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DRAFT STATUTORY INSTRUMENTS

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**2019 No.**

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

**PART 5**

**Amendment of Part 5 (marketing authorisations)**

**Amendment of regulation 48 (application of Part 5)**

**47.**—(1) Regulation 48(1) is amended as follows.

(2) In paragraph (2)—

(a) at the appropriate place insert—

““EU reference medicinal product” means a medicinal product which falls within paragraph (b) of the definition of “reference medicinal product””;

(b) for the definition of “generic medicinal product”, substitute—

““generic medicinal product”, in relation to a reference medicinal product, means a medicinal product—

(a) that has the same qualitative and quantitative composition in active substances as the reference medicinal product;

(b) that has the same pharmaceutical form as the reference medicinal product; and

(c) whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies”;

(c) for the definition of “parallel import licence” substitute—

““parallel import licence” means a licence that is granted by the licensing authority under this Part authorising the holder to place on the market a medicinal product imported in to the United Kingdom from an EEA State where that product—

(a) has been granted an EU marketing authorisation or a marketing authorisation in an EEA State under the 2001 Directive; and

(b) is essentially similar to a product that has been granted a UK marketing authorisation”;

(d) for the definition of “reference medicinal product”, substitute—

““reference medicinal product” means a medicinal product—

(a) authorised under regulation 49(1)(a), in accordance with the provisions of regulation 50; or

(b) in relation to which an EU marketing authorisation was in force on exit 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.”.

(3) After paragraph (2) insert—

“(3) In this Part, references to a medicinal product to be imported that is “essentially similar to a product that has been granted a UK marketing authorisation” are to be read as references to a medicinal product to be imported that—

- (a) has been manufactured to the same formulation as a product that has been granted a UK marketing authorisation (“the UK product”);
- (b) contains the same active ingredients as the UK product;
- (c) has the same therapeutic effect as the UK product,

and for the purposes of sub-paragraph (a), any differences in a product’s formulation are to be ignored in so far as they are considered to be immaterial by the licensing authority.

(4) For the purposes of the definition of generic medicinal product—

- (a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and
- (b) the various immediate-release oral pharmaceutical forms are considered to be the same pharmaceutical form.

(5) When a medicinal product has been granted a UK marketing authorisation under regulation 49(1)(a) in accordance with the provisions of regulation 50 (“initial marketing authorisation”), any additional strengths, pharmaceutical forms, administration routes, presentations, variations and extensions in relation to which a UK marketing authorisation is granted under regulation 49(1)(a), or which are included in the initial UK marketing authorisation, belong to the same “global marketing authorisation”.

(6) Paragraph (7) applies if a medicinal product—

- (a) belongs to a global marketing authorisation but is not the initial marketing authorisation; and
- (b) is used as a reference medicinal product in accordance with regulations 51 to 53.

(7) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51(1) and (8) as if it had been authorised on the date of authorisation of the medicinal product to which the initial marketing authorisation relates.

(8) Paragraph (9) applies in relation to a medicinal product if—

- (a) it is an EU reference medicinal product;
- (b) it is used as a reference medicinal product in accordance with regulations 51 to 53; and
- (c) it belongs to a global marketing authorisation, as described in the second paragraph of Article 6(1) of the 2001 Directive; but
- (d) it is not the initial marketing authorisation for the purposes of that global marketing authorisation.

(9) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51(1) and (8) as if it had been authorised on the date of authorisation of the initial marketing authorisation for the purposes of the global marketing authorisation to which the product belongs.”.

### **Amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence)**

- 48.**—(1) Regulation 49(2) is amended as follows.
- (2) In paragraph (1), after “regulation 58,” insert “58C, 58E, 58F and 58G,”.
- (3) After paragraph (1) insert—
- “(1A) The licensing authority may only grant a parallel import licence if it is able to obtain the information necessary, whether from a competent authority of an EEA State or otherwise, to satisfy itself that the medicinal product to be imported—
- (a) has been granted an EU marketing authorisation or a marketing authorisation under the 2001 Directive; and
- (b) is essentially similar to a product that has already been granted a UK marketing authorisation.”.
- (4) In paragraph (3), for “European Union” substitute “United Kingdom.”
- (5) After paragraph (3) insert—
- “(3A) An application for a parallel import licence may not be made by—
- (a) the holder of the marketing authorisation, within the meaning of the 2001 Directive, or the EU marketing authorisation, in respect of the relevant medicinal product to be imported; or
- (b) a company which is in the same group as the holder of that marketing authorisation.”.
- (6) At the end insert—
- “(9) In this regulation “group” has the same meaning as in Part 15 of the Companies Act 2006(3) (see section 474(1) of that Act).”.

### **Amendment of regulation 50 (accompanying material)**

- 49.**—(1) Regulation 50(4) is amended as follows.
- (2) In paragraph (4), omit “from a country other than an EEA State”.
- (3) After paragraph (5) insert—
- “(5A) The Ministers may by regulations amend Schedule 8B (modifications of Annex I) for the purpose of further modifying Annex I to the 2001 Directive in order to take account of scientific and technical progress.
- (5B) The licensing authority may publish, for the purposes of applications made pursuant to this regulation—
- (a) guidance on the presentation and content of the material specified in Schedule 8;
- (b) scientific guidelines relating to the quality, safety and efficacy of medicinal products; and
- (c) guidelines describing the active substance manufacturing process and process controls.
- (5C) Unless replaced by guidance or guidelines published under the power conferred by paragraph (5B), the following guidance and guidelines continue to apply as they applied

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(2) Regulation 49 was amended by [S.I. 2014/1878](#).

(3) [2006 c.46](#).

(4) Regulation 50 was amended by [S.I. 2014/1878](#).

immediately before exit day (subject to any amendments or variations published under that paragraph)—

- (a) the guidance published by the European Commission in the rules governing medicinal products in the European Community, Volume 2B, Notice to Applicants, Medicinal Products for human use, Presentation and content of the dossier, Common Technical Document(5);
- (b) the scientific guidelines relating to the quality, safety and efficacy of medicinal products as adopted by the Committee for Medicinal Products for Human Use and published by the EMA and the other pharmaceutical Community guidelines published by the European Commission in the different volumes of the rules governing medicinal products in the European Community(6); and
- (c) guidelines published by the EMA for the purposes of paragraph 3.2.1.2 of Part I of Annex I to the 2001 Directive(7).”.

(4) In paragraph (6), before sub-paragraph (a), insert—

- “(za) regulation 50A (requirement for certain applications to include results of paediatric investigation plan);
- (zb) regulation 50E (application for paediatric use marketing authorisation);
- (zc) regulation 50F (other applications including paediatric indications);
- (zd) regulation 50G (applications relating to orphan medicinal products);
- (ze) regulation 50H (applications relating to advanced therapy medicinal products);
- (zf) regulation 50I (applications relating to conditional marketing authorisations);
- (zg) regulation 50J (applications relating to medicinal products containing or consisting of genetically modified organisms);”.

(5) After paragraph (6), insert—

“(7) The licensing authority may make appropriate arrangements with any EEA State or the EMA in order to obtain the information it considers necessary to satisfy itself that a product to be imported under a parallel import licence is essentially similar to a product that has been granted a UK marketing authorisation.

(8) If the licensing authority makes arrangements under paragraph (7), it must publish a list of the EEA States or the organisation with which it has made such arrangements.”.

### **Amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation)**

**50.**—(1) Schedule 8(8) is amended as follows.

(2) In paragraph 12—

- (a) in sub-paragraph (a), after “pharmacovigilance” insert “who is ordinarily resident, and operates, in the United Kingdom”;
- (b) omit sub-paragraph (b); and

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- (5) The guidance is 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.
  - (6) 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.
  - (7) The guidance is 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.
  - (8) Schedule 8 was amended by [S.I. 2013/1855](#).

- (c) in paragraph (e) at the end insert “or, if kept in electronic form, from which it can be accessed, which in either case, must be in the United Kingdom”.
- (3) For paragraph 18 substitute—
  - “**18.** Where 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.”.
- (4) In paragraph 19, for “a member state or by a third country”, substitute “a country other than the United Kingdom or by the European Commission”.
- (5) Omit paragraph 20.
- (6) In paragraph 21, for “a member state or by a third country”, substitute “a country other than the United Kingdom”.
- (7) Omit paragraph 22.
- (8) In paragraph 23—
  - (a) for “Article 23 of Regulation (EC) No 726/2004” substitute “regulation 202A”;
  - (b) before “statement”, insert “symbol and”; and
  - (c) before “This”, insert “▼”.
- (9) After paragraph 25, insert—
  - “**25A.** In the case of an advanced therapy medicinal product which contains cells or tissues, a detailed description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin.”.
- (10) After paragraph 35, insert—
  - “**36.** In the case of an advanced therapy medicinal product—
    - (a) references in this Part of this Schedule to administration of a product include references to the advanced therapy medicinal product’s use, application or implantation; and
    - (b) descriptions, instructions and warnings must include explanatory drawings and pictures where necessary.”.

#### **Amendment of Schedule 8A (material to accompany an application for a parallel import licence)**

- 51.** Paragraph 6 of Schedule 8A(9) is amended as follows—
  - (a) in sub-paragraph (a), after “pharmacovigilance” insert “who resides and operates in the United Kingdom”;
  - (b) omit sub-paragraph (b); and
  - (c) in paragraph (e) at the end inset “or, if kept in electronic form, from which it can be accessed, which in either case, must be in the United Kingdom”.

#### **Amendment of Schedule 9 (undertakings by non-United Kingdom manufacturers)**

- 52.**—(1) Schedule 9 is amended as follows.
  - (2) In the heading, for “EEA” substitute “United Kingdom”.
  - (3) In each place where it occurs, insert “UK” before “marketing authorisation”.

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(9) Schedule 8A was inserted by [S.I. 2014/1878](#).

## **New regulation 50A to 50J (applications in relation to particular medicinal products)**

53. After regulation 50, insert—

### **“Requirement for certain applications to include results of paediatric investigation plan**

**50A.**—(1) This regulation applies in relation to an application—

- (a) under regulation 49 for a UK marketing authorisation for a relevant medicinal product which is an initial marketing authorisation for the purposes of a global marketing authorisation, as described in regulation 48(5), or
- (b) under regulation 49 or 65C for a new indication (including a paediatric indication), a new pharmaceutical form or a new route of administration in relation to a relevant medicinal product which is already the subject of a UK marketing authorisation.

(2) Paragraph (1)(b) only applies if the medicinal product in relation to which the new indication, new pharmaceutical form or new route of administration is sought is protected in the United Kingdom by a supplementary protection certificate or a patent which qualifies for the granting in the United Kingdom of a supplementary protection certificate.

(3) An applicant making an application to which this regulation applies must, in addition to the material specified in regulation 50, or in Schedule 10A, provide to the licensing authority the results of all studies performed, and details of all information collected, in compliance with an agreed paediatric investigation plan.

(4) Where paragraph (1)(b) applies, the material provided pursuant to paragraph (3) must cover both the existing and new indication, pharmaceutical form or route of administration.

(5) Paragraph (3) does not apply—

- (a) to the extent that the licensing authority has, in relation to all or part of the paediatric population, granted—
  - (i) a deferral under regulation 50C of the initiation or completion of some or all of the measures set out in a paediatric investigation plan, or
  - (ii) a waiver under regulation 50D of the obligation to produce the information referred to in paragraph (3); or
- (b) if one of regulations 51 to 54 applies to the application.

(6) The applicant making an application to which this regulation applies must include in the application details of the measures intended to ensure the follow up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product.

### **Agreement and modification of paediatric investigation plan**

**50B.**—(1) Any person may prepare a paediatric investigation plan and submit it to the licensing authority with a request for agreement.

(2) A paediatric investigation plan must—

- (a) specify the timing and measures proposed to assess the safety, quality and efficacy of a medicinal product in the paediatric population; and
- (b) describe any measures to adapt the formulation of the medicinal product so as to make its use more acceptable, easier, safer or more effective for different subsets of the paediatric population.

(3) A person who requests the agreement of a paediatric investigation plan must submit it to the licensing authority not later than upon completion of the human pharmaco-kinetic

studies in adults in relation to the medicinal product to which the plan relates, as specified in section 5.2.3 of Part I of Annex I to the 2001 Directive, unless the licensing authority agrees to accept a later request.

(4) The licensing authority may request the person applying for agreement of a paediatric investigation plan to supply further information in relation to the plan or to submit proposed modifications to it.

(5) The licensing authority must decide whether or not—

- (a) the proposed studies will ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or subsets of it; and
- (b) the expected therapeutic benefits of the medicinal product justify the studies proposed; and

in doing so must consider whether or not the measures proposed to adapt the formulation of the medicinal product for use in different subsets of the paediatric population are appropriate.

(6) If, following a decision by the licensing authority to agree a paediatric investigation plan, the person carrying out the plan encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate, that person may propose changes or request a deferral or a waiver, by submitting a request to the licensing authority, explaining the grounds for the request.

(7) Schedule 11 makes provision about advice and representations in relation to proposals to agree, or to refuse to agree, a paediatric investigation plan under paragraph (5) or to grant, or to refuse to grant, a deferral or waiver requested under paragraph (6).

### **Deferral of initiation or completion of measures in paediatric investigation plan**

**50C.—**(1) At the same time as the paediatric investigation plan is submitted under regulation 50B(1), the person requesting agreement of it may request the agreement of the licensing authority to a deferral of the initiation or completion of some or all of the measures set out in the plan.

(2) If the licensing authority is satisfied that a deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan can be justified on scientific and technical grounds, or on grounds related to public health, it may—

- (a) agree to a request by the applicant to grant a deferral; or
- (b) decide of its own motion to grant a deferral.

(3) If the licensing authority is satisfied as set out in paragraph (2), it must decide to grant a deferral where it is satisfied that—

- (a) it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population; or
- (b) studies in the paediatric population will take longer to conduct than studies in adults.

(4) If the licensing authority grants an application to which regulation 50A applies, it must, if it also grants a deferral in accordance with this regulation—

- (a) record that fact in the product's summary of product characteristics, and, if it considers that it would be appropriate to do so, in the package leaflet; and
- (b) specify in the document notifying the applicant of the grant of the deferral the time limits for the initiation or completion of the measures to which the deferral relates.

(5) Schedule 11 makes provision about advice and representations in relation to proposals to grant, or to refuse to grant, a deferral under paragraph (2) or (3).

### **Waiver of production of information in a paediatric investigation plan**

**50D.**—(1) The applicant making an application to which regulation 50A applies is exempt from the obligation to provide to the licensing authority the results of all studies performed, and details of all information collected, in compliance with an agreed paediatric investigation plan, if a waiver is granted in accordance with this regulation.

(2) The licensing authority may grant a waiver in accordance with this regulation if it is satisfied that there is evidence showing that—

- (a) the medicinal product or class of medicinal products is likely to be ineffective or unsafe in all or part of the paediatric population;
- (b) the disease or condition for which the medicinal product or class of medicinal products is intended occurs only in adult populations; or
- (c) the medicinal product does not represent a significant therapeutic benefit over existing treatments for patients in the paediatric population.

(3) The licensing authority may grant a waiver in accordance with this regulation—

- (a) in respect of the entire paediatric population, or a subset of it;
- (b) in respect of all of the therapeutic indications for the medicinal product concerned, or only some of them;
- (c) of its own motion, or at the request of the applicant; or
- (d) in respect of a specific product or a class of medicinal products.

(4) A person who requests a waiver in accordance with this regulation must submit the request to the licensing authority not later than upon completion of the human pharmacokinetic studies in adults in relation to the medicinal product concerned, as specified in section 5.2.3 of Part I of Annex I to the 2001 Directive, unless the licensing authority agrees to accept a later application.

(5) The licensing authority must maintain and publish a list of waivers which are granted under this regulation in respect of a class of medicinal products.

(6) The licensing authority may review a waiver which it has granted under this regulation and may revoke it if it considers it appropriate, having regard to the matters specified in paragraph (2).

(7) If the licensing authority revokes a waiver granted under this regulation, the holder of the UK marketing authorisation to which the waiver relates must, at the end of the period of 36 months beginning with the date of publication of the decision to revoke the waiver, submit the information referred to in regulation 50A(3) to the licensing authority.

(8) If the licensing authority grants an application to which regulation 50A applies, it must, if it also grants a waiver in accordance with this regulation, record that fact in the product's summary of product characteristics, and, if it considers that it would be appropriate to do so, in the package leaflet.

(9) Schedule 11 makes provision about advice and representations in relation to proposals to grant, or to refuse to grant, a waiver in response to a request made in accordance with paragraph (4) and to revoke a waiver under paragraph (6).



### **Application for paediatric use marketing authorisation**

**50E.**—(1) This regulation applies in relation to an application for a UK marketing authorisation—

- (a) for a relevant medicinal product which is not protected in the United Kingdom by a supplementary protection certificate or by a patent which qualifies for the granting of a supplementary protection certificate; and
- (b) which covers exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets of it, including the appropriate strength, pharmaceutical form or route of administration for that product.

(2) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority material necessary to establish the quality, safety and efficacy of the product in the paediatric population, including any specific data needed to support an appropriate strength, pharmaceutical form or route of administration for the product, in accordance with an agreed paediatric investigation plan.

(3) An application to which this regulation applies may, in accordance with regulations 51 to 55, refer to material supplied by the holder of a UK marketing authorisation.

(4) The applicant for a UK marketing authorisation to which this regulation applies must include in the application details of the measures intended to ensure the follow up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product.

### **Other applications including paediatric indications**

**50F.**—(1) This regulation applies in relation to an application to which neither regulation 50A nor 50E applies and which is—

- (a) an application for a UK marketing authorisation for a relevant medicinal product which includes a paediatric indication; or
- (b) an application to include a paediatric indication in an existing UK marketing authorisation.

(2) The applicant making an application to which this regulation applies must include in the application details of the measures intended to ensure the follow up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product.

### **Applications relating to orphan medicinal products**

**50G.**—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product in relation to which the applicant intends to demonstrate that the orphan criteria are met.

(2) The orphan criteria are that—

- (a) the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition;
- (b) either—
  - (i) the condition referred to in sub-paragraph (a) affects not more than five in 10,000 persons in the United Kingdom; or
  - (ii) the medicinal product is unlikely, when marketed, to generate sufficient financial return to justify the necessary investment; and

- (c) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the United Kingdom, or if such method exists, the medicinal product will be of significant benefit to those affected by the condition.
- (3) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority material that demonstrates that the orphan criteria are met.
- (4) Schedule 9A makes further provision about the orphan criteria and terms used in regulation 58D.
- (5) The Ministers may by regulations amend Schedule 9A.

### **Applications relating to advanced therapy medicinal products**

**50H.**—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product which is an advanced therapy medicinal product.

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

(3) In relation to an application for a UK marketing authorisation for a combined advanced therapy medicinal product, the applicant must, in addition to the material specified in regulation 50 and paragraph (2), provide to the licensing authority evidence of conformity with the requirements of the Medical Devices Regulations 2002<sup>(10)</sup>, including, where available, the results of the assessment of a notified body in accordance with those Regulations.

### **Applications relating to conditional marketing authorisations**

**50I.**—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product which falls within paragraph (2).

- (2) A relevant medicinal product falls within this paragraph if it is—
  - (a) aimed at the treatment, prevention or diagnosis of seriously debilitating or life-threatening diseases; or
  - (b) to be used in emergency situations, in response to public health threats.
- (3) The applicant for a UK marketing authorisation to which this regulation applies may request that the licensing authority grant a conditional marketing authorisation if—
  - (a) comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied; and
  - (b) the applicant can demonstrate that—
    - (i) the positive therapeutic effects of the product outweigh the risks to the health of patients or of the public associated with the product,
    - (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data,
    - (iii) unmet medical needs will be fulfilled, and

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<sup>(10)</sup> S.I. 2002/618, as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

- (iv) the benefit to the public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

(4) In this regulation, “unmet medical needs” means medical needs in relation to a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the United Kingdom, or, even if such method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected.

(5) The applicant for a UK marketing authorisation to which this regulation applies must include in the application material which demonstrates that the criteria in paragraph (3)(b) are met.

### **Applications in relation to medicinal products containing or consisting of genetically modified organisms**

**50J.**—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product which contains or consists of genetically modified organisms.

(2) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority—

- (a) a copy of the consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes given pursuant to—
  - (i) regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002(**11**),
  - (ii) regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(**12**),
  - (iii) regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**13**), or
  - (iv) regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(**14**);
- (b) a complete technical dossier supplying the information specified in Annexes III and IV to [Directive 2001/18/EC](#);
- (c) an environmental risk assessment in accordance with the principles set out in Annex II to [Directive 2001/18/EC](#); and
- (d) the results of any investigations performed for the purposes of research or development.

(3) In this regulation, “genetically modified organism” has the meaning given in Article 2(2) of [Directive 2001/18/EC](#).”.

### **Insertion of new Schedule in relation to orphan provisions**

**54.** Schedule 4 inserts a new Schedule 9A after Schedule 9.

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(11) S.I. 2002/2443, as amended by S.I. 2004/2411.

(12) S.I. 2002/3188, as amended by S.I. 2005/1913.

(13) S.S.I. 2002/541, as amended by S.S.I. 2004/439.

(14) S.R. 2003/167, as amended by S.R. 2005/272.

### Amendment of Schedule 10 (national homoeopathic products)

**55.** In paragraph 4(4)(a) of Schedule 10 (exceptions to requirement to submit safety data) insert “UK” before “marketing authorisation”.

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

**56.** For regulation 51 substitute—

“(1) An applicant for a UK marketing authorisation 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 which is or has been authorised for not less than eight years—

- (a) under regulation 49(1)(a) (subject to paragraphs (2) and (3)); or
- (b) if the product is an EU reference medicinal product, under Regulation (EC) No 726/2004.

(2) If, after exit day but before the date of grant of the UK marketing authorisation in relation to the reference medicinal product, an EU marketing authorisation took effect in relation to that product, the period of not less than eight years referred to in paragraph (1) is treated as having started on the date on which the EU marketing authorisation took effect.

(3) If, after exit day but before the date of grant of the UK marketing authorisation in relation to the reference medicinal product, the competent authority of an EEA state granted a marketing authorisation in relation to that product, the period of not less than eight years referred to in paragraph (1) is treated as having started on the date on which the marketing authorisation in the first EEA state in which the product was authorised took effect.

(4) 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.

(5) 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 (6).

(6) 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 (5).

(7) Until replaced by guidelines published under paragraph (6), the guidelines published by the EMA under Article 10(2)(b) of the 2001 Directive<sup>(15)</sup> continue to apply on and after exit day as they applied immediately before exit day (subject to any amendments or variations published under paragraph (6)).

(8) If the licensing authority grants a UK marketing authorisation 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 the United Kingdom before the expiry of ten years beginning with—

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(15) 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) the date on which the reference medicinal product was granted a UK marketing authorisation;
- (b) the date referred to in paragraph (2) or (3), if earlier than the date in subparagraph (a); or
- (c) if the reference medicinal product is an EU reference medicinal product, the date on which the EU marketing authorisation for the reference medicinal product took effect.

(9) Paragraph (10) applies where an EU reference medicinal product is used as a reference medicinal product for the purposes of this regulation.

(10) 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 exit day.

(11) Paragraph (12) applies if—

- (a) during the first eight of the ten years referred to in paragraph (8) the marketing authorisation holder for the reference medicinal product obtained a UK marketing authorisation 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.

(12) Where this paragraph applies, the period of ten years referred to in paragraph (8) is extended to eleven years, subject to the provisions of paragraphs (13) and (14).

(13) Where the European Commission, or an EEA state, has granted or varied a marketing authorisation in relation to the new therapeutic indication before the licensing authority does so, the one year extension of the period of ten years referred to in paragraph (8) is reduced by the period of time—

- (a) beginning on the date on which the EU or EEA state marketing authorisation took effect or was varied; and
- (b) ending immediately before the date on which the licensing authority granted or varied the UK marketing authorisation.

(14) If the period of time by which the one year extension is to be reduced in accordance with paragraph (13) is one year or longer, paragraph (12) does not apply.

(15) Paragraph (16) applies where—

- (a) an application 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.

(16) Where this paragraph applies, the applicant for a UK marketing authorisation under paragraph (1) or regulation 52 or 53 may not refer in its application to the studies mentioned in paragraph (15)(b) for the period of one year beginning on the date on which the licensing authority grants or varies a UK marketing authorisation in relation to the new indication (subject to paragraphs (17) and (18)).

(17) Where the European Commission, or an EEA state, has granted or varied a marketing authorisation in relation to the new indication before the licensing authority does so, the period of one year referred to in paragraph (10) is reduced by the period of time—

- (a) beginning on the date on which the EU or EEA state marketing authorisation took effect or was varied; and

(b) ending immediately before the date on which the licensing authority granted or varied the UK marketing authorisation.

(18) If the period of time by which the one year period in paragraph (16) is to be reduced in accordance with paragraph (17) is one year or longer, paragraph (16) does not apply.”.

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

57.—(1) Regulation 52 is amended as follows.

(2) In paragraph (1)(a), for “as reference medicinal product” substitute—

“which is or has been authorised for not less than eight years—

- (i) under regulation 49(1)(a) (subject to paragraphs (2) and (3) of regulation 51), or
- (ii) if the reference medicinal product is an EU reference medicinal product, under Regulation (EC) No 726/2004; and”.

(3) For paragraph (1)(b) substitute—

- “(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.”.

(4) For paragraph (2), substitute—

- “(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).”.

(5) In paragraph (3)—

- (a) for “Regulation 51(2)” substitute “Paragraphs (2) to (14) of regulation 51”; and
- (b) for “it applies” substitute “they apply”.

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

58.—(1) Regulation 53 is amended as follows.

(2) In paragraph (1), for the words from “any of the reasons” to the end, substitute “differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product.”

(3) For paragraph (2), substitute—

- “(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 appropriate pre-clinical tests or clinical trials relating to the differences referred to in paragraph (1).

(2A) 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 (2B), or (as the case may be) as mentioned in paragraph (2C).

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

(2C) Unless replaced by guidelines published under paragraph (2B), the guidelines published by the EMA under Article 10(4) of the 2001 Directive<sup>(16)</sup> continue to apply on and after exit day as they applied immediately before exit day (subject to any amendments or variations published under that paragraph).”

(4) In paragraph (3) —

(a) for “Regulation 51(2)” substitute “Paragraphs (2) to (8) of regulation 51”; and

(b) for “it applies” substitute “they apply”.

#### **Amendment of regulation 54 (applications relating to products in well-established medicinal use)**

**59.**—(1) Regulation 54 is amended as follows.

(2) In paragraph (1) before “European Union”, insert “United Kingdom or the”.

(3) For paragraph (2), substitute—

“(2) The applicant may, by way of derogation from paragraph 10 of Schedule 8, replace the results of pre-clinical tests or clinical trials with appropriate scientific literature.”.

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

**60.**—(1) Regulation 55 is amended as follows.

(2) In paragraph (1)(a), omit “, the 2001 Directive or Regulation (EC) No 726/2004”.

(3) For paragraph (2), substitute—

“(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.”.

#### **Amendment of regulation 56 (applications containing information supplied in relation to another product with consent)**

**61.** In regulation 56(2), omit “in accordance with Article 10c of the 2001 Directive”.

#### **Amendment of regulation 58 (consideration of application)**

**62.**—(1) Regulation 58 is amended as follows.

(2) After paragraph (4), insert—

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

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<sup>(16)</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.

- (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 sub-paragraphs (a) and (b) in relation to certain types of medicinal products only; and
- (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).”.

(3) Omit paragraphs (6) and (7).

### **Amendment of Schedule 11 (advice and representations)**

**63.**—(1) Schedule 11 is amended as follows.

(2) In paragraph 1 (application of Part 1)—

(a) in sub-paragraph (1)—

- (i) in sub-paragraph (b) omit “and”, and
- (ii) at the end insert—

“(d) a proposal to agree, or to refuse to agree, a paediatric investigation plan;

(e) a proposal to grant, or to refuse to grant, or to revoke, a waiver or deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan; and

(f) a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.”;

(b) after sub-paragraph (1) insert—

“(1A) Paragraphs 12 and 13 of this Part also apply to—

- (a) an application for the grant of a parallel import licence;
- (b) an application to renew a parallel import licence;
- (c) a proposal to revoke, vary or suspend a parallel import licence (including variation by the variation or removal of a condition to which a parallel import licence is subject) other than a proposal to vary the licence on the application of or by agreement with its holder; and
- (d) a refusal to vary a parallel import licence following an application for a variation by the holder.”; and

(c) omit sub-paragraph (2).

(3) In paragraph 12 (licensing authority decision in other cases), in sub-paragraphs (1), (2) and (5)—

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

(b) insert “, licence” after “the authorisation” in each place it appears.



- (4) In paragraph 14(a) (application of Part 2), for the words from “Article 2(3)” to the end, substitute “paragraph 1 of Schedule 10A; and”.
- (5) In paragraph 15(2) and (3)(b), insert “UK” before “marketing authorisation”.
- (6) In paragraph 16—
  - (a) in sub-paragraph (2)(b), insert “UK” before “marketing authorisation”; and
  - (b) in sub-paragraph (5), omit the words from “or in any Directive” to the end.
- (7) Omit paragraph 17.
- (8) In Part 3 (referral to the Committee for Herbal Medicinal Products)—
  - (a) in the heading to Part 3, for “Committee for Herbal Medicinal Products” substitute “appropriate committee for traditional herbal registrations”;
  - (b) in paragraph 24—
    - (i) in sub-paragraph (1), for the words from “Committee” to the end substitute “appropriate committee in accordance with regulation 130A(1)”; and
    - (ii) omit sub-paragraph (2); and
  - (c) in paragraph 29(1), for “proceed with its proposal” substitute “grant or refuse the application”.
- (9) Omit Part 4 (exceptions to Schedule).

#### **Insertion of provisions concerning consideration of certain applications for UK marketing authorisations**

- 64.** After regulation 58, insert—

##### **“Paediatric rewards**

- 58A.**—(1) Paragraph (2) applies if—
- (a) an application 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, is granted by the licensing authority; and
  - (b) the licensing authority is satisfied that the material provided by the applicant pursuant to regulation 50A(3) demonstrates compliance with the agreed paediatric investigation plan.
- (2) Where this paragraph applies, the licensing authority must—
- (a) include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); and
  - (b) ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.
- (3) Where paragraph (2) applies, 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) and (5)).

- (4) Paragraph (3) does not apply if the grant of the application referred to in paragraph (1) (a)—
- (a) relates to a new paediatric indication; and
  - (b) the holder of the UK marketing authorisation—
    - (i) is entitled to a one year extension of the ten year period referred to in regulation 51(8), under regulation 51(12),
    - (ii) is entitled to an extension of that ten year period of less than one year by virtue of the application of regulation 51(13), or
    - (iii) would have been entitled to a one year extension of that ten year period but for the application of regulation 51(14).

(5) If the UK marketing authorisation to which this regulation applies is an orphan marketing authorisation, paragraph (3) does not apply and regulation 58D(5) (orphan rewards) applies.

(6) Paragraphs (7) and (8) apply if the licensing authority grants a UK marketing authorisation in response to an application to which regulation 50E (paediatric use marketing authorisation) applies.

(7) Where this paragraph applies, the medicinal product to which the paediatric use marketing authorisation relates may retain the name of any medicinal product which contains the same active substance and in respect of which the holder of the paediatric use marketing authorisation has been granted a UK marketing authorisation for use in adults.

(8) Where this paragraph applies, the holder of the paediatric use marketing authorisation is entitled to benefit from the periods of data and marketing exclusivity referred to in regulation 51(1) and (8) in relation to the material supplied pursuant to regulation 50E(2).

### **Publication of information relating to paediatric marketing authorisations**

**58B.—**(1) The licensing authority must publish a register of UK marketing authorisations—

- (a) which include a paediatric indication following completion of an agreed investigation paediatric plan; and
- (b) in relation to which the medicinal product was placed on the market for other indications before the holder obtained that paediatric indication.

(2) The register referred to in paragraph (1) must include the date by which the product must be placed on the market taking account of the paediatric indication in accordance with regulation 78A(4) (post-authorisation requirements in relation to UK marketing authorisations to which paediatric specific provisions apply).

(3) The licensing authority must publish a list of the marketing authorisation holders which have—

- (a) benefitted from any of the rewards in regulation 58A; or
- (b) failed to comply with any of the obligations in regulation 78A.

(4) The licensing authority must publish decisions made under—

- (a) regulation 50B(5) or (7) (agreement and modification of paediatric investigation plan);
- (b) regulation 50C(2) (deferral of the initiation or completion of measures in a paediatric investigation plan); and
- (c) regulation 50D(2) (waiver of production of information in a paediatric investigation plan) in relation to a specific medicinal product.

(5) The decisions referred to in paragraph (4) must be published, with the omission of information of a commercially confidential nature, as soon as reasonably practicable after the decision has been made.

### **Consideration of applications relating to orphan medicinal products**

**58C.**—(1) If the licensing authority is satisfied in relation to an application for a UK marketing authorisation—

- (a) the orphan criteria are met in relation to all of the therapeutic indications to which the application relates; and
- (b) it is otherwise appropriate to grant a UK marketing authorisation in respect of the application under regulation 49(1)(a),

it may grant a UK marketing authorisation which is known as an orphan marketing authorisation.

(2) The licensing authority must publish and keep up to date a list of orphan marketing authorisations.

(3) Schedule 11 makes provision about advice and representations in relation to proposals to grant a UK marketing authorisation in respect of which the applicant intended to demonstrate that the orphan criteria were met, in cases where the licensing authority considers that those criteria are not met.

### **Orphan rewards**

**58D.**—(1) Subject to the following provisions of this regulation, for the period of ten years beginning with the date on which the licensing authority grants an orphan marketing authorisation, the licensing authority must not—

- (a) grant an application for a UK marketing authorisation; or
- (b) grant an application to vary a UK marketing authorisation;

in relation to a medicinal product which is similar to the medicinal product to which the orphan marketing authorisation relates and in respect of the therapeutic indications which are covered by the orphan marketing authorisation.

(2) Paragraph (3) applies if—

- (a) an EU marketing authorisation took effect in relation to the medicinal product to which an orphan marketing authorisation relates on or after exit day but before the licensing authority granted the orphan marketing authorisation; and
- (b) the EU marketing authorisation was granted on the basis that the product was an orphan medicinal product within the meaning of the Orphan Regulation.

(3) Where this paragraph applies, the period of ten years referred to in paragraph (1) is reduced by the period of time—

- (a) beginning on the date on which the EU marketing authorisation took effect; and
- (b) ending immediately before the date on which the licensing authority granted the orphan marketing authorisation.

(4) The period of ten years referred to in paragraph (1) may be reduced to six years if, at the end of the fifth year beginning on the date referred to in paragraph (1), the licensing authority is satisfied that the orphan criteria are no longer met in relation to the medicinal product.

(5) The period of ten years referred to in paragraph (1) is extended to twelve years if regulation 58A(2) (paediatric rewards) applies to the orphan marketing authorisation.

- (6) Paragraph (1) does not apply if—
- (a) the holder of the orphan marketing authorisation consents to the grant or variation of a UK marketing authorisation in relation to a similar medicinal product;
  - (b) the licensing authority is satisfied that the holder of the orphan marketing authorisation is unable to supply sufficient quantities of the medicinal product to which the orphan marketing authorisation relates; or
  - (c) a subsequent applicant can establish to the satisfaction of the licensing authority that the medicinal product to which the application relates, although similar to the medicinal product to which the orphan marketing authorisation relates, is safer or more effective than, or clinically superior to, that product.

### **Consideration of applications relating to combined advanced therapy medicinal products**

**58E.**—(1) When determining an application to which regulation 50H(3) (applications relating to combined advanced therapy medicinal products) applies, the licensing authority must—

- (a) assess the entire combined advanced therapy medicinal product in accordance with these Regulations; and
  - (b) recognise the results of the assessment of the notified body, if supplied.
- (2) The licensing authority may request the notified body, if relevant, to provide it with information related to the results of the assessment.
- (3) Paragraph (4) applies if an application to which regulation 50H(3) applies does not include the results of the assessment of a notified body, or if the notified body fails to supply information related to the results of the assessment when requested by the licensing authority.
- (4) Where this paragraph applies, the licensing authority must seek an opinion on the conformity of the device part in accordance with the Medical Devices Regulations 2002<sup>(17)</sup> from a notified body identified in conjunction with the applicant, unless the licensing authority decides that the involvement of a notified body is not required.

### **Consideration of applications relating to conditional marketing authorisations**

**58F.**—(1) If the licensing authority is satisfied in relation to an application to which regulation 50I (applications relating to conditional marketing authorisations) applies that—

- (a) the criteria in regulation 50I(3)(b) are met; and
- (b) it is otherwise appropriate to grant a UK marketing authorisation in respect of the application in accordance with regulation 49(1)(a),

it may grant a UK marketing authorisation which is known as a conditional marketing authorisation.

(2) Where regulation 50I(2)(b) (applications relating to conditional marketing authorisations) applies, the licensing authority may grant a conditional marketing authorisation if, in addition to comprehensive clinical data, comprehensive pre-clinical or pharmaceutical data have not been supplied.

(3) The licensing authority may, of its own motion, propose that a conditional marketing authorisation be granted if, having consulted the applicant for a UK marketing authorisation, it considers that the criteria in regulation 50I(3)(b) are met.

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(17) S.I. 2002/618, as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

(4) If the licensing authority grants a conditional marketing authorisation in relation to a medicinal product, it may at any time decide that it is appropriate to grant a UK marketing authorisation in relation to that product which is not a conditional marketing authorisation.

(5) If the licensing authority grants a conditional marketing authorisation, the product's summary of product characteristics and package leaflet must include a statement to that effect, and the summary of product characteristics must include the date on which the conditional marketing authorisation is due for renewal.

### **Consideration of applications in relation to medicinal products containing or consisting of genetically modified organisms**

**58G.**—(1) When determining an application for a UK marketing authorisation in relation to which regulation 50J (applications relating to medicinal products containing or consisting of genetically modified organisms) applies, the licensing authority must be satisfied that the application respects the environmental safety requirements laid down by [Directive 2001/18/EC](#).

(2) In reaching its view under paragraph (1), the licensing authority must consult the bodies responsible for the giving of consent pursuant to the legislation referred to in regulation 50J(2)(a).”.

### **Amendment of regulation 59 (conditions of UK marketing authorisation or parallel import licence: general)**

**65.**—(1) Regulation 59(18) is amended as follows.

(2) For paragraph (3) substitute—

“(3) 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.”.

(3) After paragraph (3), insert—

“(3A) The Ministers may by regulations make provision specifying the situations in which post-authorisation efficacy studies may be required by virtue of the condition referred to in paragraph (2)(f).

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

(4) In paragraph (4), insert “UK” before “marketing authorisation”.

(5) After paragraph (4), insert—

“(4A) Where the application is one to which regulation 50A, 50E or 50F (applications to which paediatric-specific provisions apply) applies, the licensing authority must, if it considers that there is a particular cause for concern, grant the UK marketing authorisation subject to a condition that—

- (a) a risk management system be set up comprising a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of those interventions; or
- (b) specific post-marketing studies be performed and submitted for review.

(4B) The licensing authority may request the holder to submit, in addition to the assessment required to be submitted pursuant to Part 9 of Schedule 12A (post-authorisation safety studies), a report assessing the effectiveness of any risk management system, and the results of any studies performed, in compliance with a condition imposed under paragraph (4A).

(4C) If the licensing authority grants a conditional marketing authorisation—

- (a) it must impose, as a condition of the conditional marketing authorisation, an obligation on the holder of the authorisation to complete ongoing studies, or to conduct new studies, with a view to confirming that the positive therapeutic effects of the product outweigh the risks to the health of patients or the public associated with the product, and to provide the additional data referred to in regulation 50I(3)(a);
- (b) it may impose, as a condition of the conditional marketing authorisation, an obligation on the holder of that authorisation in relation to collection of pharmacovigilance data.

(4D) If the licensing authority grants a UK marketing authorisation in relation to an advanced therapy medicinal product, it must, if it considers that there is a particular cause for concern, grant the UK marketing authorisation subject to a condition that—

- (a) a risk management system be set up which is designed to identify, characterise, prevent or minimise risks related to advanced therapy medicinal products, including an evaluation of the effectiveness of that system; or
- (b) that specific post-marketing studies be carried out and submitted for review by the licensing authority.

(4E) The licensing authority may request the holder to submit, in addition to the assessment required to be submitted pursuant to Part 9 of Schedule 12A, a report assessing the effectiveness of any risk management system, and the results of any studies performed, in compliance with a condition imposed under paragraph (4D).”.

(6) Omit paragraph (5).

**Amendment of regulation 60 (conditions of UK marketing authorisation: exceptional circumstances)**

66. In regulation 60, omit paragraph (9).

**Insertion of new regulations 60A (condition as to the submitting of samples and other information to the appropriate authority)**

67. After regulation 60, insert—

**“Condition as to the submitting of samples and other information to the appropriate authority**

**60A.—(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>(19)</sup>;

“appropriate documentation”, in relation to a sample of a batch submitted to the appropriate authority in accordance with the batch testing condition or pursuant to a notification under paragraph (12), means—

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<sup>(19)</sup> 2012 c.7.

- (a) any certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products that relates to the sample of the batch submitted to the appropriate authority with that certificate; and
- (b) such other documentation as the appropriate authority notifies the holder of the UK 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 paragraph (5), and “approved country for batch testing and certification of biological medicinal products” means a country included in that list;

“the batch testing condition”, in respect of a UK marketing authorisation, is a condition to the effect that, unless the batch testing exemption applies, the holder of the UK 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 the United Kingdom 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 batch is in conformity with the approved specifications in the UK marketing authorisation; and

“the batch testing exemption” means that—

- (a) a certificate has been issued by a laboratory in a country other than the United Kingdom;
- (b) 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
- (c) 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.

(2) The licensing authority may impose the batch testing condition in respect of a UK marketing authorisation for a medicinal product that is—

- (a) a live vaccine;
- (b) an immunological medicinal product used in the primary immunisation of infants or other groups at risk;
- (c) an immunological product used in public health immunisation programmes;
- (d) subject to paragraph (3), a new immunological product manufactured using new or altered kinds of technology or new for a particular manufacturer; or
- (e) derived from human blood or human plasma.

(3) If the licensing authority imposes a condition in respect of a UK marketing authorisation for a medicinal product of a kind mentioned in paragraph (2)(d), it must, in imposing that condition, specify a period of time for the duration of the condition.

(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) The appropriate authority must publish a list, to be known as the approved country list for batch testing and certification of biological medicinal products, specifying the countries that are approved for the purposes of the appropriate authority's assessment under paragraph (6).

(6) Where a holder of a UK marketing authorisation, in order to comply with the batch testing condition, 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.

(7) In order to determine whether a country should be included in the approved country list for batch testing and certification of biological medicinal products, the appropriate authority may, in particular, take into account whether the relevant certification process in that country is based on testing performed under a quality assurance system that undergoes regular external assessment to ensure it meets an appropriate standard of competence for testing biological medicines.

(8) The appropriate authority must—

- (a) review the countries it has included in the approved country list for batch testing and certification of biological medicinal products 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
- (b) undertake that review at least every three years beginning with the date on which that country is included in the list.

(9) The appropriate authority must—

- (a) publish a list of countries, or organisations, with whom the United Kingdom has an agreement for the purposes of the application of the batch testing exemption;
- (b) include in that list any conditions or restrictions in that agreement that affect the applicability of the batch testing exemption; and
- (c) update that list as soon as reasonably practicable if—
  - (i) the United Kingdom no longer has an agreement with a country or organisation included in the list,
  - (ii) any such agreement is amended, or
  - (iii) the United Kingdom enters in to a new agreement with a country or organisation.

(10) Where a holder of a UK 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 the United Kingdom.

(11) Paragraph (12) 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.



(12) Where this paragraph applies, the appropriate authority must, subject to paragraph (13), notify the holder of the UK 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 the United Kingdom 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 UK marketing authorisation.

(13) The appropriate authority may only exercise its powers under paragraph (12) 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 (11).”.

#### **Amendment of regulation 61 (conditions of UK marketing authorisation)**

**68.**—(1) Regulation 61 is amended as follows.

(2) For paragraph (4), substitute—

“(4) The obligation in this paragraph is—

- (a) to conduct a post-authorisation safety study; or
- (b) to comply with such other conditions or restrictions as the licensing authority considers essential for the safe and effective use of the medicinal product.”.

(3) For paragraph (6) substitute—

“(6) If concerns as described in paragraph (2) apply to more than one medicinal product, 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.”.

(4) For paragraph (7) substitute—

“(7) 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

(7A) The Ministers may by regulations make provision specifying the situations in which post-authorisation efficacy studies may be required by virtue of the obligation under paragraph (5).

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

(5) Omit paragraph (13).

#### **Amendment of regulation 64 (duties of licensing authority in connection with determination)**

**69.** In regulation 64(4)(d), for “established in accordance with Articles 21a, 22 and 22a of the 2001 Directive” substitute “imposed under regulations 59 to 61”.

#### **Obligation of licensing authority in case of change of classification**

**70.** After regulation 64, insert—

##### **“Obligation of licensing authority in case of change of classification**

**64A.**—(1) In this regulation, “classification”, in relation to a medicinal product, means the term of the product’s UK marketing authorisation which determines the way in which the product is to be made available, as described in regulation 62(1).

(2) This regulation applies where—

- (a) the licensing authority grants or varies a UK marketing authorisation;
- (b) the grant or variation of the UK marketing authorisation involves a change of the classification of the medicinal product to which the authorisation relates; and
- (c) the application for the UK marketing authorisation or variation was supported by the results of significant pre-clinical tests or clinical trials relating to the proposed classification.

(3) Where this regulation applies, the licensing authority may not, for the period of one year beginning with the date on which the UK marketing authorisation was granted or varied, refer to the results of the tests or trials referred to in paragraph (2)(c) when examining an application by another applicant or UK marketing authorisation holder for a change of classification of the same kind as that to which the tests or trials relate.”.

#### **Amendment of regulation 65 (validity of UK marketing authorisation)**

**71.** In regulation 65(5) before sub-paragraph (a) insert—

“(za) regulation 65B;”.

#### **Validity of conditional marketing authorisation and variation of a UK marketing authorisation**

**72.** After regulation 65A(20), insert—

##### **“Validity of conditional marketing authorisation**

**65B.**—(1) A conditional marketing authorisation remains in force—

- (a) for an initial period of one year beginning with the date on which it is granted; and
- (b) if it is renewed in accordance with regulation 66B, for further periods of one year beginning with the date on which the renewal is granted.

(2) If an application for the renewal or further renewal of a conditional marketing authorisation is made in accordance with regulation 66B the authorisation remains in force until the licensing authority notifies the applicant of its decision on the application.

### **Variation of a UK marketing authorisation**

**65C.**—(1) A UK marketing authorisation holder may apply to vary the authorisation.

(2) Any such application must be made in accordance with Schedule 10A.

(3) Schedule 10A does not apply to the transfer of a UK marketing authorisation from one person to another.

(4) The licensing authority may publish guidance on the details of the various categories of variations, on the operation of the procedures laid down in Schedule 10A, and on the documentation to be submitted pursuant to those procedures.

(5) Any guidance referred to in paragraph (4) must be regularly reviewed and, when necessary, updated.

(6) Unless replaced by guidelines published under paragraph (4), the guidelines published by the Commission under Article 4 of Regulation (EC) No 1234/2008<sup>(21)</sup> which applied immediately before exit day, insofar only as they concern applications under Chapter IIa of that Regulation, continue to apply to—

(a) applications made under regulation 65C on or after exit day; or

(b) applications made before exit day to which regulation 65C and Schedule 10A apply by virtue of Parts 3 and 5 of Schedule 33A.

(7) The Ministers may by regulations amend Schedule 10A.”.

### **Insertion of new Schedule 10A (variations to a UK marketing authorisation)**

73. Schedule 5 inserts a new Schedule 10A after Schedule 10.

### **Amendment of regulation 66 (application for renewal of authorisation)**

74. In regulation 66(2), for “European Union” substitute “United Kingdom”.

### **Amendment of regulation 66A (application for renewal of a parallel import licence)**

75. In regulation 66A(2)<sup>(22)</sup>, for “European Union” substitute “United Kingdom”.

### **Renewal of conditional marketing authorisation**

76. After regulation 66A, insert—

#### **“Renewal of conditional marketing authorisation**

**66B.**—(1) The licensing authority may renew a conditional marketing authorisation in relation to an application made to it by the holder of the authorisation.

(2) The application must be made at least six months before the date on which the conditional marketing authorisation is due to expire.

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(21) 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.

(22) Regulation 66A was inserted by [S.I. 2014/1878](#).

(3) The application must include an interim report on the fulfilment of the obligations to which the conditional marketing authorisation is subject.

(4) When considering an application under paragraph (1), the licensing authority must consider whether—

- (a) the positive therapeutic effects of the product continue to outweigh the risks to the health of patients and the public associated with the product; and
- (b) the obligations referred to in regulation 59(4C) and any time limits for their fulfilment remain appropriate, modifying or removing them if necessary.

(5) The provisions of regulation 66(2), (3), (4), (6) and (8) apply to an application for renewal of a conditional marketing authorisation.”.

### **Amendment of regulation 68 (revocation, variation and suspension of UK marketing authorisation or parallel import licence)**

77.—(1) Regulation 68(23) is amended as follows.

(2) In paragraph (5), after “exceptional circumstances”, insert “, regulation 60A (conditions as to testing of samples by the appropriate authority)”.

(3) In paragraph (7)—

- (a) after “authorisation” insert “or licence”; and
- (b) for “European Union” substitute “United Kingdom”.

(4) In paragraph (8)(b), for “states other than EEA states” substitute “countries other than approved countries for import”.

(5) Omit paragraph (9).

(6) In paragraph (10)—

- (a) in sub-paragraph (a) for “authorisation; or” substitute “authorisation or licence.”; and
- (b) omit sub-paragraph (b).

(7) In paragraph (11)(a), after authorisation insert “or licence”.

(8) After paragraph (11A), insert—

“(11B) Condition L is that the licensing authority thinks that the term of the authorisation which specifies the way in which the product is to be made available, as described in regulation 62(1), is incorrect.

(11C) Condition M is that, in respect of a parallel import licence, the UK marketing authorisation in respect of the medicinal product that was specified in the application for that licence under paragraph 4 of Schedule 8A, has been varied, suspended or revoked by the licensing authority under this regulation.

(11D) Condition N is that, in respect of a parallel import licence, the licensing authority is no longer satisfied that the product is essentially similar to a product that has been granted a UK marketing authorisation.

(11E) The licensing authority may not exercise its powers under paragraph (1) by virtue of the condition in paragraph (11D)—

- (a) before the end of the period of one year beginning with exit day; and
- (b) in any event, in a way that prevents the import of any medicinal product in respect of which a qualified person undertook the certification referred to in Article 51(3) of the 2001 Directive before exit day.

(11F) Condition O is that the licensing authority thinks that a variation of a UK marketing authorisation is necessary as a result of the submission of the results of a study by the holder of that authorisation under regulation 78A(14).”.

(9) In paragraph (12)—

- (a) after “UK marketing authorisation”, insert “or parallel import licence”; and
- (b) after “an authorisation” insert “or licence”.

(10) Omit paragraph (13).

#### **Amendment of regulation 69 (suspension of use etc of relevant medicinal product)**

**78.** In regulation 69(24), omit paragraph (10).

#### **Omission of regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive)**

**79.** Omit regulation 70.

#### **Amendment of regulation 71 (withdrawal of medicinal product from the market)**

**80.**—(1) Regulation 71(25) is amended as follows.

(2) In paragraph (1)—

(a) for sub-paragraph (a) substitute—

“(a) under regulation 68 the licensing authority revokes or suspends a UK marketing authorisation or parallel import licence; or”; and

(b) in sub-paragraph (b)—

- (i) omit “or Article 20(4) of Regulation (EC) No 726/2004”; and
- (ii) insert “UK” before “marketing authorisation”.

#### **Amendment of regulation 72 (sale etc of suspended medicinal product)**

**81.** In regulation 72(1) omit “or 70(2) or Article 29(4) of Regulation (EC) No 726/2004”.

#### **Amendment of regulation 73 (obligation to notify placing on the market etc)**

**82.**—(1) Regulation 73(26) is amended as follows.

(2) In paragraph (5A)(c), for “third country” substitute “country other than the United Kingdom”.

(3) Omit paragraph (5C).

#### **Amendment of regulation 75 (obligation to provide information relating to safety etc)**

**83.** In regulation 75(5)(27)—

(a) for sub-paragraph (a) substitute—

“(a) in a country other than the United Kingdom;” and

(b) in sub-paragraph (b), insert “UK” before “marketing authorisation”.

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(24) Regulation 69 was amended by [S.I. 2014/1878](#).

(25) Regulation 71 was amended by [S.I. 2014/1878](#).

(26) Regulation 73 was amended by [S.I. 2013/2593](#): regulation 3 inserted sub-paragraphs (5A) to (5C).

(27) Regulation 75 was amended by [S.I. 2014/1878](#).

**Amendment of regulation 76 (obligation in relation to product information)**

84. In regulation 76(2)(28) for the words from “European medicines web-portal” to the end, substitute “the UK web-portal established in accordance with regulation 203(1).”

**Amendment of regulation 77 (record-keeping obligations)**

85. In regulation 77, insert “UK” before “marketing authorisation”.

**Amendment of regulation 78 (obligation to ensure appropriate and continued supplies)**

86. In regulation 78, insert “UK” before “marketing authorisation”.

**Post authorisation requirements in relation to UK marketing authorisations with paediatric aspects and advanced therapy medicinal products**

87. After regulation 78, insert—

**“Post authorisation requirements in relation to UK marketing authorisations to which paediatric specific provisions apply**

78A.—(1) Paragraph (2) applies where—

- (a) a holder of a UK marketing authorisation intends to discontinue supply of the product to which that authorisation relates;
- (b) the holder of the authorisation benefited from a reward or incentive under regulation 58A(3) or (8) or 58D(5) in relation to the product; and
- (c) the period of protection provided pursuant to those regulations has expired.

(2) Where this paragraph applies, the holder of the UK marketing authorisation must—

- (a) either—
  - (i) transfer the UK marketing authorisation to another person who has declared an intention to continue to supply the product; or
  - (ii) allow such a person to use the pharmaceutical, pre-clinical and clinical documentation contained in the file on that product in accordance with regulation 56; and
- (b) notify the licensing authority of its intention to cease to supply the product before the beginning of the period of six months ending immediately before the day on which the holder does so.

(3) Paragraph (4) applies to the holder of a UK marketing authorisation if—

- (a) that authorisation includes a paediatric indication following completion of an agreed paediatric investigation plan; and
- (b) the product was placed on the market for other indications before that holder obtained that paediatric indication.

(4) Where this paragraph applies, the holder of the UK marketing authorisation must place the product on the market taking account of the paediatric indication before the end of the period of two years beginning immediately after the day on which the paediatric indication is authorised.

(5) Paragraph (6) applies if—

- (a) a decision by the licensing authority in respect of a paediatric investigation plan is addressed to a person (“PIP sponsor”); and
  - (b) the plan refers to clinical trials carried out in a country other than the United Kingdom (“non-UK clinical trials”).
- (6) Where this paragraph applies, the PIP sponsor must send to the licensing authority the details set out in Article 11 of the Clinical Trials Directive in relation to the non-UK clinical trials within whichever is the later of—
- (a) the period of one month beginning after the day on which the decision was received; or
  - (b) the period of one month beginning after the day on which the necessary permission to conduct the clinical trial was received from the competent authorities in the country where the clinical trial is to take place.
- (7) Where paragraph (6) applies, the PIP sponsor must submit the results of those clinical trials to the licensing authority within the period of twelve months beginning with the day on which the last of those trials ended, subject to paragraph (8).
- (8) Paragraph (7) does not apply in the case of a clinical trial which forms part of a paediatric study to which paragraph (12) applies.
- (9) Paragraph (10) applies in relation to the sponsor of a paediatric clinical trial in the United Kingdom in respect of a medicinal product if—
- (a) the product has a UK marketing authorisation but the sponsor is not the holder of the authorisation; or
  - (b) the product does not have a UK marketing authorisation.
- (10) Where this paragraph applies, the sponsor of the clinical trial must submit the results of the trial to the licensing authority within the period of twelve months beginning with the day on which the trial ended.
- (11) Paragraph (12) applies in relation to the holder of a UK marketing authorisation who sponsors a paediatric clinical trial in respect of the medicinal product to which that authorisation relates.
- (12) Where this paragraph applies, the holder of the UK marketing authorisation must submit the results of the trial to the licensing authority within the period of six months beginning with the day on which the trial ended.
- (13) Paragraph (14) applies in relation to the holder of a UK marketing authorisation who sponsors a study which involves the use in the paediatric population of a medicinal product to which that UK marketing authorisation relates, irrespective of whether or not—
- (a) the studies are conducted in accordance with an agreed paediatric investigation plan; or
  - (b) the marketing authorisation holder intends to apply for a marketing authorisation for a paediatric indication in relation to the product.
- (14) Where this paragraph applies, the holder of the UK marketing authorisation must submit the results of the study to the licensing authority within the period of six months beginning with the day on which the study ended.
- (15) Where the licensing authority has granted a deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan, in accordance with regulation 50C, the person to whom that decision was addressed must submit to the licensing authority an annual report providing an update on progress with the paediatric studies to which the deferral relates.

(16) The first report referred to in paragraph (15) must be submitted within the period of twelve months beginning with the date on which the licensing authority granted the deferral.

### **Post authorisation requirements in relation to UK marketing authorisations for advanced therapy medicinal products**

**78B.**—(1) The holder of a UK marketing authorisation in respect of an advanced therapy medicinal product must—

- (a) establish and maintain a system ensuring that the individual product and its starting raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used;
- (b) where the product contains human tissues or cells, ensure that the traceability system is complementary to and compatible with requirements imposed pursuant to—
  - (i) 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<sup>(29)</sup>,
  - (ii) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005<sup>(30)</sup>, and
  - (iii) 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<sup>(31)</sup>;
- (c) keep the data referred to in paragraph (a) for a minimum of 30 years after the expiry of the date of the product, or longer if required by the licensing authority as a term of the UK marketing authorisation; and
- (d) in the event of the UK marketing authorisation holder’s bankruptcy or liquidation occurring within the period of time for which that holder is required to keep the data referred to in paragraph (a), transfer that data to another person or the licensing authority.

(2) The holder of a UK marketing authorisation who is subject to the obligations in paragraph (1) remains subject to them even if the UK marketing authorisation is suspended or revoked.”.

### **Omission of regulation 79 (failure to provide information on marketing authorisations to EMA)**

**88.** Omit regulation 79.

### **Amendment of regulation 80 (urgent safety restrictions)**

**89.**—(1) Regulation 80 is amended as follows.

(2) In the introductory words, insert “UK” before “marketing authorisation”.

(3) In sub-paragraph (a) for “or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008” substitute “in accordance with paragraph 14(1) of Schedule 10A”.

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<sup>(29)</sup> 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.

<sup>(30)</sup> 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.

<sup>(31)</sup> S.I. 2007/1523.



(4) In sub-paragraph (b) from “or the European Commission” to the end substitute “in accordance with paragraph 14(3) of Schedule 10A; or”.

(5) For sub-paragraph (c) substitute—

“(c) fails to submit an application for variation of the UK marketing authorisation to the licensing authority in accordance with paragraph 14(4) of Schedule 10A before the end of the period of fifteen days beginning with the day after—

(i) the taking under paragraph 14(1) of Schedule 10A or, as the case may be,

(ii) the imposition under paragraph 14(3) of that Schedule,

of an urgent safety restriction.”.

#### **Omission of regulations 81 to 94 (offences relation to EU marketing authorisations)**

**90.** Omit regulations 81 to 94(32).

#### **Omission of regulation 94A (offences relating to Commission Regulation 2016/161)**

**91.** Omit regulation 94A(33).

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

**92.**—(1) Regulation 95 is amended as follows.

(2) In the introductory words, insert “UK” before “marketing authorisation”.

(3) Omit sub-paragraphs (c) and (d).

#### **Amendment of regulation 96 (provision of misleading information)**

**93.**—(1) Regulation 96(34) is amended as follows.

(2) In paragraph (1)—

(a) insert “UK” before “marketing authorisation”; and

(b) omit sub-paragraphs (b) and (c).

(3) In paragraph (2), for “these Regulations; or” to the end substitute “these Regulations.”.

#### **Amendment of regulation 97 (breach of pharmacovigilance condition)**

**94.**—(1) Regulation 97(35), is amended as follows.

(2) In each place where it occurs—

(a) for “a marketing authorisation” substitute “a UK marketing authorisation”; and

(b) for “the marketing authorisation” substitute “the UK marketing authorisation”.

(3) In paragraph (2), after “exceptional circumstances)” insert “, regulation 60A (condition as to the testing of samples by the appropriate authority)”.

#### **Amendment of regulation 98 (general offence of breach of Part 5)**

**95.** In regulation 98(2)(a), insert “UK” before “marketing authorisation”.

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(32) Regulation 82 was previously amended by [S.I. 2013/2593](#) and regulation 84 was amended by [S.I. 2013/1855](#).

(33) Regulation 94A was inserted by [S.I. 2019/62](#).

(34) Regulation 96 was amended by [S.I. 2014/1878](#).

(35) Regulation 97 was substituted by [S.I. 2014/1878](#).

**Amendment of regulation 99 (penalties)**

96.—(1) Regulation 99 is amended as follows.

(2) In paragraph (1), omit “other than a breach of regulation 79 (failure to provide information on marketing authorisation to EMA)”.

(3) Omit paragraph (2).

**Amendment of regulation 101 (defences)**

97.—(1) Regulation 101(36) is amended as follows.

(2) In paragraph (1), insert “UK” before “marketing authorisation”.

(3) In paragraph (3), for “any of regulations 88 to 93,” substitute “either of regulations”.

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(36) Regulation 101 was amended by [S.I. 2014/1878](#).