STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 3

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

New regulation B17 and C17 (good manufacturing practice and good distribution practice)

13. After regulation A17(**1**) insert—

"Chapter 1A

Good manufacturing practice and good distribution practice

Regulations on good manufacturing practice

B17.—(1) The Ministers may by regulations set out principles and guidelines of good manufacturing practice in respect of medicinal products and investigational medicinal products.

(2) Regulations under paragraph (1) may in particular make provisions as to—

(a) inspections;

(b) compliance with good manufacturing practice and, where relevant, the UK marketing authorisation;

(c) quality assurance systems;

(d) personnel;

(e) premises and equipment;

(f) documentation;

(g) production;

(h) quality control;

(i) the contracting out of work;

(j) complaints and product recall;

(k) self-inspection.

(3) Subject to any provision made in regulations under paragraph (1), the principles and guidelines set out in the Good Manufacturing Practice Directive have effect on and after exit day as they had effect immediately before exit day, but subject to the modifications specified in Schedule 2A.

(**1**) Regulation A17 was inserted by S.I. 2013/1855.

(4) The Ministers may by regulations amend or revoke Schedule 2A.

Guidelines on good manufacturing practice and good distribution practice

C17.—(1) The licensing authority may publish—

(a) detailed guidelines of good manufacturing practice in respect of medicinal products, and investigational medicinal products, referred to in Article 46(f) of the 2001 Directive, including guidelines as to the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients;

(b) principles and guidelines of good manufacturing practice for active substances, referred to in the first paragraph of point (f) of Article 46 and in Article 46b of that Directive;

(c) principles and guidelines of good distribution practice referred to in the first paragraph of point (f) of Article 46, and Article 84, of that Directive.

(2) Guidelines or principles under paragraph (1) may replace, amend or otherwise modify any guidelines or principles published or adopted by the European Commission under the second, third, fourth or fifth paragraph of Article 47, or Article 84, of the 2001 Directive.

(3) Unless replaced by principles or guidelines published under paragraph (1), principles and guidelines published or adopted by the European Commission under the second, third, fourth or fifth paragraph of Article 47, or Article 84, of the 2001 Directive, as they applied immediately before exit day(**2**), continue to apply on and after exit day (subject to any amendments or modifications published under paragraph (1)).

(4) Before exercising the power under paragraph (1), the licensing authority must consult such persons as it considers appropriate.

(5) The licensing authority may only exercise its power under paragraph (1) if it considers that it is necessary in order to take account of technical or scientific progress.

(6) If the licensing authority publishes principles and guidelines under paragraph (1), any reference in these Regulations to any principle or guideline adopted under the provisions of the 2001 Directive specified in those paragraphs is instead to be read as a reference to the principle or guideline published under paragraph (1), or that principle or guideline as amended or modified (as the case may be).".

Amendment of regulation 17 (manufacturing of medicinal products)

14.—(1) Regulation 17 is amended as follows.

(2) In paragraph (1)(a), for "state other than an EEA State" substitute "country other than an approved country for import".

(3) In paragraph (3)(a), for "a marketing authorisation, Article 126a authorisation" substitute "a UK marketing authorisation".

(4) Omit paragraph (4).

(5) In paragraph (5), for "state other than EEA State" substitute "country other than an approved country for import".

(**2**) The principles and 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.

Amendment of regulation 18 (wholesale dealing in medicinal products)

15.—(1) Regulation 18(**3**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), omit "or";

(b) in sub-paragraph (b) for "distribution." substitute "distribution; or";

(c) insert at the end—

"(c) import a medicinal product from an approved country for import for either purpose.".

(3) In paragraph (6), for "a marketing authorisation, Article 126a authorisation" substitute "a UK marketing authorisation".

(4) Omit paragraph (7).

Insertion of new regulation 18A (approved country for import)

16. After regulation 18, insert—

"**Approved country for import**

18A.—(1) The licensing authority must—

(a) publish a list of countries from which medicinal products may be imported under a wholesale dealing licence ("approved country for import list"); and

(b) only include in that list a country which is included in the approved country for batch testing list.

(2) In order to determine whether a country should be included in the approved country for import list, the licensing authority may, in particular, take into account—

(a) the country's system for ensuring that each batch of a medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of that product;

(b) the country's rules for good distribution practice;

(c) the regularity of inspections to verify compliance with good distribution practice;

(d) the effectiveness of enforcement of good distribution practice;

(e) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers and distributers of medicinal products;

(f) any on-site review of that country's regulatory system undertaken by the licensing authority;

(g) any on-site inspection of a manufacturing site in that country observed by the licensing authority; and

(h) any other relevant documentation available to the licensing authority.

(3) The licensing authority must—

(a) remove a country from the approved country for import list if that country is removed from the approved country for batch testing list;

(b) in any event review the countries it has included in the approved country for import list to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(**3**) Regulation 18 was substituted by S.I. 2013/1855 and further amended by S.I. 2016/186.

(c) undertake that review at least every three years beginning with the date on which that country is included in that list.".

Amendment of regulation 19 (exemptions from requirement for wholesale dealer's licence)

17.—(1) Regulation 19(**4**) is amended as follows.

(2) In paragraph (1)(a), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In paragraph (1)(b), after "or assembled the product" insert "in the United Kingdom".

Amendment of Schedule 3 (applications for licences under Part 3)

18.—(1) Schedule 3 is amended as follows.

(2) In paragraph 1(2)(g), for "marketing authorisation, Article 126a authorisation," substitute "UK marketing authorisation".

(3) In paragraph 2(1), for "state other than an EEA state" substitute "country other than an approved country for import".

(4) In paragraph 3—

(a) in sub-paragraph (2)(d) at the end insert "or the responsible person (import)".

(b) in sub-paragraph (3)(b)—

(i) in paragraph (i), insert "UK" before "marketing authorisation",

(ii) omit paragraph (iv), and

(iii) after paragraph (iii) insert—

"(v) an authorisation granted by an authority in a country other than the United Kingdom to sell or supply the medicinal product in that other country;";

(c) in sub-paragraph (3)(d)—

(i) in paragraph (i) omit "or",

(ii) in paragraph (ii) for "etc);" substitute "etc), or",

(iii) at the end insert—

"(iii) to be distributed by means of export to an approved country for import;"; and

(d) for sub-paragraph (4) substitute—

"(4) In sub-paragraph (2)(d)—

"the responsible person" means the person who has the functions described in regulation 45(2);

"the responsible person (import)" means the person who has the functions described in regulation 45AA(4).".

Amendment of regulation 23 (grant or refusal of licence)

19. In regulation 23(1)(b), omit "and any European Union obligation".

Amendment of Schedule 4 (standard provisions of licences under Part 3)

20.—(1) Schedule 4 is amended as follows.

(**4**) Regulation 19 was amended by S.I. 2013/1855.

(2) In paragraph 13(b), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In the heading of Part 2, for "State Other Than an EEA State" substitute "Country other than an Approved Country for Import".

(4) In paragraphs 15, 22(1) and 23, for "state other than an EEA State" substitute "country other than an approved country for import".

(5) In paragraph 25(m), for the words "referred to in Article 8(2) of Directive 2004/23/EC", substitute—

"assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990(**5**), as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**6**), as regards other human tissues and cells.".

(6) In paragraph 33, for "another EEA State" substitute "an approved country for import".

Amendment of regulation 26 (general power to suspend, revoke or vary licences)

21. In regulation 26(5)(a), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of Schedule 5 (review upon oral representations)

22.—(1) Schedule 5(**7**) is amended as follows.

(2) In paragraph 1(2)(e), 3(11)(b) and 5(2)(d) after—

(a) "UK marketing authorisation," in each place it appears, insert "parallel import licence,"; and

(b) "an authorisation," or "the authorisation," in each place it appears, insert "licence,".

(3) In paragraph 3 omit sub-paragraph (11)(b)(iii).

(4) In paragraph 5 omit sub-paragraph (2)(c).

Amendment of regulation 29 (variation of licence on the application of the holder)

23. In regulation 29(5)—

(a) in sub-paragraph (b) omit "or";

(b) in sub-paragraph (c) for "granted." substitute "granted; or"; and

(c) at the end insert—

"(d) the responsible person (import) under regulation 45AA.".

Amendment of regulation 31 (certification of manufacturer's licence)

24.—(1) Regulation 31 is amended as follows.

(2) In paragraph (1)(c), for "an EEA State" substitute "the United Kingdom".

(3) In paragraphs (3)(b), (5)(a) and (5)(b) insert "UK" before "marketing authorisation".

(**5**) 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.
(**6**) S.I. 2007/1523.
(**7**) Schedule 5 was amended by S.I. 2013/1855.

Amendment of regulation 33 (offence concerning data for advanced therapy medicinal products)

25.—(1) Regulation 33 is amended as follows.

(2) In paragraph (1)(a)—

(a) for "Article 15(1) of Regulation 1394/2007" substitute "paragraph 8 of Schedule 6"; and

(b) for "Article 15(4) of that Regulation" substitute "paragraph 9 of that Schedule".

(3) In paragraph (1)(b), for "Article 15(1)" substitute "paragraph 8".

(4) In paragraph (2) for "Article 15(4)" substitute "paragraph 9".

Amendment of Schedule 6 (manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products)

26.—(1) Schedule 6 is amended as follows.

(2) In paragraph 3, for "Directive 2004/23/EC", substitute—

"requirements imposed pursuant to—

(a) paragraphs 6 to 9 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards gametes and embryos; and

(b) paragraphs 9 to 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other tissues and cells.".

(3) In paragraph 4, for the words "laid down in" to the end, substitute—

"imposed pursuant to—

(a) Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards gametes and embryos; and

(b) Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other tissues and cells.".

(4) In paragraph 5, for the words from "Commission" to the end substitute "the Blood Quality and Safety Regulations 2005(**8**)".

(5) In paragraph 11, for the words from "laid down in" to the end, substitute—

"imposed pursuant to—

(a) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990(**9**);

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005; and

(c) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007;".

Amendment of regulation 36 (conditions for manufacturer's licence)

27. In regulation 36(**10**), omit paragraphs (4) to (7).

(**8**) S.I. 2005/50. It was amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/554, 2016/604, 2017/1320 and 2018/231.
(**9**) Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.
(**10**) Regulation 36 was amended by S.I. 2013/1855 and 2019/62.

Amendment of regulation 37 (manufacturing and assembly)

28.—(1) Regulation 37(**11**) is amended as follows.

(2) In paragraph (4)(b)—

(a) for "third country" substitute "country other than an approved country for import"; and

(b) for "competent authority of a member State" substitute "appropriate authority for the registration of such persons in the approved country for import".

(3) In paragraph (5)(b), for "paragraph 5 of Article 47 of the 2001 Directive" substitute "the guidelines which apply under or by virtue of regulation C17".

(4) In paragraph (6)(b), for "marketing authorisations, Article 126a authorisations" substitute "UK marketing authorisations".

(5) In paragraph (9)(a), from "Commission" to the end substitute "the Blood Quality and Safety Regulations 2005(**12**); or".

(6) In paragraph (11)—

(a) for "competent authority of a member State" substitute "licensing authority"; and

(b) insert "UK" before "marketing authorisation".

Amendment of regulation 38 (imports)

29.—(1) Regulation 38(**13**) is amended as follows.

(2) In the heading, for "states other than EEA states" substitute "countries other than approved countries for import".

(3) In paragraphs (2) and (3)(b), for "state other than an EEA State" substitute "country other than an approved country for import".

Amendment of regulation 39 (further requirements for manufacturer's licence)

30. In regulation 39(8)(**14**), omit ", 43A".

Amendment of regulation 42 (conditions for wholesale dealer's licence)

31.—(1) Regulation 42(**15**) is amended as follows.

(2) In paragraph (1), for "45" substitute "45AA".

(3) Omit paragraphs (4) and (5).

Amendment of Schedule 7 (qualified persons)

32.—(1) Schedule 7(**16**) is amended as follows.

(2) In Part 1—

(a) in paragraph 3, for "the member State in which it is studied" substitute "the licensing authority";

(**11**) Regulation 37 was substituted by S.I. 2013/1855.
(**12**) S.I. 2005/50. It has been amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/554, 2016/604, 2017/1320 and 2018/231.
(**13**) Regulation 38 was amended by S.I. 2015/1503.
(**14**) Regulation 39 was amended by S.I. 2013/1855, 2015/354 and 2019/62.
(**15**) Regulation 42 was amended by S.I. 2013/1855 and 2019/62.
(**16**) Schedule 7 was amended by S.I. 2019/62.

(b) in paragraph 6, for "the member State in which the courses take place" substitute "the licensing authority".

(3) In Part 3 (obligations of qualified person)—

(a) in paragraph 12—

(i) the existing text becomes sub-paragraph (1),

(ii) in paragraph (a) of that sub-paragraph—

(aa) for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation",

(bb) after "herbal registration" insert ", or an equivalent authorisation,", and

(cc) insert "and" at the end,

(iii) in paragraph (b) of that sub-paragraph—

(aa) for "medicinal products imported from a non-EEA State, irrespective of whether the products have been manufactured in an EEA State" substitute "medicinal products imported from a country other than approved country for import, irrespective of whether the products have been manufactured in the United Kingdom or an approved country for import", and

(bb) in paragraph (iii), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation", and

(cc) after "herbal registration" insert ", or an equivalent authorisation,",

(iv) omit paragraph (c) of that sub-paragraph, and

(v) after that sub-paragraph insert—

"(2) In this paragraph "equivalent authorisation" means, in respect of a medicinal product that does not have a UK marketing authorisation, certificate of registration or traditional herbal registration, such equivalent authorisation or registration granted by an appropriate authority for the licensing of medicinal products in an approved country for import.".

(b) omit paragraph 13;

(c) in paragraph 14—

(i) in sub-paragraph (1)(a) for "country other than an EEA State" substitute "country other than approved country for import",

(ii) in sub-paragraph (1)(b)—

(aa) for "European Union" substitute "licensing authority",

(bb) for "that country" substitute "the country from which those products are imported", and

(cc) in sub-paragraph (i), for "laid down by the European Union" substitute "in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17",

(iii) at the end insert—

"(3) The licensing authority must publish a list of the countries with whom it has made appropriate arrangements under sub-paragraph (1)(b) ("approved country for batch testing list").

(4) A country may be included in the approved country for batch testing list subject to any condition or restriction that the licensing authority considers

appropriate, including as to categories of medicinal product, and any such condition or restriction must be included in the list.

(5) In order to satisfy itself of the matters specified in sub-paragraph (1)(b)(i) and (ii), the licensing authority may, in particular, take into account—

(a) the country's rules for good manufacturing practice;

(b) the regularity of inspections to verify compliance with good manufacturing practice;

(c) the effectiveness of enforcement of good manufacturing practice;

(d) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers;

(e) any on-site review of that country's regulatory system undertaken by the licensing authority;

(f) any on-site inspection of a manufacturing site in that country observed by the licensing authority;

(g) any other relevant documentation available to the licensing authority.

(6) The licensing authority must—

(a) review any appropriate arrangements it has made under sub-paragraph (1)(b) to determine if that country still satisfies the requirements of sub-paragraph (1)(b)(i) and (ii), and whether any condition or restriction in those arrangements remains appropriate;

(b) if it is not so satisfied, remove that country from the approved country for batch testing list or, as the case may be, amend or remove that condition or restriction; and

(c) undertake such a review at least every three years beginning with the date on which the country is included in that list.".

Amendment of regulation 43 (obligations of licence holder)

33.—(1) Regulation 43(**17**) is amended as follows.

(2) In paragraph (1), for "by the European Commission in accordance with Article 84 of the 2001 Directive" substitute "under, or that apply by virtue of, regulation C17".

(3) In paragraph (5)(a) and 7(b)(ii), for "marketing authorisation, Article 126a authorisation", substitute "UK marketing authorisation".

(4) In paragraph (6)—

(a) in sub-paragraph (a), insert at the end "in the United Kingdom"; and

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

"(b) the export to an approved country for import, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that country without—

(i) a marketing authorisation, certificate of registration or traditional herbal registration within the meaning of the 2001 Directive, by virtue of legislation adopted by that country under Article 5(1) of that Directive, where the approved country for import is an EEA State, or

(**17**) Regulation 43 was amended by S.I. 2013/1855 and 2016/186.

(ii) such equivalent authorisation, certificate or registration in the approved country for import, under legislation in that country that makes provision that is equivalent to Article 5(1) of the 2001 Directive, where the approved country for import is not an EEA State.".

(5) In paragraph (7)—

(a) in sub-paragraph (b)—

(i) in sub-paragraph (i), for "the competent authority of any EEA State" substitute "an appropriate authority for the licensing of medicinal products in an approved country for import", and

(ii) in sub-paragraph (ii), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation"; and

(b) omit sub-paragraph (c)(vii).

(6) For paragraph (8) substitute—

"(8) Paragraph (8A) applies to a person ("P") who—

(a) imports a medicinal product, other than for the sole purpose of wholesale distribution of that product to a person in a country other than the United Kingdom; but

(b) is not the holder of a UK marketing authorisation, certificate of registration or traditional herbal registration in respect of that product.

(8A) Where this paragraph applies, P must—

(a) notify—

(i) the holder of any authorisation, certificate or registration, granted by an authority in the country from which the product is exported, to sell or supply that product in that country, and

(ii) the licensing authority,

of the intention to import that product; and

(b) pay a fee to the licensing authority in accordance with the Fees Regulations.".

(7) Omit paragraphs (10) and (11).

(8) In paragraph (13), insert "UK" before "marketing authorisation holder".

(9) Omit paragraph (15).

Omission of regulation 43A (requirement for wholesale dealer to decommission the unique identifier)

34. Omit regulation 43A(**18**).

Amendment of regulation 44 (requirement for wholesale dealers to deal only with specified persons)

35.—(1) Regulation 44(**19**) is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (b), for "another EEA State" substitute "an approved country for import"; and

(**18**) Regulation 43A was inserted by S.I. 2019/62.
(**19**) Regulation 44 was amended by S.I. 2013/1855, 2015/1503 and 2016/186.

(b) in sub-paragraph (c), for "from a third country ("A") for export to a third country ("B")", substitute "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")".

(3) In paragraph (5)(b), for "competent authority of another EEA State" substitute "appropriate authority of an approved country for import that is responsible for".

(4) In paragraph (5)(e)—

(a) for "third countries" substitute "countries other than approved countries for import"; and

(b) for "third country concerned" substitute "country to which the product is supplied".

(5) In paragraph (6)—

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

(b) omit sub-paragraph (e) (and "and" immediately preceding it).

Amendment of regulation 45 (requirement as to responsible persons)

36.—(1) Regulation 45 is amended as follows.

(2) In paragraph (1), for "The licence holder" insert substitute "Subject to regulation 45AA, the licence holder".

(3) In paragraph (2)(b) for "marketing authorisations, Article 126a authorisations" substitute "UK marketing authorisations".

Insertion of new regulations 45AA and 45AB (responsible persons: import)

37. After regulation 45, insert—

"**Requirement as to responsible persons where licence holder imports from an approved country for import**

45AA.—(1) Subject to paragraph (2), this regulation applies where the licence holder imports a medicinal product from an approved country for import under a wholesale dealer's licence.

(2) The requirements of this regulation do not apply where an unlicensed medicinal product falling under paragraph (1) is imported—

(a) from an approved country for import for the sole purpose of distribution by way of wholesale dealing as a special medicinal product; or

(b) for the sole purpose of wholesale distribution of that product to a person in a country other than an approved country for import.

(3) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person (import)") whose name is included in the register established under regulation 45AB.

(4) A responsible person (import) must—

(a) carry out the functions under regulation 45(2), unless a responsible person under regulation 45 is performing those functions in respect of the licence; and

(b) ensure that there is appropriate evidence to confirm that each production batch of a medicine imported from an approved country for import under the licence has been certified as provided for in Article 51 of the 2001 Directive, or such equivalent certification procedure as applies in the approved country for import.

(5) The licensing authority must publish guidance on the documentation that it considers to be appropriate evidence for the purposes of paragraph (4)(b).

(6) Guidance published under paragraph (5) may be taken into account by the licensing authority in determining whether it considers there has been a failure to comply with this regulation.

(7) The licence holder must apply to vary the licence if a change is proposed to the responsible person (import).

(8) The licence holder must not permit any person to act as a responsible person (import) other than the person named in the licence.

(9) Paragraph (10) applies if—

(a) the person acting as responsible person (import) in respect of the licence is no longer included in the register under 45AB;

(b) the licensing authority thinks, after giving the licence holder and a person acting as a responsible person (import) the opportunity to make representations (orally or in writing), that the responsible person (import) is failing to carry out the functions referred to in paragraph (4) adequately or at all.

(10) Where this paragraph applies the licensing authority—

(a) must notify the licence holder in writing that the person is not permitted to act as a responsible person (import) in respect of that licence; and

(b) may, subject to regulation 45AB(3)(b), remove that person's name from the register under regulation 45AB.

(11) In this regulation, "unlicensed medicinal product" means a medicinal product in respect of which—

(a) there is no marketing authorisation, within the meaning of the 2001 Directive, in any EEA State in respect of that product, where the product is imported from an approved country for import that is an EEA State; or

(b) there is no licence or authorisation in respect of that product as regards its sale or supply in the approved country for import, where the product is imported from an approved country for import that is not an EEA State.

Register for responsible persons (import)

45AB.—(1) The licensing authority must maintain a register of persons ("the responsible person (import) register") who may carry out the role of responsible person (import) under regulation 45AA.

(2) The licensing authority may only include a person's name in the responsible person (import) register if that person—

(a) holds—

(i) a diploma, certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, or

(ii) such other qualification as the licensing authority is satisfied is equivalent;

(b) is a member of—

(i) the Royal Society of Biology,

(ii) the Royal Pharmaceutical Society,

(iii) the Pharmaceutical Society of Northern Ireland,

(iv) the Royal Society of Chemistry, or

(v) such other body as may be specified by the licensing authority for the purpose of this paragraph; and

(c) has a minimum of 2 years' experience in performing the functions of a responsible person under regulation 45, or in performing such other functions that appear to the licensing authority to be equivalent.

(3) The licensing authority—

(a) may remove a person's name from the responsible person (import) register if it no longer considers that the person satisfies the requirements of paragraph (2); but

(b) it may not exercise that power unless it has given that person the opportunity to make representations to it (orally or in writing).".

Amendment of regulation 45A (brokering in medicinal products)

38.—(1) Regulation 45A(**20**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a) for paragraphs (i) and (ii) substitute—

"(i) by the licensing authority, or

(ii) by an appropriate authority responsible for the licensing of medicinal products in an approved country for import,";

(b) in sub-paragraph (b)—

(i) in paragraph (i), for "a competent authority of a member State" substitute "the licensing authority",

(ii) in paragraph (ii), omit "except where the person is validly registered with the competent authority of another EEA State", and

(iii) in paragraph (iii), for "published by the European Commission in accordance with Article 84 of the 2001 Directive" substitute "which apply under, or by virtue of, regulation C17".

(3) In paragraph (2)—

(a) in sub-paragraph (a), for "a competent authority of a member State" substitute "the licensing authority";

(b) in sub-paragraph (c), for "competent authority of a member State" substitute "licensing authority".

(4) Omit paragraph (3).

Amendment of regulation 45D (grant or refusal of a broker's registration)

39. In regulation 45D(1)(b)(**21**) omit sub-paragraph (ii) (and "and" immediately preceding it).

Amendment of regulation 45E (criteria of broker's registration)

40. In regulation 45E(3)(**22**)—

(a) in sub-paragraph (b)(i), for "the competent authority of any EEA State" substitute "an appropriate authority responsible for the licensing of medicinal products in an approved country for import"; and

(**20**) Regulation 45A was inserted by S.I. 2013/1855.
(**21**) Regulation 45D was inserted by S.I. 2013/1855.
(**22**) Regulation 45E was inserted by S.I. 2013/1855.

(b) omit sub-paragraph (d)(iii).

Amendment of regulation 45F (provision of information)

41. In regulation 45F(1)(**23**) for sub-paragraph (b) substitute—

"(b) either—

(i) the UK marketing authorisation holder; or

(ii) 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;".

Amendment of regulation 45M (criteria for importation, manufacture or distribution of an active substance)

42.—(1) Regulation 45M(**24**) is amended as follows.

(2) In paragraph (2)(a), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In paragraph (3), omit "from a state other than an EEA State".

Amendment of Schedule 7A (information to be provided for registration as an importer, manufacturer or distributor of active substances)

43.—(1) Schedule 7A(**25**) is amended as follows.

(2) In paragraph 13(b), omit "from third countries".

(3) In paragraph 15(c), omit "to a third country".

Amendment of regulation 45O (requirements for registration as an importer, manufacturer or distributor of an active substance)

44.—(1) Regulation 45O(**26**) is amended as follows.

(2) In paragraph (1), for "the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies" substitute "principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply".

(3) In paragraph (2), for "the Commission has adopted principles and guidelines of good distribution practice under the fourth paragraph of Article 47 of the 2001 Directive which applies" substitute "principles and guidelines of good distribution practice have been published under, or apply by virtue of, regulation C17, which apply".

(4) In paragraph (3)—

(a) for "the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies" substitute "principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply";

(b) for "imported from a third country" substitute "so imported";

(c) in sub-paragraph (c)—

(**23**) Regulation 45F was inserted by S.I. 2013/1855.
(**24**) Regulation 45M was inserted by S.I. 2013/1855.
(**25**) Schedule 7A was inserted by S.I. 2013/1855.
(**26**) Regulation 45O was inserted by S.I. 2013/1855.

(i) omit "third" in both places it appears,

(ii) in paragraph (ii), for "Union" substitute "United Kingdom", and

(iii) in paragraph (iii), for "Union" substitute "licensing authority".

(5) In paragraph (4)—

(a) in sub-paragraph (a), for "Article 111b of the 2001 Directive" substitute "paragraph (6)"; and

(b) in sub-paragraph (b)(i), for "competent authority of a member State" substitute "licensing authority or an appropriate authority responsible for the licensing of medicinal products in a country included in a list under paragraph (6)".

(6) At the end insert—

"(6) The licensing authority may publish a list of countries which it is satisfied have a regulatory framework applicable to active substances exported to the United Kingdom that is equivalent to the regulatory framework in the United Kingdom, in that the respective control and enforcement activities in those countries ensures an equivalent level of protection of public health.

(7) Before including a country in the list under paragraph (6), the licensing authority must assess the equivalence referred to in that paragraph by—

(a) reviewing relevant documentation; and

(b) unless the country is included in the approved country for batch testing list, carrying out—

(i) an on-site review of the country's regulatory system, and

(ii) if the licensing authority considers it necessary, an inspection of one or more of that country's manufacturing sites for active substances.

(8) In carrying out an assessment under paragraph (7) the licensing authority must in particular take account of the—

(a) country's rules for good manufacturing practice;

(b) regularity of inspections to verify compliance with good manufacturing practice;

(c) effectiveness of enforcement of good manufacturing practice; and

(d) regularity and rapidity of information provided by that country relating to non-compliant producers of active substances.

(9) The licensing authority must—

(a) review the list under paragraph (6) to determine if a country included in it still satisfies the requirements for inclusion in the list, and if it is not so satisfied, remove that country; and

(b) undertake such a review at least every three years, beginning with the date on which a country is included in the list .".