (b) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or UKMA(UK), regulation 69 or Article 20(4) of Regulation (EC) No 726/2004.”.”.

**60.** In regulation 82 (amendment of regulation 73 (obligation to notify placing on the market etc) for paragraph (3) substitute—

“(3) In paragraph (5C), for “UK marketing authorisation” insert “UKMA(NI) or UKMA(UK)”.”.

**61.** For regulation 84 (amendment of regulation 76 (obligation in relation to product information)) substitute—

“**84.** For regulation 76(2), substitute—

“(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of—

- (a) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or a UKMA(UK)—
  - (i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and
  - (ii) the UK web-portal established in accordance with regulation 203(1);
- (b) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), the UK web-portal established in accordance with regulation 203(1).”.”.

**62.** Omit regulation 85 (amendment of regulation 77 (record-keeping obligations)).

**63.** Omit regulation 86 (amendment of regulation 78 (obligation to ensure appropriate and continued supplies)).

**64.** In regulation 87 (post authorisation requirements in relation to UK marketing authorisations with paediatric aspects and advanced therapy medicinal products), in the inserted regulation 78B (post authorisation requirements in relation to UK marketing authorisations for advanced therapy medicinal products)—

- (a) in the heading to the regulation for “UK marketing authorisations” substitute “UKMA(GB)”;
- (b) for “UK marketing authorisation” in each place it appears substitute “UKMA(GB)”.

**65.** For regulation 88 (omission of regulation 79 (failure to provide information on marketing authorisations to EMA)) substitute—

**“Amendment of regulation 79 (failure to provide information on marketing authorisations to EMA)**

**88.** In regulation 79 (failure to provide information on marketing authorisations to EMA)

- (a) in paragraph (1), for the first reference to “a marketing authorisation” substitute “a UKMA(NI) or UKMA(UK)”;
- (b) in paragraph (2), for the first reference to “a marketing authorisation” substitute “UKMA(NI) or UKMA(UK)”.”.

**66.** In regulation 89 (amendment of regulation 80 (urgent safety restrictions))—

- (a) for paragraph (3) substitute—
  - “(3) For paragraph (a) substitute—
    - “(a) fails—
      - (i) in respect of a UKMA(GB) or UKMA(UK), to inform the licensing authority in accordance with paragraph 14(1) of Schedule 10A, or
      - (ii) in respect of a UKMA(NI), UKMA(UK) or EU marketing authorisation, to inform the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008,
    - that the holder has taken urgent safety restrictions on the holder’s own initiative;”.
- (b) for paragraph (4) substitute—
  - “(4) For paragraph (b) substitute—
    - “(b) fails—
      - (i) in respect of a UKMA(GB), to implement an urgent safety restriction imposed on the holder by the licensing authority in accordance with paragraph 14(3) of Schedule 10A, or
      - (ii) in respect of a UKMA(NI) or UKMA(UK), to implement an urgent safety restriction imposed on the holder by the European Commission under Article 22(2) of Regulation (EC) No 1234/2008; or”.
- (c) after paragraph (4) insert—
  - “(4A) In paragraph (c) after “fails” insert “in respect of a UKMA(NI)”.
- (d) in paragraph (5)—
  - (i) for “For sub-paragraph (c) substitute” substitute “After paragraph (c) insert”;
  - (ii) renumber the paragraph inserted as sub-paragraph (d);
  - (iii) in the paragraph inserted, after “fails” insert “in respect of a UKMA(GB)”.

**67.** For regulation 90 (omission of regulations 81 to 94 (offences relation to EU marketing authorisations) substitute—

**“Application of regulations 81 to 94 (offences relating to EU marketing authorisations)**

**90.** Before regulation 81 (obligation to update information supplied in connection with EU application), insert—

**“Application of regulations 81 to 94**

**A81.** Regulations 81 to 94 apply in relation to medicinal products for sale or supply in Northern Ireland.”.

**Amendment of regulation 89 (offences in connection with withdrawal of product from market)**

**90A.** In regulation 89(1)(b) (offences in connection with withdrawal of product from market) for “any of Articles 36, 37 and 38” substitute “Article 37 or 38”.

**Omission of regulation 91 (failure to notify results of third country clinical trials)**

**90B.** Omit regulation 91.”.

**68.** For regulation 91 (omission of regulation 94A (offences relating to Commission Regulation 2016/161)) substitute—

**“Amendment of regulation 94A (offences relating to Commission Regulation 2016/161)**

**91.** In regulation 94A—

(a) for paragraph (1) substitute—

“(1) A person who is—

- (a) the holder of a UKMA(NI), UKMA(UK) or parallel import licence, or
- (b) a parallel distributor,

is guilty of an offence if the holder fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).”;

(b) for paragraph (3) substitute—

“(3) In this regulation “parallel distributor” means a person who imports into Northern Ireland from an EEA state a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004 and in relation to which that person is not the holder of a UKMA(NI), UKMA(UK), Article 126a authorisation, COR(NI), COR(UK), THR(NI) or THR(UK).”.

**69.** For regulation 92 (amendment of regulation 95 (offences in connection with application)) substitute—

**“Amendment of regulation 95 (offences in connection with application)**

**92.** In regulation 95—

(a) in sub-paragraph (c), before “fails” insert “, in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,”;

(b) in sub-paragraph (d), before “provides” insert “, in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland.”.

**70.** Omit regulation 93 (amendment of regulation 96 (provision of misleading information)).

**71.** In regulation 94 (amendment of regulation 97 (breach of pharmacovigilance condition)), omit paragraph (2).

**72.** Omit regulation 95 (amendment of regulation 98 (general offence of breach of Part 5)).

**73.** Omit regulation 96 (amendment of regulation 99 (penalties)).

**74.** Omit regulation 97 (amendment of regulation 101 (defences)).

**75.** In regulation 98 (amendment of regulation 102 (regulation-making power to amend regulation 102(4) to (6))), for the paragraphs to be inserted substitute—

“(7) The Secretary of State may make regulations in respect of Great Britain to amend paragraphs (4) to (6).

(8) The Secretary of State may only exercise the power in paragraph (7) if the Secretary of State considers that it is necessary to do so because of new scientific evidence.”.

**76.** In regulation 99 (amendment of regulation 103 (application for certificate of registration))—

(a) after paragraph (1) insert—

“(1A) After paragraph (1) insert—

- “(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part (“under the unfettered access route”) and grant a COR(GB) only where—
- (a) there is already in place, or will be at the time the COR(GB) is granted, a certificate of registration in respect of the product authorising sale or supply in Northern Ireland,
  - (b) the applicant complies with the requirements in paragraph (5B), and
  - (c) the registrable homoeopathic medicinal product satisfies the definition of qualifying Northern Ireland goods.
- (1B) A certificate of registration must state whether it is in force in—
- (a) the whole United Kingdom;
  - (b) Great Britain only; or
  - (c) Northern Ireland only,
- and in these Regulations the meaning of a reference to that certificate of registration being “in force” is limited to that territory.”;
- (b) in paragraph (2) for “for “European Union”” to the end substitute—  
“for “must be established in the European Union” substitute—  
“, where it is applying for—
- (a) a COR(NI)—
    - (i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;
    - (ii) on any other basis, must be established in the United Kingdom;
  - (b) a COR(GB)—
    - (i) under the unfettered access route, must be established in Northern Ireland;
    - (ii) other than under the unfettered access route, must be established in the United Kingdom;
  - (c) a COR(UK), must be established in the United Kingdom.”;
- (c) after paragraph (2) insert—
- “(2A) After paragraph (5) insert—
- “(5A) The application must include a statement indicating whether the certificate sought is for sale or supply of the product in—
- (a) the whole United Kingdom;
  - (b) Great Britain only; or
  - (c) Northern Ireland only.
- (5B) The applicant for the grant of a COR(GB) under the unfettered access route must provide—
- (a) the application form submitted in connection with the granting of the COR(NI) which authorises the sale or supply of the product in Northern Ireland;
  - (b) a copy of all material submitted in support of the application for the COR(NI) which authorises the sale or supply of the product in Northern Ireland; and

(c) a copy of the COR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in paragraph (8) which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.”.”.

77. For regulation 100 (amendment of regulation 104 (consideration of application)) substitute—

“**100.**—(1) Regulation 104 (consideration of application) is amended as follows.

(2) After paragraph (6) insert—

“(7) In the case of an application under the unfettered access route, the licensing authority may grant a COR(GB) (notwithstanding paragraph (3)) where the licensing authority—

(a) has considered the application under the unfettered access route and the accompanying material,

(b) is satisfied that the applicant has complied with the application requirements, and

(c) is satisfied that the conditions in regulation 103(1A) will continue to be met.

(8) The licensing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.”.”.

78. In regulation 101 (amendment of regulation 108 (application for renewal of certificate)) for “for “European Union”” to the end substitute—

“for “must be established in the European Union” substitute—

“, where it is applying for renewal of—

(a) a COR(NI) and originally granted—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a COR(GB) and originally granted—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) in the whole United Kingdom, must be established in the United Kingdom.”.”.

79. After regulation 101 (amendment of regulation 108 (application for renewal of certificate)) insert—

**“Amendment of regulation 109 (failure to place on the market etc.)**

**101A.**—(1) Regulation 109 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after “in the United Kingdom” insert “(or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)”.

(3) In paragraph (2) after “in the United Kingdom” insert “(or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)”.”.

## PART 5

### Amendment of Part 6 (amendment of Part 6 (certification of homoeopathic products))

**80.** In regulation 102 (amendment of regulation 110 (revocation, variation and suspension of certificate of registration))—

(a) for paragraph (2) substitute—

“(2) In paragraph (7) for “established in the European Union” substitute—

“established in—

(a) the United Kingdom; or

(b) in relation to a COR(NI), either the United Kingdom or the European Union, in accordance with the requirements of these Regulations.””;

(b) after paragraph (2) insert—

“(2A) After paragraph (8A) insert—

“(8B) Condition I is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.””.

**81.** For regulation 107 (amendment of regulation 116 (obligation in relation to product information)) substitute—

#### “Amendment of regulation 116 (obligation in relation to product information)

**107.** For regulation 116(2), substitute—

“(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product authorised by a COR(NI) or COR(UK)—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product authorised by a COR(GB), the UK web-portal established in accordance with regulation 203(1).””.

## PART 6

### Amendment of Part 7 (amendment of Part 7 (Traditional Herbal Registrations))

**82.** In regulation 110 (amendment of regulation 125 (traditional herbal medicinal products)) for “125(5)(b)” to the end substitute—

“125(5) for sub-paragraph (b) substitute—

“(b) in relation to—

(i) a THR(NI) or THR(UK), the product has been in medicinal use in the European Union for a continuous period of at least 15 years;

(ii) a THR(GB), the product has been in medicinal use in the United Kingdom or a country included in the list published under regulation 125A(1) for a continuous period of at least 15 years.””.



**83.** In regulation 112 (insertion of new italic heading and regulation 126A (list of herbal substances, preparations and combinations for use in traditional herbal medicinal products)), in the inserted regulation 126A(1), after “traditional herbal medicinal products” insert “for which a THR(GB) may be granted”.

**84.** For regulation 113 (amendment of regulation 127 (application for grant of traditional herbal registration)) substitute—

“**113.**—(1) Regulation 127 (application for grant of traditional herbal registration) is amended as follows.

(2) After paragraph (1) insert—

“(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part (“under the unfettered access route”) and grant a THR(GB) only where—

- (a) there is already in place, or will be at the time the THR(GB) is granted, a traditional herbal registration in respect of the product authorising sale or supply in Northern Ireland,
- (b) the applicant complies with the requirements in regulation 128(1A), and
- (c) the traditional herbal medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A traditional herbal registration must state whether it is in force in—

- (a) the whole United Kingdom;
- (b) Great Britain only; or
- (c) Northern Ireland only,

and in these Regulations the meaning of a reference to that traditional herbal registration being “in force” is limited to that territory.”.

(3) In paragraph (3) for “must be established in the European Union” substitute—

“, where it is applying for—

- (a) a THR(NI)—
  - (i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;
  - (ii) on any other basis, must be established in the United Kingdom;
- (b) a THR (GB)—
  - (i) under the unfettered access route, must be established in Northern Ireland;
  - (ii) other than under the unfettered access route, must be established in the United Kingdom;
- (c) a THR(UK), must be established in the United Kingdom.”.

(4) After paragraph (4) insert—

“(4A) The application must include a statement indicating whether the traditional herbal registration sought is for sale or supply of the product in—

- (a) the whole United Kingdom;
- (b) Great Britain only; or
- (c) Northern Ireland only.”.

**85.** For regulation 114 (amendment of regulation 128 (accompanying material)) substitute—

“**114.**—(1) Regulation 128 (accompanying material) is amended as follows.

(2) For paragraph (1) substitute—

“**128.**—(1) The applicant for the grant of a traditional herbal registration other than a THR(GB) under the unfettered access route must provide the material specified in Schedule 12 in relation to the product.

(1A) The applicant for the grant of a THR(GB) under the unfettered access route must provide—

- (a) the application form submitted in connection with the granting of the THR(NI) which authorises the sale or supply of the product in Northern Ireland;
- (b) a copy of all material submitted in support of the application for the THR(NI) which authorises the sale or supply of the product in Northern Ireland; and
- (c) a copy of the THR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in Schedule 12 which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.”.

(3) In paragraph (3), after “of the 2001 Directive” insert “where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB)”.

**86.** For regulation 115(3)(a) (amendment of Schedule 12 (material to accompany an application for a traditional herbal registration)) substitute—

“(a) after “Article 23 of Regulation (EC) No 726/2004” insert “or regulation 202A, as the case may be”.

**87.** In regulation 116 (amendment of regulation 130 (consideration of application))—

(a) in paragraph (3) for “for “Article” to the end substitute—

“for “is subject to” to the end substitute—

“—

(a) where the application is for a THR(NI) or THR(UK), is subject to Article 16c(4) of the 2001 Directive (procedure where product has been used in the European Union for less than 15 years);

(b) where the application is for a THR(GB), is subject to regulation 130A.”.

(b) in paragraph (4) for “for “list referred to” to the end substitute—

“after “of the 2001 Directive” insert “where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB)”.

(c) for paragraph (5) substitute—

“(5) In paragraph (9), after “Where” insert “, in relation to an application for a THR(NI) or THR(UK),”.

(d) in paragraph (6) for “for “Article 16h(3)” to the end substitute—

“for “in Article 16h(3)” to the end substitute—

“—

(i) in Article 16h(3) of the 2001 Directive, where the application is for a THR(NI) or THR(UK);

- (ii) in regulation 143A, where the application is for a THR(GB), that the authority thinks relevant to the application; or”.”;
- (e) for paragraph (7) substitute—
  - “(7) In paragraph (12), after “This regulation does not apply where” insert “, in relation to an application for a THR(NI) or THR(UK),”.”;
- (f) after paragraph (7) insert—
  - “(8) After paragraph (13) insert—
    - “(14) In the case of an application under the unfettered access route, the licensing authority may grant a THR(GB) (notwithstanding paragraph (4)) where the licensing authority—
      - (a) has considered the application under the unfettered access route and the accompanying material,
      - (b) is satisfied that the applicant has complied with the application requirements, and
      - (c) is satisfied that the conditions in regulation 127(1A) will continue to be met.
    - (15) The licencing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.”.”.

**88.** In regulation 117 (Insertion of regulation 130A (procedure where less than 15 years use of traditional herbal medicinal product)), in the inserted regulation 130A(1), for “traditional herbal registration” substitute “THR(GB) (other than an application under the unfettered access route)”.

**89.** In regulation 118 (amendment of regulation 133 (application for renewal of registration)) for “for “European Union”” to the end substitute—

“for “must be established in the European Union” substitute—

“, where it is applying for renewal of—

- (a) a THR(NI)—
  - (i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;
  - (ii) on any other basis, must be established in the United Kingdom;
- (b) a THR(GB)—
  - (i) under the unfettered access route, must be established in Northern Ireland;
  - (ii) other than under the unfettered access route, must be established in the United Kingdom;
- (c) a THR(UK), must be established in the United Kingdom.”.”.

**90.** After regulation 118 amendment of regulation 133 (amendment of regulation 133 (application for renewal of registration)) insert—

**“Amendment of regulation 134 (failure to place on the market etc.)**

**118A.**—(1) Regulation 134 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after “in the United Kingdom” insert “(or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)”.

(3) In paragraph (2) after “in the United Kingdom” insert “(or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)”.

**91.** In regulation 119 (amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration))—

(a) after paragraph (1) insert—

“(1A) For paragraph (6) substitute—

“(6) Condition E is that the holder of the registration has ceased to be established in—

(a) the United Kingdom; or

(b) in relation to a THR(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.”;

(b) in paragraph (2), for “for “from states” to the end substitute “after “states other than EEA states” insert “/ countries other than approved countries for import”.”;

(c) for paragraph (3) substitute—

“(3) In paragraph (8)(a) omit “other than the United Kingdom”.”;

(d) in paragraph (4) for “omit sub-paragraph” to the end substitute “in sub-paragraph (b), at the beginning insert “in the case of a THR(NI) or THR(UK),”.”;

(e) after paragraph (4) insert—

“(4A) After paragraph (10A) insert—

“(10B) Condition K is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.”.

**92.** In regulation 120(2) (amendment of regulation 136 (revocation by licensing authority: further provisions)) for “for “list referred to in” to the end substitute—

“for “the list referred to in” to the end substitute—

“—

(i) the list referred to in Article 16f(1) of the 2001 Directive, in the case of a THR(NI) or THR(UK);

(ii) the list established under regulation 126A where the application is for a THR(GB); and”.

**93.** In regulation 123 (amendment of regulation 140 (withdrawal of traditional herbal medicinal product from the market) for “140(1)(a)” to the end substitute “140(1) for sub-paragraph (a) substitute—

“(a) under—

(i) regulation 135 or 136, in the case of a THR(GB);

(ii) regulation 135 or 136 or Article 34(3) of the 2001 Directive, in the case of a THR(NI) or THR(UK),

the licensing authority revokes or suspends the registration; or”.

**94.** In regulation 125 (amendment of regulation 142 (obligation to notify placing on the market etc)) for “Omit regulation 142(5C)” substitute “In regulation 142(5C), for “traditional herbal registration” substitute “THR(NI) or THR(UK)”.

**95.** In regulation 126 (insertion of new regulation 143A (establishment of herbal monographs)), in the inserted regulation 143A(1), after “traditional herbal medicinal products” insert “to be placed on the market in Great Britain”.

**96.** For regulation 127 (amendment of regulation 144 (obligation following new herbal monograph)) substitute—

**“Substitution of regulation 144 (obligation following new herbal monograph)**

**127.** For regulation 144 substitute—

“**144.**—(1) Paragraph (2) applies where a new herbal monograph of the kind referred to—

(a) in the case of a THR (NI) or THR (UK), in Article 16h(3) of the 2001 Directive, or

(b) in the case of a THR (GB), in regulation 143A,

is established.

(2) Where this paragraph applies, the holder of the THR(GB), THR(NI) or THR(UK) to which the monograph relates must as soon as is reasonably practicable—

(a) consider whether to modify the registration dossier; and

(b) notify any modification to the licensing authority.”.

**97.** For regulation 129 (amendment of regulation 146 (obligation in relation to product information)) substitute—

“**129.** For regulation 146(2), substitute—

“(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product for sale or supply in Northern Ireland—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product for sale or supply in Great Britain only, the UK web-portal established in accordance with regulation 203(1).”.

**98.** In regulation 131 (amendment of regulation 149 (urgent safety restrictions)) substitute—

**“Substitution of regulation 149 (urgent safety restrictions)**

**131.** For regulation 149 substitute—

“**149.**—(1) The holder of a THR(NI) or a THR(UK) is guilty of an offence if the holder—

(a) fails to inform the licensing authority or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008 that the holder has taken urgent safety restrictions on the holder’s own initiative;

(b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority or the European Commission under Article 22(2) of that Regulation; or

- (c) fails to submit an application for variation of the traditional herbal registration to the licensing authority or the European Commission in accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—
  - (i) the taking under Article 22(1) or, as the case may be,
  - (ii) the imposition under Article 22(2),
 of that Regulation of an urgent safety restriction;
- (2) The holder of a THR(GB) is guilty of an offence if the holder—
  - (a) fails to inform the licensing authority in accordance with regulation 148A(1) that the holder has taken urgent safety restrictions on the holder’s own initiative;
  - (b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority in accordance with regulation 148A(2); or
  - (c) fails to submit an application for variation of the traditional herbal registration to the licensing authority in accordance with regulation 148A(4) before the end of the period of 15 days beginning with the day after—
    - (i) the taking under regulation 148A(1), or
    - (ii) the imposition under regulation 148A(2),
 of an urgent safety restriction.”.”.

## PART 7

### Amendment of Part 8 (omission of Part 8 (Article 126a authorisations))

**99.** For regulation 132 (omission of Part 8), substitute—

#### **“Amendment of regulation 156 (article 126a authorisations)**

**132.** In regulation 156—

- (a) in paragraph (1)—
  - (i) after “126a authorisation for” insert “sale or supply of”;
  - (ii) after “medicinal product” insert “in Northern Ireland only”;
- (b) in paragraph (2), after “is in force” insert “in Northern Ireland”;
- (c) in paragraph (3), after “traditional herbal registration” insert “to be in force in Northern Ireland”;
- (d) in paragraph (4) for “the United Kingdom” substitute “Northern Ireland”; and
- (e) in paragraph (5) for “another member State” substitute “an EU member State”.

#### **Amendment of regulation 157 (requests from other member States)**

**132A.** In regulation 157(1)—

- (a) in the heading for “other member States” substitute “EU member States”; and
- (b) in paragraph (1)—
  - (i) after “where the licensing authority” insert “, in relation to a UKMA(NI),”; and

(ii) for “another member State” substitute “a member State”.”.

## PART 8

### Amendment of Part 9 (amendment of Part 9 (borderline products))

**100.** In regulation 133 (amendment of regulation 159 (provisional determination)) for paragraph (b) substitute—

“(b) for “Article 126a authorisation” insert “, only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,”.”.

**101.** In regulation 134 (amendment of regulation 164 (effect of determination)) for paragraph (b) substitute—

“(b) for “Article 126a authorisation” insert “, only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,”.”.

## PART 9

### Amendment of Part 10 (amendment of Part 10 (exceptions to requirement for marketing authorisations etc))

**102.** Before regulation 135 (amendment of regulation 168 (use of non-prescription medicines in the course of a business)) insert—

#### “**New regulation 135ZA (amendment of regulation 167 (supply to fulfil special patient needs))**”

**135ZA.** In regulation 167 (supply to fulfil special patient needs)—

(a) in paragraph (6), for “or imported into the United Kingdom from a country other than an EEA State” substitute “, imported into Northern Ireland from a country other than an EEA State or Great Britain, or imported into Great Britain from a country other than an approved country for import or Northern Ireland”;

(b) in paragraph (7)—

(i) for “imported from an EEA State” substitute “imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import”;

(ii) for sub-paragraph (a) substitute—

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

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

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

(iii) for sub-paragraph (b) substitute—

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

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

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

**103.** For regulation 135 (amendment of regulation 168 (use of non-prescription medicines in the course of a business)), substitute—

**“Amendment of regulation 168 (use of non-prescription medicines in the course of a business)**

**135.** In regulation 168 (use of non-prescription medicines in the course of a business), for paragraph (8) substitute—

“(8) Condition G is that if the medicinal product is—

(a) manufactured or assembled in the United Kingdom or imported into the United Kingdom from—

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

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

it is manufactured, assembled or imported by the holder of a manufacturer’s licence that relates specifically to the manufacture, assembly or importation of special medicinal products, or

(b) imported into—

(i) Northern Ireland from an EEA State, it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State, or

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

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

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

**104.** In regulation 136 (amendment of regulation 169 (mixing of general sale medicinal products)), for “insert “UK” before “marketing authorisation”” substitute “for “marketing authorisation” substitute “UK marketing authorisation or EU marketing authorisation””.

**105.** In regulation 137 (amendment of regulation 171 (exempt advanced therapy medicinal products)), for “substitute “regulation 49(1)”” substitute—



“substitute—

“—

- (i) in the case of a product for sale or supply in Northern Ireland, Regulation (EC) No 726/2004, and
- (ii) in the case of a product for sale or supply in Great Britain, regulation 49(1).”.

**106.** In regulation 138 (amendment of regulation 173 (exemption for certain radiopharmaceuticals)), for “insert “UK” before “marketing authorisation”” substitute “for “marketing authorisation” substitute “UK marketing authorisation or EU marketing authorisation””.

## PART 10

### Amendment of Part 11 (amendment of Part 11 (Pharmacovigilance))

**107.** In regulation 139 (amendment of regulation 177 (application of part and interpretation))—

(a) for paragraph (2) substitute—

“(2) After paragraph (1) insert—

“(1A) Schedule 12A applies in relation to medicinal products that are the subject of a UKMA(GB) or a THR(GB).”.

(b) in paragraph (3) omit sub-paragraphs (b) and (c);

(c) in paragraph (4) omit sub-paragraphs (b) and (c);

(d) omit paragraph (5);

(e) for paragraph (6) substitute—

“(6) In paragraph (5)—

(a) for “Schedule 33” substitute “Schedules 33 and 33A”;

(b) in paragraph (c) of the definition of “relevant post-authorisation safety study”, omit “and”; and

(c) after that definition, insert—

““signal” means, in relation to a UKMA(GB) or THR(GB), information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, which is judged to be of sufficient likelihood to justify verificatory action; and”.

**108.** After regulation 139 (amendment of regulation 177 (application of part and interpretation)) insert—

### “Amendment of regulation 179 (obligation on licensing authority to operate pharmacovigilance system)

**139A.** In regulation 179—

(a) in paragraph (1), after “pharmacovigilance system” insert “in relation to medicinal products for sale or supply in Great Britain”;

(b) after paragraph (1) insert—

“(1A) The licensing authority must operate a pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland.”;

- (c) in paragraph (2) for “The pharmacovigilance system” substitute “Each pharmacovigilance system”; and
- (d) in paragraph (3)(a) for “the pharmacovigilance system” substitute “each pharmacovigilance system”.”.

**109.** In regulation 140 (amendment of regulation 180 (obligation on licensing authority to audit pharmacovigilance system))—

- (a) in paragraph (2)—
  - (i) before “omit” insert—
    - “(a) after “its pharmacovigilance system” insert “relating to medicinal products for sale or supply in Great Britain” and”;
    - (ii) from “omit” to the end becomes sub-paragraph (b);
  - (b) after paragraph (2) insert—
    - “(2A) After paragraph (1) insert—
      - “(1A) The licensing authority must perform a regular audit of its pharmacovigilance system relating to medicinal products for sale or supply in Northern Ireland and report the results of that audit to the European Commission.”.”;
    - (c) after paragraph (3) insert—
      - “(4) After paragraph (2) insert—
        - “(3) The results of the audit referred to in paragraph (1A) must be reported to the European Commission—
          - (a) on the first occasion no later than 21st September 2021;
          - (b) every two years after the first occasion.”.”.

**110.** For regulation 141 (omission of regulation 181 (delegation of obligations under Part 11)) substitute—

**“Amendment of regulation 181 (delegation of obligations under Part 11)**

**141.** In regulation 181(1), for “to another EEA State” substitute “in connection with its pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland to an EEA State”.”.

**111.** In regulation 142 (amendment of regulation 182 (obligation on holder to operate a pharmacovigilance system))—

- (a) in paragraph (2) for “for “resides and operates” to the end substitute “after “in the EU” insert “or United Kingdom””;
- (b) after paragraph (2) insert—
  - “(2A) In paragraph (2)(b), after “pharmacovigilance system master file” insert “and ensure it is permanently and immediately available for inspection electronically in the United Kingdom at the single point from which the reports referred to in regulation 187(4) are accessible”.
  - (2B) After paragraph (2) insert—
    - “(2A) Where the person the holder has permanently and continuously at its disposal under paragraph (2)(a) (“the qualified person”) does not reside and operate in the United Kingdom, the holder must nominate a contact person for pharmacovigilance at a national level who reports to the qualified person,

resides and operates in the United Kingdom and has permanent access to the pharmacovigilance system master file.

(2B) Paragraph (2A) has effect from the day twelve months after IP completion day.”.”; and

(c) for paragraph (3) substitute—

“(3) For paragraph (3) substitute—

“(3) Without prejudice to the requirements set out in regulation 65C and Schedule 10A (variations to a UK marketing authorisation) the holder must keep the licensing authority informed at all times of the name and contact details of—

- (a) the appropriately qualified person mentioned in paragraph (2)(a); and
- (b) the nominated person mentioned in paragraph (2A).

(3A) The holder must—

- (a) ensure that the pharmacovigilance system master file is accessible electronically from the single point within the United Kingdom from which the reports referred to in regulation 187(4) are accessible; and
- (b) immediately notify the licensing authority of any change to the single point where the pharmacovigilance system master file may be accessed electronically.”.”.

**112.** In regulation 143 (amendment of regulation 184 (obligation on holder to audit pharmacovigilance system)), in the inserted paragraph (3) after “The holder” insert “of a UKMA(GB) or THR(GB)”.

**113.** For regulation 145 (amendment of regulation 186 (reporting obligations on the licensing authority)) substitute—

“**145.** In regulation 186—

(a) in paragraph (1), for sub-paragraphs (d) and (e) substitute—

“(d) submit reports of serious suspected adverse reactions in Northern Ireland that it has recorded under regulation 185 in relation to—

- (i) a UKMA(NI),
- (ii) a UKMA(UK),
- (iii) a THR(NI),
- (iv) a THR(UK), or
- (v) an Article 126a authorisation,

to the EMA before the end of the period of 15 days beginning on the day following the day on which the report was received; and

(e) submit reports of non-serious suspected adverse reactions in Northern Ireland that it has recorded under regulation 185 in relation to—

- (i) a UKMA(NI),
- (ii) a UKMA(UK),
- (iii) a THR(NI),
- (iv) a THR(UK), or
- (v) an Article 126a authorisation,

to the EMA before the end of the period of 90 days beginning on the day following the day on which the report was received.”.”;

(b) omit paragraph (4).”.

**114.** In regulation 147 (amendment of regulation 187 (recording obligations on holders)) for paragraph (2) substitute—

“(2) In paragraph (1) for “in the EEA or in third countries” substitute “in the United Kingdom or another country”.”.

**115.** In regulation 148 (amendment of regulation 188 (reporting obligations on holders))—

(a) in paragraph (3), before sub-paragraph (a) insert—

“(za) for “Subject to paragraph (2), the holder” substitute “The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation”.”;

(b) after paragraph (3) insert—

“(3A) After paragraph (1) insert—

“(1A) The holder of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation must, in relation to the product—

(a) submit electronically to the Eudravigilance database a report on all serious suspected adverse reactions that occur in the UK and other countries before the end of the period of 15 days beginning on the day on which the holder gained knowledge of the reaction;

(b) submit electronically to the Eudravigilance database a report on all non-serious suspected adverse reactions that occur in an EEA State or Northern Ireland before the end of the period of 90 days beginning on the day on which the holder gained knowledge of the reaction;

(c) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the Eudravigilance database by way of an update to the original report within the specified time period; and

(d) collaborate with the EMA and the competent authorities of the EEA States in the detection of duplicates of suspected adverse reaction reports.”.”;

(c) for paragraph (4) substitute—

“(4) In paragraph (2)—

(a) after “holder” insert “of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation”;

(b) for “paragraph (1)(a) or (b)” substitute “paragraph (1A)(a) or (b)”;

(c) for “paragraph (1)(d)” substitute “paragraph (1A)(c)”.

(4A) In paragraph (3) for “paragraph (4)” substitute “paragraph (4A)”.”;

(d) after paragraph (5) insert—

“(5A) After paragraph (4) insert—

“(4A) The holder of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation must—

(a) monitor medical literature other than the monitored publications for reports of suspected adverse reactions to the product; and

(b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1A).”.”.

**116.** In regulation 149 (amendment of regulation 189 (signal detection: licensing authority obligations)) for paragraph (3) substitute—

“(3) In paragraphs (2) and (3), for “The licensing” insert “In relation to medicinal products subject to a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the licensing”.”.

**117.** For regulation 150 (amendment of regulation 190 (signal detection: holder obligation)) substitute—

“**150.** For regulation 190(1) substitute—

“(1) The holder must inform—

- (a) the licensing authority, and
- (b) in respect of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the EMA,

without delay if it detects any relevant changes in relation to the product.”.”.

**118.** In regulation 151 (amendment of regulation 191 (obligation on holder to submit periodic safety update reports: general requirements))—

(a) in paragraph (2) for “for “EMA” substitute “licensing authority”” substitute “after “EMA” insert “and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,”;

(b) omit paragraph (4);

(c) in paragraph (5), in the inserted paragraph (4A), after “A PSUR” insert “in relation to a product authorised under a UKMA(GB)”;

(d) in paragraph (6), in the inserted paragraph (8A), after “conditional marketing authorisation” insert “in relation to a product authorised under a UKMA(GB)”;

(e) for paragraph (7) substitute—

“(7) In paragraph (10)—

(a) for sub-paragraph (b) substitute—

“(b) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has not yet been placed on the market within the EEA or Northern Ireland, at least every six months following authorisation until the placing on the market within the EEA or Northern Ireland, or

(ii) in relation to a product authorised under a UKMA(GB), the product has not yet been placed on the market in Great Britain, at least every six months following authorisation until the placing on the market within Great Britain; and”;

(b) for sub-paragraph (c) substitute—

“(c) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has been placed on the market within the EEA or Northern Ireland—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

- (cc) every three years after that;
- (ii) in relation to a product authorised under a UKMA(GB), the product has been placed on the market in Great Britain—
  - (aa) at least every six months during the first two years following the initial placing on the market,
  - (bb) once a year for the following two years, and
  - (cc) every three years after that.”.”.

**119.** In regulation 152 (amendment of regulation 192 (obligation to submit periodic safety reports: derogation from general requirements))—

- (a) in paragraph (3), for “for “EMA” to the end substitute “after “EMA” insert “and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,”;
- (b) for paragraph (4) substitute—
  - “(4) In paragraph (9), after “paragraph (3)(a)” insert “from the holder of a UKMA(UK), UKMA(NI), THR(UK), THR(NI) or Article 126a authorisation”.”.

**120.** In regulation 153 (amendment of regulation 193 (harmonisation of PSUR frequency or date of submission))—

- (a) for paragraph (2) substitute—
  - “(2) In paragraph (1) substitute—
    - “(1) Where products that are subject to different authorisations or registrations contain the same active substance or the same combination of active substances, the frequency and dates of submission may be amended and harmonised in accordance with—
      - (a) Article 107c(4) of the 2001 Directive, where—
        - (i) any of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation; and
        - (ii) none of the authorisations or registrations is a UKMA(GB) or THR(GB); or
      - (b) paragraphs (2A), (3) and (4A), where—
        - (i) any of the authorisations or registrations is a UKMA(GB) or THR(GB); and
        - (ii) none of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation.”.”;
- (b) after paragraph (2) insert—
  - “(2A) In paragraph (2), after “holder” insert “of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation”.”;
- (c) in paragraph (3)—
  - (i) for “For paragraph (2) substitute—” substitute “After paragraph (2) insert—”;
  - (ii) the text to be inserted is renumbered as paragraph (2A);
  - (iii) in the text to be inserted, after “the holder” insert “of a UKMA(GB) or THR(GB)”;
- (d) in paragraph (4)—

- (i) for “For paragraph (4) substitute—” substitute “After paragraph (4) insert—”;
- (ii) the text to be inserted is renumbered as paragraph (4A);
- (iii) in the text to be inserted, after “from a holder” insert “of a UKMA(GB) or THR(GB)”;
- (e) in paragraph (5)—
  - (i) for sub-paragraph (a) substitute—
    - “(a) after “of the 2001 Directive” insert “or paragraph (2A) (as the case may be)””; and
  - (ii) for sub-paragraph (b) substitute—
    - “(b) after “EMA” insert “or licensing authority (as the case may be)””;
- (f) in paragraph (6)—
  - (i) for “For paragraph (6) substitute” substitute “After paragraph (6) insert”; and
  - (ii) the substituted paragraphs (6) and (6A) become paragraphs (6A) and (6B) respectively; and
  - (iii) in the substituted paragraph (6) for “(6A)” substitute “(6B)”;
- (g) in paragraph (7) for “(6A)” substitute “(6B)”.

**121.** In regulation 154 (omission of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive))—

- (a) in the heading, for “omission” substitute “amendment”; and
- (b) for “Omit regulation 194.” substitute “In regulation 194(1) after “medicinal product” insert “authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation”.”.

**122.** In regulation 155 (amendment of regulation 195 (obligation on licensing authority to assess PSURs))—

- (a) after paragraph (2) insert—
  - “(2A) Before paragraph (1) insert—
    - “(A1) This regulation applies in the circumstances specified in paragraphs (1) and (1A).”.
  - (2B) In paragraph (1)—
    - (a) after “relating to a medicinal product” insert “authorised for sale or supply authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation”; and
    - (b) in sub-paragraph (a)(i) omit “other than the United Kingdom”.”;
- (b) in paragraph (3)—
  - (i) for “For” substitute “After”;
  - (ii) for “substitute” substitute “insert”;
  - (iii) the inserted paragraph (1) becomes inserted paragraph (1A);
  - (iv) in the inserted paragraph (1A), after “to a medicinal product” insert “authorised for sale or supply under a UKMA(GB) or THR(GB)”;
- (c) omit paragraph (5).

**123.** Before regulation 156 insert—

**“Amendment of regulation 196 (urgent action)**

**156ZA.** In regulation 196—

- (a) in the italic heading immediately preceding it, after “Urgent action” insert “and major safety review”;
- (b) in paragraph (1), for “The licensing authority must initiate the Section 4 procedure by informing” substitute “In the case of a medicinal product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation, the licensing authority must inform”;
- (c) omit sub-paragraph (2B);
- (d) omit paragraphs (4) to (7);
- (e) in paragraph (8), omit the definition of “EU urgent action procedure” and “Section 4 procedure”.

**124.** In regulation 156 (substitution of regulation 196 (urgent action))—

- (a) for the heading to the regulation, substitute “Insertion of new regulation 196A (major safety review by the licensing authority)”;
- (b) for “For regulation 196 and the italic heading immediately preceding it” substitute “After regulation 196 insert”;
- (c) in the text to be inserted by that regulation—
  - (i) omit the italic heading “Major safety review”;
  - (ii) renumber the regulation as regulation 196A.

**125.** In regulation 157 (omission of regulation 197 (EU urgent action procedure))—

- (a) in the heading for “Omission” substitute “Amendment”;
- (b) for “Omit” substitute “In;
- (c) after “regulation 197” insert “, in paragraph (1), after “class of medicinal products” insert “authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation””.

**126.** In regulation 158 (amendment of regulation 198 (post-authorisation safety studies: general provisions))—

- (a) in paragraph (2), for “for “competent authorities” to the end substitute—  
“—
  - (a) “the competent authorities” to the end becomes sub-paragraph (a);
  - (b) in sub-paragraph (a), at the end insert “and the licensing authority, where the product is subject to a marketing authorisation, traditional herbal registration or Article 126a authorisation for sale or supply in Northern Ireland;”
  - (c) after sub-paragraph (a) insert—
    - “(b) the licensing authority, where the product is subject to a marketing authorisation or traditional herbal registration for sale or supply in Great Britain only.”;
- (b) in paragraph (3)—
  - (i) in sub-paragraph (a) for “for “relevant competent authorities” to the end substitute—
    - “(i) “for “the relevant competent authorities” substitute—  
“—



- (i) the relevant competent authorities and the licensing authority, where paragraph (2)(a) applies;
- (ii) the licensing authority where paragraph (2)(b) applies,”
- (ii) “any new information” to the end becomes full-out words;”;
- (ii) in sub-paragraph (b) for “for “competent authorities” to the end substitute—  
“—
  - (i) “the competent authorities of the EEA States in which the study was conducted” becomes paragraph (i);
  - (ii) in paragraph (i), after “the study was conducted” insert “and the licensing authority, where paragraph (2)(a) applies;”
  - (iii) after paragraph (i) insert—
    - “(ii) the licensing authority, where paragraph (2)(b) applies;”;
  - (iv) “before the end of the period” to the end becomes full-out words.”.

**127.** In regulation 159 (amendment of regulation 199 (submission of draft study protocols for required studies))—

- (a) for paragraph (2) substitute—
  - “(2) In paragraph (2) for “to the body specified in paragraph (3)” to the end substitute—  
“to—
    - (a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation is a UKMA(NI) or UKMA(UK);
    - (b) the licensing authority, where the authorisation is a UKMA(GB),  
before the study is commenced.”.”;
- (b) for paragraph (3) substitute—
  - “(3) In paragraph (4)—
    - (a) after “protocol is submitted” insert “only”;
    - (b) after “paragraphs (2) and (3)(a)” insert “(and is not submitted to the Pharmacovigilance Risk Assessment Committee)”.”;
- (c) omit paragraphs (4) to (6).

**128.** In regulation 160 (amendment of regulation 200 (amendment to study protocols for required studies))—

- (a) for paragraph (2) substitute—
  - “(2) In paragraph (2) for “to the body specified in paragraph (3)” to the end substitute—  
“to—
    - (a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);
    - (b) the licensing authority, where the authorisation for the product is a UKMA(GB),  
before their implementation.”.”;
- (b) for paragraph (3) substitute—
  - “(3) In paragraph (4)—
    - (a) after “protocol is submitted” insert “only”;

(b) after “paragraphs (2) and (3)(a)” insert “(and is not submitted to the Pharmacovigilance Risk Assessment Committee)”.”;

(c) omit paragraphs (4) and (5).

**129.** In regulation 161 (amendment of regulation 201 (submission and evaluation of final study reports for required studies))—

(a) for paragraph (2) substitute—

“(2) In paragraph (2) for “to the body specified in paragraph (3)” to the end substitute—  
“to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation for the product is a UKMA(GB), a final study report and an abstract of the study results.”.”;

(b) omit paragraph (3);

(c) in paragraph (4) for “omit from” to the end substitute “omit “for reports falling under paragraph (3)(a)” and “for reports falling under paragraph (3)(b)””.

**130.** For regulation 162 (omission of regulation 202 (follow up of final study reports)) substitute—

**“Amendment of regulation 202 (follow up of final study reports)**

**162.** In regulation 202(1), after “This regulation applies” insert “in respect of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation”.”.

**131.** For regulation 164(3) (amendment of regulation 203 (obligations on licensing authority in relation to national medicines web-portal)) substitute—

“(3) In paragraph (2), after sub-paragraph (d) insert—

“(da) the list published by the licensing authority under, or which applies by virtue of, regulation 202A;”.”.

**132.** In regulation 165 (omission of regulation 204 (obligation on licensing authority in relation to public announcements))—

(a) in the heading for “Omission” substitute “Amendment”;

(b) for “Omit” substitute “In”;

(c) after “regulation 204” insert “, in paragraph (1), after “pharmacovigilance concerns” insert “which relate to products authorised under a UKMA(NI) or UKMA(UK)””.

**133.** In regulation 166 (amendment of regulation 205 (obligations on holders in relation to public announcements))—

(a) in paragraph (2) for “for “bodies listed” to the end substitute “after “bodies listed in paragraph (3)” insert “where the product is subject to a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation, or the licensing authority where the product is subject to a UKMA(GB) or THR(GB),””;

(b) omit paragraph (3).

**134.** In regulation 167 (insertion of regulation 205A (further obligations in respect of pharmacovigilance activities)), in the inserted regulation 205A—

- (a) in paragraph (1), after “Schedule 12A” insert “applies in relation to medicinal products for sale or supply under a UKMA(GB) or THR(GB) and”;
  - (b) in paragraph (2)—
    - (i) for “The Ministers” substitute “The Secretary of State”;
    - (ii) after “by regulations” insert “in respect of Great Britain”.
- 135.** In regulation 170 (amendment of regulation 206 (infringement notices)) for paragraphs (2) and (3) substitute—
- “(2) In paragraph (3), after “paragraph (1)” insert “in relation to a product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI) or THR(UK)”.
  - (3) In paragraph (4) after sub-paragraph (a) insert—
    - “(aa) Schedule 12A;”.
- 136.** Omit regulations 172 (amendment regulation 208 (false and misleading information)), 173 (amendment of regulation 209 (penalties)) and 174 (Omission of regulation 210 (offences relating to pharmacovigilance obligations under Regulation [\(EC\) No 726/2004](#))).
- 137.** In regulation 175 (amendment of regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation))—
- (a) in paragraph (2)—
    - (i) for “for” substitute “after”;
    - (ii) for “substitute “Schedule 12A”” substitute “insert “and Schedule 12A””;
  - (b) in paragraph (3) for sub-paragraphs (a) and (b) substitute—
    - “(a) in sub-paragraph (a), at the beginning insert “in relation to a UKMA(NI), UKMA(UK), THR(NI) THR(UK) or Article 126a authorisation,”;
    - (b) after sub-paragraph (a) insert—
      - “(aa) in relation to a UKMA(GB) or THR(GB), fails to comply with any requirement or obligation contained in a provision of Schedule 12A listed in paragraph (2A); or”.
  - (c) in paragraph (4)—
    - (i) for “For paragraph (2) substitute” substitute “After paragraph (2) insert”;
    - (ii) the inserted paragraph (2) becomes inserted paragraph (2A);
    - (iii) omit the inserted paragraphs (3) and (4);
  - (d) after paragraph (4) insert—
    - “(5) In paragraph (4), after “Implementing Regulation” insert “, or of paragraph 26(8) or 29(1) of Schedule 12A,”.
- 138.** Omit regulation 176 (amendment of regulation 211 (persons liable)).
- 139.** For regulation 177 (amendment of regulation 212 (transitional amendments)) substitute—
- “**177.** In regulation 212, omit “182, 186, 188, 191, 192”.
- 140.** In regulation 178 (amendment of Schedule 33 (transitional arrangements: pharmacovigilance)) for “4” substitute “5”.

## PART 11

### Amendment of Part 12 (amendment of Part 12 (dealings with medicinal products))

**141.** For regulation 187 (amendment of regulation 229 (exemption for supply by national health services bodies and local authorities)) substitute—

“**187.** In regulation 229(3), for sub-paragraph (f) substitute—

“(f) when the product is supplied—

(i) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(ii) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.””.

**142.** For regulation 188 (amendment of regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)) substitute—

“**188.** For regulation 230(8) substitute—

“(8) Condition G is that when the product is supplied or (as the case may be) administered —

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.””.

**143.** For regulation 189 (amendment of regulation 231 (exemption for supply etc under a PGD by independent hospitals etc)) substitute—

“**189.** For regulation 231(8) substitute—

“(8) Condition G is that when the product is supplied—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.””.

**144.** For regulation 190 (amendment of regulation 232 (exemption for supply etc under a PGD by dental practices and clinics: England and Wales)) substitute—

“**190.** For regulation 232(8) substitute—

“(8) Condition F is that when the product is supplied, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK) is in force in relation to it.””.

**145.** For regulation 191 (amendment of regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)) substitute—

“**191.** For regulation 233(7) substitute—

“(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered—

- (a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or
- (b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.”.

**146.** For regulation 192 (amendment of regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)) substitute—

“**192.** For regulation 234(9) substitute—

“(9) Condition H is that when the product is supplied—

- (a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or
- (b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.”.

**147.** In regulation 193 (amendment of Schedule 17 (exemptions for sale, supply or administration by certain persons)—

- (a) in paragraph (2), for “insert “UK” before “marketing authorisations”.” substitute “for “marketing authorisations” substitute “UK marketing authorisations, EU marketing authorisations”;
- (b) in paragraph (3), for “insert “UK” before “marketing authorisation”.” substitute “for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation”.

**148.** In regulation 194 (amendment of regulation 249 (restrictions on persons to be supplied with medicinal products)), for paragraphs (b) and (c) substitute—

“(b) after sub-paragraph (a) insert—

“(aa) an EU marketing authorisation;”.

**149.** After regulation 194 (amendment of regulation 249 (restrictions on persons to be supplied with medicinal products) insert—

**“Amendment of regulation 251 (compliance with standards specified in certain publications)**

**194A.** In regulation 251 (compliance with standards specified in certain publications), after paragraph (5) insert—

“(6) In paragraph (1), (2) or (3) a product is to be treated as complying with the standard specified in the relevant monograph where—

- (a) the product complies with the standard specified in a relevant marketing authorisation for the product concerned, and
- (b) the standard specified in that marketing authorisation does not comply with the standard specified in the relevant monograph.

(7) In paragraph (6), “relevant marketing authorisation” means—

- (a) an EU marketing authorisation;
- (b) an authorisation granted by the licencing authority under Chapter 4 of Title III to the 2001 Directive; or
- (c) a UKMA(GB) granted under the unfettered access route.”.”.

**150.** For regulation 196 (omission of regulation 255A to 255C (enforcement and offences relating to Commission Regulation 2016/161)) substitute—

**“Amendment of regulation 255A (enforcement notices relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public)**

**196.** In regulation 255A(1), after “purpose of sale or supply,” insert “in Northern Ireland.”.

**Amendment of regulation 255B (exception to Article 25 of Commission Regulation 2016/161: health care institutions)**

**196A.** In regulation 255B, after “medicinal products to the public” in the first place it occurs insert “in Northern Ireland”.”.

## PART 12

### Amendment of Part 13 (omission of Part 12A (sale of medicines to the public at a distance))

**151.** For regulation 197 (omission of Part 12A) substitute—

**“Amendment of Part 12A**

**197.—(1)** Before regulation 256A (interpretation) insert—

**“Application of Part**

**256ZA.** This part applies to Northern Ireland only.”.

(2) In regulation 256A(1) (interpretation)—

- (a) in the definition of “the list”, for “competent authority of a member State in which the person named on the list is established” substitute “licensing authority”;
- (b) omit the definition of “relevant website of the member State”;
- (c) at the appropriate place in the alphabetical order insert—

““website of the licensing authority” means a website of the licensing authority providing information on—

- (a) the national legislation applicable to the offering of medicinal products for sale at a distance to the public by information society services;
- (b) the differences between Northern Ireland and EEA States regarding classification of medicinal products and the conditions for their supply;
- (c) the purpose of the common logo;

- (d) the list of persons offering medicinal products for sale at a distance by means of information society services as well as their website addresses;
  - (e) background information about the risks related to medicinal products supplied illegally to the public by means of information society services;
  - (f) a hyperlink to the website of the EMA;”;
- (d) in the definition of “website of the EMA”—
- (i) in paragraph (a)—
    - (aa) for “relevant website of the member State” substitute “website of the licensing authority”;
    - (bb) for “that member State” substitute “Northern Ireland”;
  - (ii) in paragraph (e), for “hyperlinks to the relevant website of the member State” substitute “a hyperlink to the website of the licensing authority”.
- (3) In regulation 256B (person who may sell medicinal products by information society services)—
- (a) before paragraph (1) insert—

“(A1) This regulation applies to a person who is an established service provider (as defined in regulation 2(1) of the Electronic Commerce (EC Directive) Regulations 2002<sup>(6)</sup>) in Northern Ireland.”;
  - (b) in paragraph (2), omit “of persons selling medicinal products at a distance that is published on the relevant website of the member State”;
  - (c) for paragraph (3) substitute—

“(3) Condition B is that the product to be sold by information society services is covered by a UK marketing authorisation or an authorisation granted—

    - (a) under Regulation (EC) No 726/2004; or
    - (b) by a competent authority of the member State in which that product is destined to be sold.

(3A) Condition B does not apply to—

    - (a) a special medicinal product;
    - (b) a medicinal product where the product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of any provision of section 10 of the Medicines Act 1968<sup>(7)</sup>; or
    - (c) a medicinal product where—
      - (i) the product is a result of a process of assembly of a medicinal product that is an authorised medicinal product within the meaning of regulation 3(15);
      - (ii) regulation 17(1) does not apply to the process of assembly by virtue of any provision of section 10 of the Medicines Act 1968;
      - (iii) the process of assembly results in a change in the presentation of the authorised medicinal product; and

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<sup>(6)</sup> S.I. 2002/2013, as amended by S.I. 2012/1809 and prospectively amended with effect from IP completion day by S.I. 2019/87.  
<sup>(7)</sup> 1968 c.67, as amended by section 26 of the Health Act 2006 (c.28) and S.I. 1971/1445, 1994/2987, 2006/2407, 2011/2581 and 2012/1916, and in relation to Scotland by paragraph 5 of Schedule 3 to the Regulation of Care (Scotland) Act 2001 (asp 8).

- (iv) by reason of the change in paragraph (iii) the product does not comply with condition B.”;
- (d) in paragraph (4), omit “in the member State in which that person is established”;
- (e) in paragraphs (6), for “the competent authority in a member State in which the person is established” substitute “the licensing authority”;
- (f) in each of paragraphs (8)(b) and (c), for “the competent authority of a member State” substitute “the licensing authority”.
- (4) In regulations 256C (notification requirements for sellers of medicinal products at a distance) to 256M (offences: breach of regulations and false information), for “competent authority of a member State” in each place it occurs (including in the headings to regulations 256F and 256J) substitute “licensing authority”.
- (5) In regulation 256C (notification requirements for sellers of medicinal products at a distance), in paragraph (2)(b)(iv), for “informantion” substitute “information”.
- (6) In regulation 256D(3) (procedure for listing persons who may supply medicinal products at a distance), for “that competent authority” in both places substitute “the licensing authority”.
- (7) In regulation 256G (grant or refusal to list a person)—
- (a) in paragraph (2), for “that competent authority” substitute “the licensing authority”;
- (b) in paragraph (3)—
- (i) for “that competent authority” substitute “the licensing authority”;
- (ii) for “relevant website of the member State” substitute “website of the licensing authority”.
- (8) In regulation 256H(3) (conditions to be met by a person entered on the list)—
- (a) in sub-paragraph (a), omit “which is responsible for maintaining the list on which the person selling products at a distance is included”;
- (b) in sub-paragraph (b), for “relevant website of the Member State” substitute “website of the licensing authority”.
- (9) In regulation 256J (procedure where the licensing authority proposes to suspend, vary or remove a person’s entry on the list), omit sub-paragraph (6)(b) (and the “and” at the end of sub-paragraph (a)).
- (10) In regulation 256K(1) (suspension of a person’s entry on the list in cases of urgency), for “that competent authority” substitute “the licensing authority”.
- (11) In regulation 256L (variation of a person’s entry on the list on the application of that person)—
- (a) in paragraph (3), for “that competent authority” substitute “the licensing authority”;
- (b) in paragraph (6)(b), for “that competent authority’s” substitute “the licensing authority’s”.

## PART 13

### Amendment of Part 14 (amendment of Part 13 (packaging and leaflets))

- 152.** In regulation 198 (amendment of regulation 257 (packaging requirements: general))—



- (a) in paragraph (2), after “257C” insert “where the product is for sale or supply in Great Britain only”;
- (b) in paragraph (3), in the inserted paragraph (8), after “product” insert “for sale or supply in Great Britain only”.

**153.** For regulation 199 (omission of regulations 257A and 257B (packaging requirements: medicinal products required to bear safety features and associated transitionals)) substitute—

**“Amendment of regulation 257A (packaging requirements: medicinal products required to bear safety features)**

**199.** In regulation 257A, after “either fully or partially,” insert “from a product to which Article 54a of the 2001 Directive applies”.

**Amendment of regulation 257B (transitional arrangements)**

**199A.** In regulation 257B, after “unless the product” insert “is one to which Article 54a of the 2001 Directive applies and”.

**154.** In regulation 200 (insertion of regulations 257C (packaging requirements: advanced therapy medicinal products) and 257D and 257E (guidance and regulations in relation to packing, leaflets and labelling))—

- (a) in the inserted regulation 257C(1)—
  - (i) in sub-paragraph (a), after the first reference to “advanced therapy medicinal product” insert “for sale or supply in Great Britain only”;
  - (ii) in sub-paragraph (b), for “of the product” substitute “of that product”
- (b) for the inserted regulation 257D substitute—

**“257D.—(1)** The licensing authority may publish guidance on packaging and package leaflets applicable to products for sale or supply in the whole United Kingdom or parts of the United Kingdom, as appropriate.

- (2) Guidance published under paragraph (1) may, in particular, include—
  - (a) the wording of certain special warnings for certain categories of medicinal products;
  - (b) the particular information needs relating to products that are a pharmacy medicine;
  - (c) the legibility of particulars on the labelling and package leaflet;
  - (d) the methods of identification and authentication of medicinal products;
  - (e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated.

(3) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission pursuant to Article 65 of the 2001 Directive<sup>(8)</sup>, insofar as that guidance was in force immediately before IP completion day, continues to apply as if it had been published by the licensing authority under paragraph (1).”.

**155.** In regulation 201 (amendment of Schedule 24 (packaging information requirements))—

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(8) The guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

- (a) in paragraph (2), after “regulation 257D” insert “in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive<sup>(9)</sup> or under regulation 257D that is applicable to such products.”;
- (b) in paragraph (3), for “for “marketing authorisation”” to the end substitute “for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation”.”;
- (c) omit paragraph (4);
- (d) in paragraph (5)—
  - (i) in the inserted Part 4 (outer and immediate packaging: advanced therapy medicinal products), in the heading, after “products” insert “for sale or supply in Great Britain only”;
  - (ii) in the inserted Part 5 (immediate packaging: blister packs and small packaging (advanced therapy medicinal products)), in the heading, after “products” insert “for sale or supply in Great Britain only”.

**156.** In regulation 202 (amendment of regulation 259 (packaging requirements: information for blind and partially sighted patients)), for “for “marketing authorisation” to the end substitute “for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation”.”.

**157.** In regulation 203 (amendment of regulation 260 (package leaflets))—

- (a) in paragraph (2), in the inserted paragraph (1A), after the first reference to “advanced therapy medicinal product” insert “for sale or supply in Great Britain only”;
- (b) in paragraph (3), in the inserted text, after “advanced therapy medicinal product,” insert “for sale or supply in Great Britain only”;
- (c) in paragraph (4)—
  - (i) omit “, Article 126a authorisation”;
  - (ii) after “UK marketing authorisation” insert “, EU marketing authorisation,”.

**158.** In regulation 204 (amendment of Schedule 27 (package leaflets))—

- (a) in paragraph (2), after “regulation 257D” insert “in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive<sup>(10)</sup> or under regulation 257D that is applicable to such products.”;
- (b) in paragraph (3), for “for “marketing authorisation” to the end substitute “for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation”.”;
- (c) in paragraph (4)—
  - (i) for “Omit” substitute “In”;
  - (ii) after “12” insert “after “Where the product” insert “is authorised for sale or supply in Northern Ireland and”.”;
- (d) in paragraph (5)(a)—
  - (i) for “for” substitute “after”;

<sup>(9)</sup> The guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

<sup>(10)</sup> The guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

- (ii) for “substitute “regulation 202A”” substitute “insert “in the case of products for sale or supply in Northern Ireland, or the list referred to in regulation 202A, in the case of products for sale or supply in Great Britain,””;
  - (e) in paragraph (6), in the inserted Part 3 (advanced therapy medicinal products), in the heading, after “products” insert “for sale or supply in Great Britain only”.
- 159.** Omit regulation 205 (amendment of regulation 266 (language requirements etc)).
- 160.** In regulation 206 (amendment of regulation 267 (submission of mock-ups of packaging and leaflets to licensing authority)) for “, in each place where it occurs” to the end substitute “before “marketing authorisation”, in each place where it occurs, insert “UK”.”.
- 161.** In regulation 207 (amendment of regulation 268 (offence relating to packaging and package leaflets))
- (a) after paragraph (1) insert—
    - “(1A) In the heading to the regulation, after “packaging and package leaflets” insert “in Great Britain”.”;
  - (b) for paragraph (2) substitute—
    - “(2) In paragraph (1)—
      - (a) for “marketing authorisation, Article 126a authorisation” substitute “UKMA(UK), UKMA(GB)”;
      - (b) after “the purpose of sale or supply” insert “, in Northern Ireland”.”.
- 162.** After regulation 207 (amendment of regulation 268 (offence relating to packaging and package leaflets)) insert—

**“Insertion of new regulation 268A (offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc)**

**207A.** After regulation 268 insert—

**“Offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc**

**268A.**—(1) This regulation applies to the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product who sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, in Northern Ireland, a medicinal product to which the authorisation, certificate or registration relates.

(2) A person to whom this regulation applies is guilty of an offence if—

- (a) a package or package leaflet relating to the product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or
- (b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.”.

- 163.** In regulation 208 (amendment of regulation 269 (offences relating to packaging and package leaflets: other persons))—
- (a) after paragraph (1) insert—

“(1A) In the heading to the regulation, after “packaging and package leaflets” insert “in Great Britain”.”;

(b) for paragraph (2) substitute—

“(2) In paragraph (1)—

(a) for “marketing authorisation, Article 126a authorisation” substitute “UKMA(UK), UKMA(GB)”;

(b) after “the purpose of sale or supply” insert “, in Great Britain”.”;

(c) after paragraph (2) insert—

“(2A) In paragraph (2), after “for the purpose of sale or supply,” insert “in Great Britain”.”.

**164.** After regulation 208 (amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)) insert—

**“Insertion of new regulation 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**

**208A.** After regulation 269 insert—

**“Offences relating to packaging and package leaflets in Northern Ireland: other persons**

**269A.**—(1) This regulation applies to a person, other than the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply in Northern Ireland.

(2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, in Northern Ireland knowing or having reasonable cause to believe—

(a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or

(b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.”.”.

**165.** In regulation 209 (amendment of regulation 270 (non-compliance with requirements of this Part)) for “for “marketing authorisation” to the end substitute “for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation,”.

**166.** After regulation 209 (amendment of regulation 270 (non-compliance with requirements of this Part)) insert—

**“Amendment of regulation 271 (offences: penalties)**

**209A.** In regulation 271 for “268, 269” substitute “268, 268A, 269, 269A”.”.

## PART 14

### Amendment of Part 15 (amendment of Part 14 (advertising))

**167.** For regulation 211 (amendment of regulation 279 (products without a marketing authorisation)) substitute—

“**211.** For regulation 279 substitute—

“**279.**—(1) A person may not publish an advertisement in Great Britain for a medicinal product unless one of the following is in force for the product—

- (a) a UKMA(GB) or UKMA(UK);
- (b) a COR(GB) or COR(UK); or
- (c) a THR(GB) or THR(UK).

(2) A person may not publish an advertisement in Northern Ireland for a medicinal product unless one of the following is in force for the product—

- (a) a UKMA(NI) or UKMA(UK);
- (b) a COR(NI) or COR(UK);
- (c) a THR(NI) or THR(UK);
- (d) an EU marketing authorisation; or
- (e) an Article 126a authorisation.

(3) A person may not publish an advertisement in the whole United Kingdom for a medicinal product unless, in relation to that product—

- (a) one of the authorisations or registrations specified in paragraph (1) is in force in Great Britain; and
- (b) one of the authorisations or registrations specified in paragraph (2) is in force in Northern Ireland.”.”.

**168.** In regulation 212 (amendment of regulation 280 (general principles))—

- (a) for “280(1)” substitute “280”;
- (b) in paragraph (a)—
  - (i) at the beginning, insert “in paragraph (1)”;
  - (ii) for “UK marketing authorisation or” substitute “UK marketing authorisation, EU marketing authorisation,”;
- (c) for paragraph (b) substitute—
  - “(b) after paragraph (1) insert—

“(1A) Where an advertisement mentioned in paragraph (1) relates to a product in relation to which there is a separate authorisation or registration in force in Great Britain and in Northern Ireland, it may not be published in the whole United Kingdom unless it complies with the particulars listed in the summary of the product characteristics in each of those authorisations or registrations (as the case may be).”.”.

**169.** In regulation 213 (amendment of regulation 281 (duties of authorisation holders and registration holders)) for paragraphs (b) and (c) substitute—

- “(b) omit “or” at the end of sub-paragraph (c); and
- (c) in sub-paragraph (d), after “for a medicinal product” insert—

“; or

(e) an EU marketing authorisation for a medicinal product.””.

**170.** After regulation 213 (amendment of regulation 281 (duties of authorisation holders and registration holders)) insert—

**“Insertion of new regulation 284A (Medicines with differing classification status in Great Britain and Northern Ireland)**

**213A.** After regulation 284, insert—

**“Medicines with differing classification status in Great Britain and Northern Ireland**

**284A.** In the case of a medicinal product for sale or supply in Great Britain where the product concerned is not a prescription only medicine in Great Britain but is either—

- (a) a prescription only medicine in Northern Ireland; or
- (b) not authorised for sale or supply in Northern Ireland,

any advertisement to the public must include a statement that the medicinal product is not available without a prescription, or is not available for sale or supply, in Northern Ireland (as the case may be).””.

**171.** For regulation 214 (amendment of regulation 293 (prohibition of supply to the public for promotional purposes) substitute—

**“214.** For regulation 293(1) substitute—

“(1) The holder of—

- (a) in the case of a medicinal product for sale or supply in Great Britain, a UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK); or
- (b) in the case of a medicinal product for sale or supply in Northern Ireland, a UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation or Article 126a authorisation,

may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.””.

**172.** After regulation 214 (amendment of regulation 293 (prohibition of supply to the public for promotional purposes) insert—

**“Amendment of regulation 294 (general requirements)**

**214A.** In regulation 294, after paragraph (4) insert—

“(5) In the case of an advertisement which relates to a medicinal product for sale or supply—

- (a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,
- (b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and
- (c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

- (i) the product for sale or supply in Great Britain, and
- (ii) the product for sale or supply in Northern Ireland.”.”.

**173.** For regulation 215 (amendment of regulation 295 (abbreviated advertisements)) substitute—

“**215.** In regulation 295—

(a) for paragraph (2)(d) substitute—

“(d) the name and address of the holder—

- (i) in the case of a medicinal product for sale or supply in Great Britain, of the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK) for the medicinal product, or
- (ii) in the case of a medicinal product for sale or supply in Northern Ireland, the name and address of the holder of the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation, or Article 126a authorisation for the medicinal product,

or the business name and address of the part of the holder’s business that is responsible for the sale or supply of the medicinal product.”;

(b) after paragraph (4) insert—

“(4A) In the application of this regulation to a medicinal product for sale or supply—

- (a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,
- (b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and
- (c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—
  - (i) the product for sale or supply in Great Britain, and
  - (ii) the product for sale or supply in Northern Ireland.”.”.

**174.** After regulation 215 (amendment of regulation 295 (abbreviated advertisements)) insert—

**“Amendment of regulation 298 (free samples for persons qualified to prescribe or supply medicinal products)**

**215A.** In regulation 298, for paragraph (5)(a) substitute—

“(a) is no larger than the smallest presentation of the product that is available for sale—

- (i) in the case of a medicinal product for sale or supply in Great Britain, in Great Britain, or
- (ii) in the case of a medicinal product for sale or supply in Northern Ireland, in Northern Ireland;”.”.

**175.** For regulation 216 (amendment of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply)) substitute—

“**216.** In Schedule 30—

- (a) in paragraphs 1, 2 and 6, for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation”;
- (b) after paragraph 2 insert—

“**2A.** In relation to an advertisement in Great Britain (other than an advertisement falling within the exception in regulation 296) where the medicinal product concerned is authorised under a UKMA(GB), a statement that the product concerned is authorised under a UKMA(GB).”.

**176.** In regulation 217 (amendment of regulation 299 (medical sales representatives)), for “for “marketing authorisation” to the end substitute “for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation”.”.

**177.** After regulation 217 (amendment of regulation 299 (medical sales representatives)) insert—

**“Amendment of regulation 305 (invitation to make representations about compatibility)”**

**217A.** In regulation 305—

- (a) for paragraph (3)(a) substitute—

“(a) state that the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2 and specify whether the incompatibility is insofar as the advertisement is for publication—

- (i) in Great Britain;
- (ii) in Northern Ireland; or
- (iii) in both Great Britain and Northern Ireland;”;

- (b) in paragraph (4), after “the advertisement” insert—

“—

- (a) in Great Britain;
- (b) in Northern Ireland; or
- (c) in both Great Britain and Northern Ireland”.

**Amendment of regulation 306 (decision about compatibility)”**

**217B.** In regulation 306—

- (a) in paragraph (2), after “Chapter 2” insert—

“and specify whether the incompatibility is insofar as the advertisement is for publication—

- (a) in Great Britain;
- (b) in Northern Ireland; or
- (c) in both Great Britain and Northern Ireland”;

- (b) in paragraph (4)—

- (i) in sub-paragraph (a), after “Chapter 2” insert—

“insofar as the advertisement is for publication—

- (i) in Great Britain;
- (ii) in Northern Ireland; or



- (iii) in both Great Britain and Northern Ireland”;
- (ii) after “no longer applies” insert “in Great Britain, Northern Ireland, or both Great Britain and Northern Ireland (as appropriate)”;
- (c) in paragraph (5), after “Chapter 2” insert—
  - “insofar as the advertisement is for publication—
  - (a) in Great Britain;
  - (b) in Northern Ireland; or
  - (c) in both Great Britain and Northern Ireland”;
- (d) in paragraph (7)(b), after “no longer applies” insert—
  - “
  - and where that original notice related to both Great Britain and Northern Ireland, the new notice may be expressed to apply in relation to either of or both Great Britain and Northern Ireland”;
- (e) in paragraph (8), after “the advertisement” insert—
  - “—
  - (a) in Great Britain;
  - (b) in Northern Ireland; or
  - (c) in both Great Britain and Northern Ireland”.

#### **Amendment of regulation 307 (corrective statement)**

**217C.** In regulation 307—

- (a) in paragraph (1)(a), after “subject of the notice” insert—
  - “in—
  - (i) Great Britain;
  - (ii) Northern Ireland; or
  - (iii) both Great Britain and Northern Ireland”;
- (b) in paragraph (1)(b), after “that advertisement” insert—
  - “in—
  - (i) Great Britain;
  - (ii) Northern Ireland; or
  - (iii) both Great Britain and Northern Ireland”;
- (c) in paragraph (2)(a), for “, either in full or in part; and” substitute—
  - “in respect of—
  - (i) Great Britain;
  - (ii) Northern Ireland; or
  - (iii) both Great Britain and Northern Ireland, either in full or in part; and”.

#### **Amendment of regulation 311 (application for injunction)**

**217D.** In regulation 311—

- (a) in paragraph (1)(a), for “Chapter 2; and” substitute—
  - “Chapter 2 in respect of—
  - (i) Great Britain;
  - (ii) Northern Ireland; or
  - (iii) both Great Britain and Northern Ireland; and”;
- (b) in paragraph (3), after “ the advertisement” insert—
  - “in—
  - (i) Great Britain;
  - (ii) Northern Ireland; or
  - (iii) both Great Britain and Northern Ireland,as the case may be.”.

## PART 15

### Amendment of Part 16 (amendment of Part 15 (British Pharmacopoeia))

**178.** In regulation 218 (amendment of regulation 321 (specified publications)), for paragraph (b) substitute—

- “(b) after sub-paragraph (c) insert—
  - “(ca) an EU marketing authorisation;”.

## PART 16

### Amendment of Part 17 (amendment of Part 16 (enforcement))

**179.** Omit regulation 219 (amendment of regulation 322 (validity of proceedings)).

**180.** In regulation 221 (amendment of regulation 327 (powers of inspection, sampling and seizure))—

- (a) in paragraph (2), for sub-paragraphs (b) and (c) substitute—
  - “(b) after paragraph (v), insert—
    - “(va) an EU marketing authorisation;”;
- (b) for paragraph (3) substitute—
  - “(3) In paragraph (2)(g), after paragraph (iv) insert—
    - “(iva) the requirements of Schedule 12A (further provision as to the performance of pharmacovigilance activities);”.
- (c) omit paragraphs (4) and (5).

**181.** In regulation 222 (amendment of regulation 331 (findings and reports of inspections))—

- (a) for paragraph (2) substitute—
  - “(2) In paragraph (1)—
    - (a) for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation”;
    - (b) in sub-paragraph (c), at the beginning, insert “in the case of a product authorised under a UKMA(NI) or UKMA(UK),”.

(b) for paragraph (3) substitute—

“(3) In paragraph (4)—

(a) for sub-paragraph (b) substitute—

“(b) the guidelines on good distribution practice—

(i) in the case of Great Britain, published under, or that apply by virtue of, regulation C17;

(ii) in the case of Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive;”;

(b) after sub-paragraph (c) insert—

“(d) Schedule 12A; and

(e) the Implementing Regulation (as defined in regulation 177(5)).”.

**182.** In regulation 223 (insertion of regulation 331A (guidelines on inspections)), in the inserted regulation 331A(3), for “exit day” substitute “IP completion day”.

## PART 17

### Amendment of Part 18 (amendment of Part 17 (miscellaneous and general))

**183.** Before regulation 224 (amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)) insert—

#### **“Amendment of regulation 335 (contravention due to fault of another person)**

**224ZA.** In regulation 335(6)(b) for “268 and 269” substitute “268, 268A, 269 and 269A”.

#### **Amendment of regulation 336 (warranty as defence)**

**224ZB.** In regulation 336(3)(b) for “268 and 269” substitute “268, 268A, 269 and 269A”.

#### **Amendment of regulation 340 (presumptions)**

**224ZC.** In regulation 340(5) for “268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons)” substitute “268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)”.

#### **Amendment of Schedule 32 (transitional provisions and savings)**

**224ZD.** In paragraph 3(10) of Schedule 32 for “268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons)” substitute “268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and

package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)”.

**184.** For regulation 224 (amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)) substitute—

“**224.** In regulation 341(4)—

(a) in paragraph (a), insert “UK” before “marketing authorisation”;

(b) after paragraph (a), insert—

“(aa) a decision to grant or revoke an EU marketing authorisation;”.

**185.** In regulation 225 (insertion of regulation 344A (modifications to deal with serious shortages) and 344B (regulation making powers)), in the inserted regulation 344A(5) for “exit day” substitute “IP completion day”.

**186.** For regulation 226 (amendment of regulation 345 (immunity from civil liability)) substitute—

“**226.** In regulation 345(5), for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation”.

**187.** In regulation 227 (amendment of regulation 346 (Secretary of State to carry out a review of certain provisions))—

(a) in paragraph (a), for “paragraphs (ia)” to “(xxviii)” substitute “paragraph (xix)”;

(b) in paragraph (b), for “paragraphs (ia) and (ivab)” substitute “paragraph (ia)”.

## PART 18

### Amendment of Schedule 1 (amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016)

**188.** In Schedule 1 (amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016)—

(a) before paragraph 1 insert—

#### **“Insertion of new regulation 10A (waiver for advice given to small and medium companies)**

**1ZA.** After regulation 10 insert—

#### **“Waiver for advice given to small and medium companies**

**10A.**—(1) The fee payable in connection with a meeting mentioned in any of regulations 4 to 10 is waived where the person by whom the fee would otherwise be payable is established in the United Kingdom and is—

(a) a small company, or

(b) a medium-sized company.

(2) In this regulation, “small company” and “medium-sized company” have the same meanings as in sections 382 and 465 of the Companies Act 2006<sup>(11)</sup> respectively.”.

<sup>(11)</sup> 2006 c.46.

- (b) in paragraph 1 (amendment of regulation 19 (capital fees for applications for variations of authorisations)), after sub-paragraph (a) insert—

“(aa) after paragraph (1)(d), insert—

“(e) under [Commission Regulation \(EC\) No 1234/2008](#) for the variation of a UKMA(UK) or UKMA(NI).”;

- (c) in paragraph 2 (insertion of regulations 19A–19F (fees for plasma master files, vaccine antigen master files, post-authorisation safety studies, major safety reviews, periodic safety update reports and batch testing))—

- (i) in the inserted regulation 19C (fees for assessment of post-authorisation safety studies)—

(aa) for paragraph (2) substitute—

“(2) The fee payable by the holder of a marketing authorisation upon submission of the draft protocol for a post-authorisation safety study in accordance with regulation 199(2) of the Human Medicines Regulations—

(a) where the authorisation for the medicinal product concerned is a UKMA(GB) granted under the unfettered access route or a UKMA(GB) granted where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation [\(EC\) No 726/2004](#) (an automatic recognition application), and provided a corresponding draft protocol has been submitted in respect of the related European Union marketing authorisation or UKMA(NI) for the same product, is £734;

(b) where sub-paragraph (a) does not apply and—

(i) the study is to be conducted in the United Kingdom only; or

(ii) the authorisation for the product which is the subject of the study authorises sale or supply in Great Britain only,

is £8,309; and

(c) in any other case, is £734.”;

(bb) for paragraph (3) substitute—

“(3) The fee payable by the holder of a marketing authorisation upon submission of the final study report for a post-authorisation safety study in accordance with regulation 201(2) of the Human Medicines Regulations—

(a) where the authorisation for the medicinal product concerned is a UKMA(GB) granted under the unfettered access route or a UKMA(GB) granted where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation [\(EC\) No 726/2004](#) (an automatic recognition application), and provided a corresponding final study report has been submitted in respect of the related European Union marketing authorisation or UKMA(NI) for the same product, is £734;

(b) where sub-paragraph (a) does not apply and—

(i) the study is to be conducted in the United Kingdom only; or

(ii) the authorisation for the product which is the subject of the study authorises sale or supply in Great Britain only,

- is £8,309; and
- (c) in any other case, is £734.”;
- (ii) in new regulation 19D (fee for carrying out a major safety review), in paragraph (1) —
- (aa) before “marketing authorisation” insert “United Kingdom”;
- (bb) after “a set of” insert “such”;
- (d) in paragraph 3 (amendment of regulation 23 (applications for multiple variations)), for sub-paragraphs (2) to (4) substitute—
- “(2) For paragraph (3)(b)(i) substitute—
- “(i) have agreed—
- (aa) in the case of a UKMA(NI) or UKMA(UK), in consultation with member States concerned and in accordance with Article 7(2)(c) of [Commission Regulation \(EC\) No 1234/2008](#), should be subject to the procedure for grouping of variations within the meaning of that Article;
- (bb) in the case of a UKMA(GB), should be subject to the procedure for grouping of variations within the meaning of paragraph 5(2)(c) of Schedule 10A to the Human Medicines Regulations; and”.
- (3) For paragraph (6) substitute—
- “(6) In a case where a recommendation on the classification of a variation is made in accordance with—
- (a) in the case of a UKMA(NI) or UKMA(UK), Article 5 of [Commission Regulation \(EC\) No 1234/2008](#); or
- (b) in the case of a UKMA(GB), paragraph 3 of Schedule 10A to the Human Medicines Regulations,
- the fee payable for the application made in respect of that variation is the appropriate fee for the classification given to the variation or, as the case may be, the appropriate fee which arises as a consequence of the classification given to the variation.”.
- (4) In paragraph (7)—
- (a) in the definition of “Major Variation (Type II) Group Application”—
- (i) for sub-paragraph (b) substitute—
- “(b) subject to sub-paragraph (c), the variations fall—
- (i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of [Commission Regulation \(EC\) No 1234/2008](#);
- (ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;”;
- (ii) for sub-paragraph (c)(i) substitute—
- “(i) of a kind referred to—
- (aa) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential

- variations) of Annex III to [Commission Regulation \(EC\) No 1234/2008](#);
- (bb) in the case of UKMA(GB), in paragraph 5(3)(a) or (c) of Schedule 10A to the Human Medicines Regulations;”;
- (b) in the definition of “Major Variation (Type II) Complex Group Application”—
  - (i) for sub-paragraph (b) substitute—
    - “(b) subject to sub-paragraph (c), the variations fall—
      - (i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of [Commission Regulation \(EC\) No 1234/2008](#);
      - (ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;”;
    - (ii) for sub-paragraph (c)(i) substitute—
      - “(i) of a kind referred to—
        - (aa) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to [Commission Regulation \(EC\) No 1234/2008](#);
        - (bb) in the case of a UKMA(GB), in paragraph 5(3)(a) or (c) of Schedule 10A to the Human Medicines Regulations;”;
  - (c) in the definition of “Major Variation (Type II) Extended Complex Group Application”—
    - (i) for sub-paragraph (b) substitute—
      - “(b) subject to sub-paragraph (c), the variations fall—
        - (i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of [Commission Regulation \(EC\) No 1234/2008](#);
        - (ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;”;
      - (ii) for sub-paragraph (c) substitute—
        - “(c) the variations do not include a variation of a kind referred to—
          - (i) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 of Annex III to [Commission Regulation \(EC\) No 1234/2008](#);
          - (ii) in the case of a UKMA(GB), in paragraph 5(3)(a) of Schedule 10A to the Human Medicines Regulations; and”;
    - (d) for the definition of “major variation of type II” substitute—
      - ““major variation of type II”—

- (a) in the case of a UKMA(NI) or UKMA(UK), has the meaning given in Article 2(3) of [Commission Regulation \(EC\) No 1234/2008](#); and
- (b) in the case of a UKMA(GB), has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations;”;
- (e) in the definition of “Minor Variation (Type IB) Group Application”—
  - (i) for sub-paragraph (b) substitute—
    - “(b) subject to sub-paragraph (c), the variations fall—
      - (i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of [Commission Regulation \(EC\) No 1234/2008](#);
      - (ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;”;
    - (ii) for sub-paragraph (c)(i) substitute—
      - “(i) a variation of a kind referred to—
        - (aa) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 or paragraph 2 of Annex III of [Commission Regulation \(EC\) No 1234/2008](#);
        - (bb) in the case of a UKMA(GB), in paragraph 5(3)(a) or (b) of Schedule 10A to the Human Medicines Regulations; or”;
  - (f) for the definition of “minor variation of type IA” substitute—
    - ““minor variation of type IA”—
      - (a) in the case of a UKMA(NI) or UKMA(UK), has the meaning given in Article 2(2) of [Commission Regulation \(EC\) No 1234/2008](#); and
      - (b) in the case of a UKMA(GB), has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations;”;
  - (g) for the definition of “minor variation of type IB” substitute—
    - ““minor variation of type IB”—
      - (a) in the case of a UKMA(NI) or UKMA(UK), has the meaning given in Article 2(5) of [Commission Regulation \(EC\) No 1234/2008](#); and
      - (b) in the case of a UKMA(GB), has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations; and”;
    - (h) in the definition of “work sharing”, after “means” insert “, in the case of a UKMA(NI) or UKMA(UK),”.”;
- (e) in paragraph 4 (insertion of regulation 27A (fee for renewals of a marketing authorisation)), in the inserted regulation 27A, after “renewal of a marketing authorisation” insert “in the case of a product for sale or supply in Great Britain”;
- (f) in paragraph 6 (amendment of Schedule 1 (general interpretation provisions)), in sub-paragraph (a)—
  - (i) before paragraph (i) insert—
    - “(ai) in the definition of “marketing authorisation”, in paragraph (a) after “Human Medicines Regulations” insert “(and a reference to a UKMA(GB),



- UKMA(NI) or UKMA(UK) should be construed in accordance with those Regulations”.”;
- (ii) in paragraph (iv), after the definition of “the EMA” insert—
- ““under the unfettered access route” has the meaning given by regulation 8(1) of the Human Medicines Regulations;”;
- (g) in paragraph 7 (amendment of Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates))—
- (i) for sub-paragraph (2) substitute—
- “(2) For paragraph 4(a) substitute—
- “(a) for an extension of a marketing authorisation—
- (i) in the case of a UKMA(NI) or UKMA(UK), within the meaning of Article 2(4) of [Commission Regulation \(EC\) No 1234/2008](#); or
- (ii) in the case of a UKMA(GB), within the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations; and”.”;
- (ii) in sub-paragraph (3)—
- (aa) in paragraph (a), for “paragraph 1 of Schedule 10A to the Human Medicines Regulations” substitute—
- “—
- (a) in the case of a UKMA(NI) or UKMA(UK), Article 2(5) of [Commission Regulation \(EC\) No 1234/2008](#);
- (b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations”;
- (bb) in paragraph (b), for “paragraph 1 of Schedule 10A to the Human Medicines Regulations” substitute—
- “—
- (a) in the case of a UKMA(NI) or UKMA(UK), Article 2(4) of [Commission Regulation \(EC\) No 1234/2008](#);
- (b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations”;
- (cc) in paragraph (c), for “paragraph 1 of Schedule 10A to the Human Medicines Regulations” substitute—
- “—
- (a) in the case of a UKMA(NI) or UKMA(UK), Article 2(2) of [Commission Regulation \(EC\) No 1234/2008](#);
- (b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations”;
- (iii) in sub-paragraph (4)—
- (aa) in paragraph (a), for “substitute” to the end, substitute “in the case of a UKMA(NI) or UKMA(UK), paragraph 1 (changes to active substances) or paragraph 2 (changes to strength, pharmaceutical form and route of administration) of Annex I to [Commission Regulation \(EC\) No 1234/2008](#) applies or, in the case of a UKMA(GB), sub-paragraph (a) (changes to active substances) or sub-paragraph (b) (changes to strength, pharmaceutical form and route of administration) of the definition of “extension of a UK

marketing authorisation” in paragraph 1 of Schedule 10A to the Human Medicines Regulations applies”;

(bb) in paragraph (b), for “paragraph 1 of Schedule 10A to the Human Medicines Regulations” substitute “in the case of a UKMA(NI) or UKMA(UK), Article 2(3) of [Commission Regulation \(EC\) No 1234/2008](#) or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations”;

(cc) in paragraph (c), for “paragraph 1 of Schedule 10A to the Human Medicines Regulations” substitute “in the case of a UKMA(NI) or UKMA(UK), [Commission Regulation \(EC\) No 1234/2008](#) or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations”;

(iv) in sub-paragraph (5), for the table substituted in paragraph 24, substitute—

**“Fees for marketing authorisation applications**

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
<b>1. Major Application</b>	
(a) in respect of an application relating to an orphan medicinal product to which point 6 of Part II of Annex 1 to the 2001 Directive applies	£29,732
(b) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£62,421
(c) which is a European reference product application in the case of a product for sale or supply in Northern Ireland	£62,421
(d) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for UKMA(GB)	£62,421
(e) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation <a href="#">(EC) No 726/2004</a>	£18,437
(f) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive	£62,421
(g) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation <a href="#">(EC) No 726/2004</a> (an automatic recognition application)	£18,437
(h) in any other case	£92,753

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
<b>2. Complex application</b>	
(a) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£17,330
(b) which is a European reference product application in the case of a product for sale or supply in Northern Ireland	£17,330
(c) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£17,330
(d) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£10,443
(e) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive	£17,330
(f) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£10,443
(g) in any other case	£25,643
<b>3. Standard application</b>	
(a) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£6,350
(b) which is a European reference product application in the case of a product for sale or supply in Northern Ireland	£6,350
(c) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£6,350
(d) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£5,783
(e) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted	£6,350

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of application</i>	<i>Fee payable</i>
a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive	
(f) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£5,783
(g) in any other case	£9,402
<b>4. Simple application</b>	
(a) which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£2,564
(b) which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB)	£2,564
(c) in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004	£2,564
(d) in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive	£2,564
(e) in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application)	£2,564
(f) in any other case	£2,564
<b>5. Parallel import licence applications</b>	
(a) in respect of a simple parallel import licence	£1,792
(b) in respect of a standard parallel import licence	£6,663
(c) in respect of a complex parallel import licence	£18,180
<b>6. Change of ownership application</b>	
(v) in sub-paragraph (6), in the inserted paragraph 24A—	
(aa) in the heading, for “exit day” substitute “IP completion day”;	
(bb) in sub-paragraph (1), for “exit day” substitute “IP completion day”;	
(vi) after paragraph (8) insert—	
“(8A) After paragraph 28 (application for multiple authorisations) insert—	

**“Application by pre-assessment of modules**

**28A.—**(1) Where an applicant for a United Kingdom marketing authorisation submits material in accordance with regulation 50(5) of the Human Medicines Regulations for pre-assessment by the licensing authority rather than as part of the submission of a full application for that marketing authorisation, the fee payable in respect of pre-assessment of each of the following Modules (as defined in Annex I to the 2001 Directive) is—

- (a) £23,188.25 in respect of Module 3 (chemical, pharmaceutical and biological information);
- (b) £23,188.25 in respect of Module 4 (non-clinical reports);
- (c) £23,188.25 in respect of Module 5 (clinical study reports).

(2) Where an applicant for a United Kingdom marketing authorisation for a similar biological medicinal product submits material in accordance with regulations 53, 53A or 53B of the Human Medicines Regulations for pre-assessment of a complex abridged application by the licensing authority rather than as part of the submission of a full application for that marketing authorisation, the fee payable in respect of pre-assessment of each of the following Modules (as defined in Annex I to the 2001 Directive) is—

- (a) £4,332.50 in respect of Module 3 (chemical, pharmaceutical and biological information);
- (b) £4,332.50 in respect of Module 4 (non-clinical reports);
- (c) £4,332.50 in respect of Module 5 (clinical study reports).

(3) The fee payable under sub-paragraphs (1) and (2) must be paid within a period of 14 days, commencing on the date of the written notice issued by the licensing authority requiring payment of the fee.

(4) Where a fee has been paid under this paragraph, any fee payable under regulation 12(1) in connection with an application for the grant of a United Kingdom marketing authorisation in respect of the same product is reduced by the amount paid under this paragraph provided that no further assessment of the Module concerned is required.”;

(vii) for sub-paragraph (9) substitute—

“(9) In paragraph 38—

- (a) in sub-paragraph (4)(b), after “Commission Regulation [\(EC\) 1234/2008](#)” insert “and of marketing authorisations in force in Great Britain”;
- (b) after sub-paragraph (6)—
  - (i) for Table 1 substitute—

“Table 1

**Fees for applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008**

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of variation</i>	<i>Fee payable</i>
<b>1. Application for a single kind variation</b>	
(a) Type IB Application	£277
(b) Type II Application	£277
(c) Type II Complex Variation Application	£2,493
(d) Extended Type II Complex Variation Application	£7,693
<b>2. Applications for a Group</b>	
(a) Minor Variation (Type IB) Group Application	£277
(b) Major Variation (Type II) Group Application	£496
(c) Major Variation (Type II) Complex Group Application	£2,703
(d) Major Variation (Type II) Extended Complex Group Application	£7,883”;

(ii) in Table 2—

(aa) in the heading to the table, after “[Commission Regulation \(EC\) No 1234/2008](#)” insert “and of marketing authorisations in force in Great Britain”;

(bb) after row 8 insert—

**9** Variation of a UKMA(GB) which was granted following an application made under the unfettered access route, provided a corresponding variation has been approved to the related UKMA(NI) for the same product

**10** Variation of a UKMA(GB) which was granted following an application made under the unfettered access route, provided a corresponding variation has been approved to the related European Union marketing authorisation for the same product

**11** Variation of a UKMA(UK) or a UKMA(GB) which was granted following an application other than an application made under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive, provided a corresponding

variation has been approved to the related marketing authorisation or UKMA(NI) for the same product

**12** Variation of a UKMA(GB) which was granted Apply fees following an application where the medicinal product and fee concerned has already been granted a European categories Union marketing authorisation under Regulation in table (EC) No 726/2004 (an automatic recognition 1”;; application), provided a corresponding variation has been approved to the related European Union marketing authorisation or UKMA(NI) for the same product

(viii) in sub-paragraph (12), in the inserted paragraph 40A—

(aa) in the heading for “exit day” substitute “IP completion day”;

(bb) in subparagraph (1) for “exit day” substitute “IP completion day”;

(ix) in sub-paragraph (13)—

(aa) for the inserted paragraph 56 substitute—

“**56.** Unless paragraph 57 applies, the fee payable under regulation 27A in connection with an application for the renewal of a United Kingdom marketing authorisation is—

(a) in respect of an application for renewal of a UKMA(GB) granted under the unfettered access route, £747;

(b) in respect of an application for renewal of a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), £747;

(c) in all other cases, £9,682.”;

(bb) for the inserted paragraph 57(2) substitute—

“(2) The fee payable under regulation 27A for applications to which subparagraph (1) applies is—

(a) in respect of applications for renewal of more than one UKMA(GB) granted under the unfettered access route or UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), and provided a corresponding renewal application has been made to the related European Union marketing authorisation or UKMA(NI) for the same product—

(i) £747 for the first application considered by the licensing authority; and

(ii) £747 for each other application;

(b) in all other cases—

(i) £9,682 for the first application considered by the licensing authority; and

(ii) £747 for each other application.”;

(h) after paragraph 8 insert—

**“Amendment of Schedule 6 (time for payment of capital fees: small companies)**

**8A.** In Schedule 6, in paragraph 2, for “entry 1(f)” substitute “entry 1(h)”.

**189.** In Schedule 2 (insertion of new Schedule 8B (modifications of Annex I to the 2001 Directive)), in the inserted Schedule 8B—

- (a) in the entry in the table for “Part I, paragraph 5.2(a)”, in the corresponding modification, for “regulations 51 to 56” substitute “regulations 51A, 52A, 53A and 54 to 56”;
- (b) in the entry in the table for “Part I, paragraph 5.2.1, second paragraph”, in the corresponding modification, for “regulation 51” substitute “regulation 51A”;
- (c) in the entry in the table for “Part II, paragraph 2(b)”, in the corresponding modification, for “regulation 51” substitute “regulation 51A”;
- (d) in the entry in the table for “Part II, paragraph 4, first paragraph”, in the corresponding modification, for “regulation 53” substitute “regulation 53A”.

**PART 19**

**Insertion of Schedule 2A (insertion of new Schedule 8C (material to accompany an application for a UK marketing authorisation under the unfettered access route))**

**190.** After Schedule 2 (insertion of new Schedule 8B (modifications of Annex I to the 2001 Directive)) insert—

“SCHEDULE 2A

Regulation 51A

Insertion of new Schedule 8C (Material to accompany an application for a UK marketing authorisation under the unfettered access route)

**1.** After Schedule 8B to the Human Medicines Regulations 2012, insert—

“SCHEDULE 8C

Regulation 50(1)

Material to accompany an application for a UK marketing authorisation under the unfettered access route

**1.** A copy of the application submitted in connection with the granting of the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.

**2.** A copy of all material submitted in support of the application for the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.

**3.** A copy of the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.”.



## PART 20

### Amendment of Schedule 4 (insertion of new Schedule 9A)

**191.** In Schedule 4 (insertion of new Schedule 9A), in the inserted Schedule 9A, for “the United Kingdom”, in each place it occurs (including the heading to paragraph 1) other than in paragraph 2(3), substitute “Great Britain”.

## PART 21

### Amendment of Schedule 6 (insertion of new Schedule 12A (further provision as to the performance of pharmacovigilance activities))

**192.** In Schedule 6 (insertion of new Schedule 12A (further provision as to the performance of pharmacovigilance activities)), in the inserted Schedule 12A—

- (a) in paragraphs 1(3), 12(5), 16(3), 22(1)(d) and 30(g), for “UK marketing authorisation” substitute “UKMA(GB)”;
- (b) in paragraph 2(a)—
  - (i) at the end of paragraph (iii) omit “and”;
  - (ii) in paragraph (iv), for “pharmacovigilance;” substitute “pharmacovigilance, and”;
  - (iii) after paragraph (iv) insert—
    - “(v) responsibilities and contact details of the nominated person (where a person is nominated under regulation 182(2A))”;
- (c) in paragraph 2(d), for “handing” substitute “handling”;
- (d) omit paragraph 4(4);
- (e) in paragraph 7—
  - (i) omit sub-paragraph (1);
  - (ii) in sub-paragraph (2)—
    - (aa) after “qualified person” insert “and nominated person (where a person is nominated under regulation 182(2A))”;
    - (bb) for “has” substitute “have”.

## PART 22

### Amendment of Schedule 7 (insertion of new Schedule 33A (Transitional Provision))

**193.** In Schedule 7 (insertion of new Schedule 33A (Transitional Provision)), in the inserted Schedule 33A—

- (a) for “exit day”, in each place it occurs, including in headings, substitute “IP completion day”;
- (b) for “21 months”, in each place it occurs, substitute “24 months”;
- (c) for “33 months”, in each place it occurs, substitute “36 months”;
- (d) for paragraph 6(2)(a) substitute—
  - “(a) insofar as it authorises sale or supply of a medicinal product in Great Britain, has effect on and after IP completion day as a UKMA(GB) granted under regulation 49(1) of these Regulations (but, insofar as it authorises sale or supply of

- a medicinal product in Northern Ireland, continues to operate in Northern Ireland as an EU marketing authorisation); and”;
- (e) in paragraph 6(4)(f), for “regulation 51(1) and (2)” substitute “regulation 51A(1) and (6)”;
- (f) before paragraph 26 insert—

**“Status of certain UK marketing authorisations granted before IP completion day**

- 26ZA.**—(1) This paragraph applies in relation to a UK marketing authorisation granted by the licensing authority under Chapter 4 of Title III to the 2001 Directive that was in force immediately before IP completion day.
- (2) A UK marketing authorisation to which this paragraph applies—
- (a) has effect on and after IP completion day as a UKMA(UK) granted under regulation 49(1) of these Regulations; and
- (b) is treated as including a statement that it is in force in the whole United Kingdom for the purposes of regulation 49(1C).”;
- (g) in paragraph 26(1)(a)—
- (i) omit “or” at the end of subparagraph (iii);
- (ii) for “and” at the end of subparagraph (iv) substitute—
- “or
- (v) is deemed to hold a parallel import licence under paragraph 28(2); and”;
- (h) in paragraph 26(2), after “continues to apply to a person” insert “where the UK marketing authorisation or parallel import licence authorises sale or supply of the medicinal product in Great Britain”;
- (i) in paragraphs 27(1), 33(1), 45(1) and 50(1), after “offence relating to packaging and package leaflets” insert “in Great Britain”;
- (j) after paragraph 27 insert—

**“Status of parallel import licences granted before IP completion day**

- 27A.**—(1) This paragraph applies in relation to a parallel import licence granted by the licensing authority that was in force immediately before IP completion day.
- (2) A parallel import licence to which this paragraph applies—
- (a) has effect on and after IP completion day as a parallel import licence in force in the whole United Kingdom granted under regulation 49(1) of these Regulations; and
- (b) is treated as including a statement that it is in force in the whole United Kingdom for the purposes of regulation 49(1C).”;
- (k) in paragraph 28(2), after “granted under Part 5” insert “, in force in Great Britain only.”;
- (l) in paragraph 29, after sub-paragraph (7) insert—
- “(8) This paragraph, with the exception of sub-paragraphs (3) and (4), applies equally to a medicinal product imported into the United Kingdom pursuant to a parallel import licence and accordingly any reference in this paragraph (other than in this sub-paragraph) to—
- (a) a marketing authorisation or a UK marketing authorisation is to be read as a reference to a parallel import licence for a medicinal product, and

- (b) the holder of a UK marketing authorisation is to be read as a reference to the holder of a parallel import licence.”;
- (m) after paragraph 29 insert—

**“Application of the batch testing requirement to relevant EU marketing authorisations, and batch testing of biological medicinal products in the EEA before IP completion day (regulation 60B)**

**29A.**—(1) Sub-paragraph (2) applies where—

- (a) an EU marketing authorisation was in force before IP completion day,
- (b) that authorisation is in force on IP completion day (whether or not it is suspended); and
- (c) that authorisation is for a medicinal product of a type that is specified in regulation 60B(2) (requirement to submit samples and other information to the appropriate authority).

(2) Where this sub-paragraph applies, the EU marketing authorisation is deemed to be subject to the batch testing requirement in regulation 60B on and after IP completion day.

(3) Sub-paragraph (4) applies where a holder of an EU marketing authorisation has, before IP completion day, submitted to a competent authority of an EEA State samples for testing from a batch of a medicinal product (“the relevant batch”) that—

- (a) is the subject of that authorisation; and
- (b) is of a type specified in regulation 60B(2).

(4) Where this sub-paragraph applies, the holder of the EU marketing authorisation is deemed to have satisfied the batch testing requirement in regulation 60B in respect of the relevant batch if, before IP completion day—

- (a) the competent authority of that EEA State examines the sample from the relevant batch; and
- (b) that authority declared it to be in conformity with the approved specifications (within the meaning of Article 114 of the 2001 Directive) before IP completion day.

(5) Sub-paragraphs (5) and (6) of paragraph 29 apply in relation to the appropriate authority’s management of the list published under regulation 60A(5) for the purposes of this paragraph and regulation 60B.”;

- (n) in paragraph 41, in sub-paragraphs (3), (5) and (8)—
  - (i) in paragraphs (a) and (b), omit “with which the United Kingdom concurred”;
  - (ii) in paragraph (c), omit “, or where such an opinion has been given but the United Kingdom recorded a divergent opinion.”;
- (o) after paragraph 41 insert—

**“Transitional provision in relation to global marketing authorisations under the 2001 Directive**

**41A.** Where a relevant medicinal product is subject to a global marketing authorisation as described in Article 6 of the 2001 Directive before IP completion day, a paediatric investigation plan does not need to be carried out in relation to that product.”;

- (p) omit Part 7 (transitional provision in relation to orphan medicinal products);

- (q) in paragraph 44(2), after “continues to apply to a person” insert “, in relation to a certificate of registration in force in Great Britain,”;
- (r) in paragraph 49(2), after “continues to apply to a person” insert “, only in relation to a registration in force in Great Britain, and”;
- (s) in paragraph 52(1), after “traditional herbal registration” insert “to be in force in Great Britain only”;
- (t) in paragraph 53, after “traditional herbal registration” insert “in force in Great Britain only”;
- (u) in paragraph 55(1)(a), after “traditional herbal registration” insert “to be in force in Great Britain only”;
- (v) omit paragraph 56;
- (w) omit paragraph 57;
- (x) in paragraph 58—
  - (i) in sub-paragraph (1)(a), after “specified matter” insert “in relation to a UKMA(GB) or a THR(GB)”;
  - (ii) in sub-paragraph (2), for “UK marketing authorisation or traditional herbal registration” substitute “UKMA(GB) or THR(GB)”;
  - (iii) in sub-paragraph (7)(a), after “specified matter” insert “in relation to a UKMA(GB) or a THR(GB)”;
- (y) in paragraph 59—
  - (i) in sub-paragraph (1)(a), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
  - (ii) in sub-paragraph (2)—
    - (aa) for “revocation” substitute “amendment”;
    - (bb) for “UK marketing authorisation or traditional herbal registration” substitute “UKMA(GB) or THR(GB)”;
  - (iii) in sub-paragraph (3)(a), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
- (z) in paragraph 60—
  - (i) in sub-paragraph (1)(b), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
  - (ii) in sub-paragraph (2), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
  - (iii) in sub-paragraph (3)(a), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
  - (iv) in sub-paragraph (5)(a), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
- (aa) in paragraph 61—
  - (i) in sub-paragraphs (2)(a) and (b), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
  - (ii) in sub-paragraph (4), for “revocation” substitute “amendment”;
  - (iii) in sub-paragraph (5)(b), after “holder” insert “of a UKMA(GB) or a THR(GB)”;
  - (iv) in sub-paragraph (6)—
    - (aa) for “revocation” substitute “amendment”;
    - (bb) in paragraph (b), after “holder” insert “of a UKMA(GB) or a THR(GB)”.

## PART 23

### Amendment of Schedule 8 (consequential provision)

**194.** In Schedule 8 (consequential provision)—

- (a) in paragraph 4 (amendment of the Prescription Only Medicines (Human Use) Order 1997)—
- (i) for “In article 5(1)” substitute “After article 5(1)”; and
  - (ii) for “insert “UK” before “marketing authorisation”” substitute “insert—  
“(1A) In paragraph (1) “marketing authorisation” means—
    - (a) in relation to medicinal products for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK);
    - (b) in relation to medicinal products for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), an EU marketing authorisation or a parallel import licence.”;”;
- (b) in paragraph 8 (amendment of the Blood Safety and Quality Regulations 2005)—
- (i) for “as if reference” substitute “as if the reference”;
  - (ii) after “within the meaning of” insert “paragraph (a) of the definition of that term in”;
- (c) for paragraph 7 (amendment of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003) substitute—
- “7. In regulation 1(2) of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003<sup>(12)</sup> (citation, commencement and interpretation), for the definition of “unlicensed product” substitute—
- ““unlicensed product” means—
- (a) in the case of a product to be imported or marketed in Great Britain, a medicinal product for human use, other than an excluded medicine, in respect of which no UKMA(GB), UKMA(UK), THR(UK) or THR(GB) has been granted;
  - (b) in the case of a product to be imported or marketed in Northern Ireland, a medicinal product for human use, other than an excluded medicine, in respect of which no UKMA(NI), UKMA(UK), THR(UK) or THR(NI), EU marketing authorisation or Article 126a authorisation has been granted,
- and “Article 126a authorisation”, “EU marketing authorisation”, “THR(GB)”, “THR(NI)”, “THR(UK)”, “UKMA(GB)”, “UKMA(NI)” and “UKMA(UK)” have the meanings given in regulation 8 of the 2012 Regulations;.”;
- (d) in paragraph 16 (amendment of the Branded Health Service Medicines (Costs) Regulations 2018)—
- (i) omit sub-paragraph (2)(a) to (d);
  - (ii) omit sub-paragraph (3);
  - (iii) omit sub-paragraph (4)(a)(i);
  - (iv) for sub-paragraph (4)(a)(ii) substitute—
    - “(ii) in sub-paragraph (b), after “Article 21” insert “or regulation 64(6) of the 2012 Regulations”; and”;

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<sup>(12)</sup> S.I. 2003/1680. The definition of “unlicensed product” in regulation 1(2) was amended by S.I. 2004/3224, 2005/2750 and 2012/1916.

- (v) omit sub-paragraph (4)(b);
- (vi) omit sub-paragraph (5);
- (vii) omit sub-paragraph (6).

## PART 24

### Amendment of Schedule 9 (retained EU law: revocations)

**195.** In Schedule 9 (retained EU law: revocations), in paragraph 1, after sub-paragraph (ii) insert—

- “(jj) Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use.”

## SCHEDULE 3

Regulation 5

### Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

#### **Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019**

1. In Schedule 1—
  - (a) omit paragraphs 2 to 6;
  - (b) omit paragraph 8;
  - (c) in paragraph 10, omit sub-paragraphs (3) and (4).