SCHEDULES

SCHEDULE 2

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

PART 4

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

35. In regulation 47 (amendment of regulation 48 (application of Part 5))—

(a) in paragraph (2)(a)—

(i) for the definition of "EU reference medicinal product", substitute—

""EU reference medicinal product" means a medicinal product which falls within paragraph (b)(ii) or (iii) of the definition of "reference medicinal product";";

(i) after the definition of "EU reference medicinal product", insert—

""excluded reference product" means—

(a) a medicinal product authorised on the basis that it was a generic medicinal product;

(b) a medicinal product authorised on the basis that one or more of the circumstances listed in Article 10(3) of the 2001 Directive or regulation 52(1)(b) applied; or

(c) a biological medicinal product authorised on the basis that it did not meet a condition for being a generic medicinal product for any of the reasons described in Article 10(4) of the 2001 Directive or regulation 53A(1);";

(b) in paragraph (2)(b), for the definition of "generic medicinal product", substitute—

""generic medicinal product", in relation to a reference medicinal product for an application for—

(a) a UKMA(NI) or UKMA(UK), has the meaning given in Article 10(2)(b) of the 2001 Directive;

(b) a UKMA(GB), means a medicinal product—

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

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

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

(c) in paragraph (2)(d), for the definition of "reference medicinal product" substitute—

""reference medicinal product" means—

(a) in relation to an application for a UKMA(NI), a medicinal product—

(i) authorised for sale or supply in Northern Ireland under regulation 49(1)(a), in accordance with the provisions of regulation 50; or

(ii) in relation to which an EU marketing authorisation or a marketing authorisation granted by a member State pursuant to the 2001 Directive is or has been in force,

but which is not an excluded reference product;

(b) in relation to an application for a UKMA(GB), a medicinal product—

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

(ii) in relation to which an EU marketing authorisation was in force on IP completion day, but in relation to which no UK marketing authorisation is in force because the holder of the EU marketing authorisation notified the licensing authority in accordance with paragraph 6(3) of Schedule 33A that it did not wish to be the holder of a converted EU marketing authorisation; or

(iii) in relation to which an EU marketing authorisation had ceased to be in force before IP completion day for reasons not related to safety, quality or efficacy,

but which is not an excluded reference product;

(c) in relation to an application for a UKMA(UK), a medicinal product—

(i) authorised under regulation 49(1)(a) for sale or supply in the whole of the United Kingdom, whether by virtue of one or more UK marketing authorisations, in accordance with the provisions of regulation 50; or

(ii) in relation to which an EU marketing authorisation or a marketing authorisation granted by a member State pursuant to the 2001 Directive is or has been in force,

but which is not an excluded reference product;";

(d) in paragraph (3)—

(i) in the inserted paragraph (6)(b), for "regulations 51 to 53" substitute "regulations 51 to 53B";

(ii) in the inserted paragraph (7), for "regulation 51(1) and (8)" substitute "regulation 51A(1) and (6)";

(iii) in the inserted paragraph (8)(b), for "regulations 51 to 53" substitute "regulations 51 to 53B";

(iv) in the inserted paragraph (9), for "regulation 51(1) and (8)" substitute "regulation 51A(1) and (6)".

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

(a) in paragraph (3)—

(i) renumber the inserted paragraph (1A) as paragraph (1B);

(ii) before newly renumbered paragraph (1B) insert—

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

(a) there is already in place, or will be at the time the UKMA(GB) is granted, a marketing authorisation in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in regulation 50(1A), and

(c) the medicinal product satisfies the definition of qualifying Northern Ireland goods.";

(iii) after newly renumbered paragraph (1B) insert—

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

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that authorisation or licence being "in force" is limited to that territory.";

(b) for paragraph (4) substitute—

"(4) For paragraph (3) substitute—

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

(a) a UKMA(NI)—

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

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

(b) a UKMA(GB)—

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

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

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

(c) in paragraph (6), in the text to be inserted—

(i) renumber paragraph (9) as paragraph (10);

(ii) before newly renumbered paragraph (10) insert—

"(9) The application must include a statement indicating whether the authorisation or licence sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.".

37. In regulation 49 (amendment of regulation 50 (accompanying material))—

(a) after paragraph (1) insert—

"(1A) After paragraph (1) insert—

"(1A) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide—

(a) in the case of an application under the unfettered access route—

(i) the material specified in Schedule 8C, and

(ii) any material specified in Schedule 8 which is not included in the material specified in Schedule 8C, and

(b) in all other cases, the material specified in Schedule 8,

in relation to the product.";

(1B) After paragraph (3) insert—

"(3A) Paragraph (4) does not apply in respect of an application under the unfettered access route.".";

(b) for paragraph (2) substitute—

"(2) For paragraph (4) substitute—

"(4) If any of the medicinal products to which the application for a UK marketing authorisation relates—

(a) in the case of a UKMA(NI) or a UKMA(UK), is liable to be imported from a country other than an EEA State, or

(b) in the case of a UKMA(GB), is liable to be imported,

the material or information referred to in paragraph (3) may include an undertaking from the manufacturer of the product to comply with the matters set out in Schedule 9.".";

(c) in paragraph (3)—

(i) for the inserted paragraph (5A) substitute—

"(5A) The Secretary of State may by regulations in respect of Great Britain amend Schedule 8B (modifications of Annex I) in relation to a UKMA(GB) for the purpose of further modifying Annex I to the 2001 Directive in order to take account of scientific and technical progress.";

(ii) in the inserted paragraph (5C), for "exit day" substitute "IP completion day";

(d) after paragraph (4) insert—

"(4A) In paragraph (6)—

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

"(a) regulation 51 (application for UKMA(NI) relating to generic medicinal products)

(aa) regulation 51A (application for UKMA(GB) relating to generic medicinal products);

(ab) regulation 51B (application for UKMA(UK) relating to generic medicinal products);";

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

"(b) regulation 52 (application for UKMA(NI) relating to certain medicinal products that do not qualify as generic etc)

(ba) regulation 52A (application for UKMA(GB) relating to certain medicinal products that do not qualify as generic etc);

(bb) regulation 52B (application for UKMA(UK) relating to certain medicinal products that do not qualify as generic etc);";

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

"(c) regulation 53 (application for UKMA(NI) relating to similar biological medicinal products)

(ca) regulation 53A (application for UKMA(GB) relating to similar biological medicinal products);

(cb) regulation 53B (application for UKMA(UK) relating to similar biological medicinal products);”.”.

38. In regulation 50 (amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation))—

(a) in paragraph (2)—

(i) in paragraph (a), after “in the United Kingdom” insert “or a member State”;

(ii) for paragraph (b) substitute—

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

“(b) the country (which must be either the United Kingdom or a member State) in which the appropriately qualified person resides and carries out his or her tasks;”;”;

(iii) for paragraph (c) substitute—

“(c) for paragraph (e) substitute—

“(e) a reference to the physical location where the pharmacovigilance system master file for the medicinal product can be accessed electronically, which must be in the United Kingdom.”.”;

(b) in paragraph (3), for the inserted paragraph 18, substitute—

“**18.** Where—

(a) in the case of a UKMA(NI) or a UKMA(UK), an application for authorisation for the medicinal product to be placed on the market is under consideration in one or more member States—

(i) a list of the member State or States concerned, and

(ii) in relation to each such application, a copy of the summary of the product characteristics, and the package leaflet, proposed by the applicant;

(b) in the case of a medicinal product for sale or supply in Great Britain, an application for authorisation for the medicinal product to be placed on the market is under consideration in a country other than the United Kingdom, or by the EMA, notification of that fact.”;

(c) for paragraph (4) substitute—

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

(d) for paragraph (5) substitute—

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

(e) for paragraph (6) substitute—

“(6) For paragraph 21 substitute—

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

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

(b) in the case of a medicinal product for sale or supply in Great Britain, by a country other than the United Kingdom,

details of that decision and of the reasons for it.”.”;

(f) for paragraph (7) substitute—

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

(g) for paragraph (8) substitute—

“(8) For paragraph 23 substitute—

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

(a) in the case of a medicinal product for sale or supply in Northern Ireland, in Article 23 of Regulation (EC) No 726/2004, the symbol and statement “▼ This medicinal product is subject to additional monitoring”, or

(b) in the case of a medicinal product for sale or supply in Great Britain, in regulation 202A, the symbol and statement “▼ This medicinal product is subject to additional monitoring”.”.”;

(h) in paragraph (9), in the inserted paragraph 25A, after “advanced therapy medicinal product ” insert “for sale or supply in Great Britain”;

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

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

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

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

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

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

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

(ii) after paragraph (6) insert—

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

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

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

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

(i) in paragraph (1) for "UK marketing authorisation" substitute "UKMA(GB) or UKMA(UK)";

(ii) after paragraph (4) insert—

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

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

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

(i) for paragraph (1) substitute—

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

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

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

(ii) in paragraph (2)(b)(i) and (c) for "the United Kingdom" substitute "Great Britain";

(f) in the inserted regulation 50H(1) and (3) (applications relating to advanced therapy medicinal products), for "UK marketing authorisation" substitute "UKMA(GB)";

(g) in the inserted regulation 50I (applications relating to conditional marketing authorisations)—

(i) in the heading, at the end insert "for sale or supply in Great Britain only";

(ii) in paragraph (1), for "UK marketing authorisation" substitute "UKMA(GB)".

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

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

56. For regulation 51 substitute—

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

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

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

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

(4) Where—

(a) ten years have elapsed since a UK marketing authorisation was granted otherwise than under Chapter 4 of Title III to the 2001 Directive in relation to the reference medicinal product;

(b) in relation to that product there is—

(i) an EU marketing authorisation, or

(ii) a UKMA(NI) which was granted under that Chapter; and

(c) a period of ten years has not elapsed since the authorisation mentioned in sub-paragraph (b) for sale or supply of that product in the European Union,

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

Application for UKMA(GB) relating to generic medicinal products

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

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

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

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

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

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

(5) Until replaced by guidelines published under paragraph (4), the guidelines published by the EMA under Article 10(2)(b) of the 2001 Directive(**1**) continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under paragraph (4)).

(6) If the licensing authority grants a UKMA(GB) in relation to the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation

(**1**) 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.

that the product must not be sold or supplied, or offered for sale or supply, in Great Britain before the expiry of ten years beginning with the date on which the marketing authorisation for the reference medicinal product entered into force.

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

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

(9) Paragraph (10) applies if—

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

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

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

(11) Paragraph (12) applies where—

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

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

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

Application for UKMA(UK) relating to generic medicinal products

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

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

(a) a UKMA(UK), the provisions of regulation 51(1) and (2) apply in respect of the application;

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

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

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

(b) the period specified in regulation 51A(1), in relation to the UKMA(GB) for the reference medicinal product.

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

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

(a) the period specified in regulation 51(2), in relation to the UKMA(NI) for the reference medicinal product; and

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

(6) Paragraph (7) applies where—

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

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

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

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

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

57. For regulation 52 substitute—

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

52.—(1) This regulation applies where—

(a) an application is made for a UKMA(NI) by reference to another medicinal product as reference medicinal product; and

(b) one or more of the circumstances listed in Article 10(3) of the 2001 Directive applies in respect of the application.

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

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

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

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

(a) an application is made for a UKMA(GB) in respect of a product by reference to another medicinal product as reference medicinal product which is or has been authorised for sale or supply in Great Britain for not less than eight years—

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

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

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

(i) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,

(ii) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or

(iii) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration.

(2) The applicant—

(a) may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials relating to the reference medicinal product; but

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

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

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

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

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

(a) a UKMA(UK), the provisions of regulation 52(1) and (2) apply in respect of the application;

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

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

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

(b) the period specified in regulation 52A(1), in relation to the UKMA(GB) for the reference medicinal product.

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

(a) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,

(b) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or

(c) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration,

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

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

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

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

58. For regulation 53 substitute—

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

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

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

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

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

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

(2) The applicant—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) Unless replaced by guidelines published under paragraph (6), the guidelines published by the EMA under Article 10(4) of the 2001 Directive(**3**) continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

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

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

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

60. For regulation 55 substitute—

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

(a) have not been used in that combination for therapeutic purposes; and

(b) where the application is for—

(i) a UKMA(NI), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations, the 2001 Directive or Regulation (EC) No 726/2004;

(ii) a UKMA(GB), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations; or

(iii) a UKMA(UK), have been used in medicinal products that have been the subject of—

(aa) a UKMA(UK) under these Regulations; or

(bb) a relevant Northern Ireland authorisation.

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

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

(a) a UKMA(NI) under these Regulations;

(b) a marketing authorisation under the 2001 Directive; or

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

(c) an EU marketing authorisation,

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

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

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

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

(a) an opinion of the Committee for Medicinal Products for Human Use; or

(b) the results of an assessment of an application for a marketing authorisation by the appropriate authority for the licensing of medicinal products of a country other than the United Kingdom,

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

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

(a) decide to have regard to the opinions and assessments described in that paragraph in relation to certain types of medicinal products only;

(b) determine and publish a list of the countries other than the United Kingdom whose assessments of applications for a marketing authorisation are relevant for the purposes of paragraph (4A)(b); and

(c) decide to have regard to the assessments described in paragraph (4A)(b) in relation to medicinal products that have been authorised by way of certain procedures only.

(4C) When considering an application for a UK marketing authorisation (other than an application under the unfettered access route), the licensing authority may, if it considers it appropriate and without undertaking further consideration, rely on a decision by the European Commission to authorise the medicinal product to which the application relates to establish that any or all of the conditions in paragraph (4)(a), (b) or (d) have been met.”;

(b) for paragraph (3) substitute—

“(4) After paragraph (7) insert—

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

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

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

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

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

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

(a) for paragraph (2)(c) substitute—

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

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

(b) for paragraph (4) substitute—

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

(c) for paragraph (7) substitute—

"(7) For paragraph 17 substitute—

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

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

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

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

(e) for paragraph (9) substitute—

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

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

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

(i) for paragraph (1) substitute—

"(1) Paragraph (2) applies if—

(a) an application—

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

(ii) to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan,

is granted by the licensing authority; and

(b) the licensing authority is satisfied that the material provided by the applicant pursuant to—

(i) regulation 50A(3), where paragraph (1)(a)(i) applies; or

(ii) Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,

demonstrates compliance with the agreed paediatric investigation plan.";

(ii) for paragraph (3) substitute—

"(3) Where—

(a) paragraph (2) applies; or

(b) an application to which Article 7 or 8 of the Paediatric Regulation applies—

(i) includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or

(ii) confirms completion of an EU agreed paediatric investigation plan which failed to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, the package leaflet of the medicinal product,

the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).";

(iii) for paragraph (4)(b) substitute—

"(b) the holder of the UK marketing authorisation is entitled to a one year extension of the ten year period referred to in regulation 51A(6), under regulation 51A(12).";

(iv) after paragraph (4) insert—

"(4A) Paragraph (3) does not apply where—

(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does not cover the whole of the United Kingdom; and

(b) the UK marketing authorisation in which the statement of compliance is included is not in force in the same part of the United Kingdom as the supplementary protection certificate.

(4B) Where—

(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does cover the whole of the United Kingdom; and

(b) the UK marketing authorisation in which the statement of compliance is included is in force in in Great Britain only or in Northern Ireland only,

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

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

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

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

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

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

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

(a) after paragraph (1) insert—

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

(b) omit paragraph (2);

(c) for paragraph (3) substitute—

"(3) After paragraph (3), insert—

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

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

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

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

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

(d) for paragraph (6) substitute—

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

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

"**66.** In regulation 60—

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

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

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

(d) for paragraph (9) substitute—

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

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

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

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

(b) in the inserted regulation 60A—

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

""the batch testing exemption" means that—

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

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

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

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

(ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country,

a group of countries or an organisation of which that country is a part), and

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

(ii) in paragraph (2)(b), omit "medicinal";

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

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

(v) after paragraph (13) insert—

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

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

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

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

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

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

(c) after the inserted regulation 60A insert—

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

60B.—(1) In this regulation—

"the appropriate authority" is to be construed in accordance with section 57(7) of the Health and Social Care Act 2012(**4**);

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

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

"the batch testing exemption" means that—

(**4**) 2012 c.7.

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

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

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

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

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

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

(a) must submit a sample from each batch of the medicinal product that is the subject of that authorisation to the appropriate authority, together with appropriate documentation; and

(b) must not sell or supply, or offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

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

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

(a) that is—

(i) a live vaccine;

(ii) an immunological product used in the primary immunisation of infants or other groups at risk;

(iii) an immunological product used in public health immunisation programmes;

(iv) subject to paragraph (3), a new immunological product manufactured using new or altered kinds of technology or new for a particular manufacturer; or

(v) derived from human blood or human plasma, and

(b) which is intended for sale or supply in Northern Ireland.

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

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

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

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

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

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

(a) to submit a sample from the relevant batch to the appropriate authority, together with appropriate documentation; and

(b) not to sell or supply, or to offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

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

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

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

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

(a) in paragraph (2), in the inserted paragraph (4)(b), before "to comply" insert "in relation to a UKMA(GB),";

(b) after paragraph (2) insert—

"(2A) In paragraph (6), after "one medicinal product" insert "authorised by a UKMA(NI) or UKMA(UK)".";

(c) for paragraph (3) substitute—

"(3) After paragraph (6) insert—

"(6A) If concerns as described in paragraph (2) apply to more than one medicinal product authorised by a UKMA(GB), the licensing authority—

(a) must, where the obligation is to conduct a post-authorisation safety study, encourage the UK marketing authorisation holders concerned to conduct a joint study, and

(b) may, where the obligation is to comply with any other conditions or restrictions, encourage the UK marketing authorisation holders concerned to take co-ordinated action to comply with the conditions or restrictions.".";

(d) after paragraph (3) insert—

"(3A) In paragraph (7) for "The obligation under paragraph (5) shall" substitute "In relation to a UKMA(NI) or UKMA(UK), the obligation under paragraph (5) must".";

(e) for paragraph (4) substitute—

"(4) After paragraph (7) insert—

"(7A) In relation to a UKMA(GB), the obligation under paragraph (5) must—

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

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

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

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

(f) for paragraph (5) substitute—

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

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

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

"(d) any conditions—

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

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

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

"(a) the licensing authority grants or varies—

(i) a UK marketing authorisation;

(ii) an Article 126a authorisation;

(iii) a traditional herbal registration; or

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

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

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

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

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

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

"66, for paragraph (2) substitute—

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

(a) a UKMA(NI)—

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

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

(b) a UKMA(GB)—

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

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

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

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

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

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

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

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

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

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

"(b) for "established in the European Union" substitute—

"established in—

(a) the United Kingdom; or

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

in accordance with the requirements of these Regulations.".";

(b) for paragraph (5) substitute—

"(5) In paragraph (9)(a) omit "other than the United Kingdom".";

(c) in paragraph (8)—

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

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

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

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

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

"(b) under—

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

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

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

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

"—

(a) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), regulation 69;

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

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

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

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

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

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

(a) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or a UKMA(UK)—

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

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

(b) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), the UK web-portal established in accordance with regulation 203(1).".".

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

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

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

(a) in the heading to the regulation for "UK marketing authorisations" substitute "UKMA(GB)";

(b) for "UK marketing authorisation" in each place it appears substitute "UKMA(GB)".

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

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

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

(a) in paragraph (1), for the first reference to "a marketing authorisation" substitute "a UKMA(NI) or UKMA(UK)";

(b) in paragraph (2), for the first reference to "a marketing authorisation" substitute "UKMA(NI) or UKMA(UK)".".

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

(a) for paragraph (3) substitute—

"(3) For paragraph (a) substitute—

"(a) fails—

(i) in respect of a UKMA(GB) or UKMA(UK), to inform the licensing authority in accordance with paragraph 14(1) of Schedule 10A, or

(ii) in respect of a UKMA(NI), UKMA(UK) or EU marketing authorisation, to inform the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008,

that the holder has taken urgent safety restrictions on the holder's own initiative;".";

(b) for paragraph (4) substitute—

"(4) For paragraph (b) substitute—

"(b) fails—

(i) in respect of a UKMA(GB), to implement an urgent safety restriction imposed on the holder by the licensing authority in accordance with paragraph 14(3) of Schedule 10A, or

(ii) in respect of a UKMA(NI) or UKMA(UK), to implement an urgent safety restriction imposed on the holder by the European Commission under Article 22(2) of Regulation (EC) No 1234/2008; or".";

(c) after paragraph (4) insert—

"(4A) In paragraph (c) after "fails" insert "in respect of a UKMA(NI)".";

(d) in paragraph (5)—

(i) for "For sub-paragraph (c) substitute" substitute "After paragraph (c) insert";

(ii) renumber the paragraph inserted as sub-paragraph (d);

(iii) in the paragraph inserted, after "fails" insert "in respect of a UKMA(GB)".

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

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

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

"**Application of regulations 81 to 94**

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

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

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

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

90B. Omit regulation 91.".

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

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

91. In regulation 94A—

(a) for paragraph (1) substitute—

"(1) A person who is—

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

(b) a parallel distributor,

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

(b) for paragraph (3) substitute—

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

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

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

92. In regulation 95—

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

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

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

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

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

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

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

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

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

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

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

(a) after paragraph (1) insert—

"(1A) After paragraph (1) insert—

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

(a) there is already in place, or will be at the time the COR(GB) is granted, a certificate of registration in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in paragraph (5B), and

(c) the registrable homoeopathic medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A certificate of registration must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that certificate of registration being "in force" is limited to that territory.".";

(b) in paragraph (2) for "for "European Union"" to the end substitute—

"for "must be established in the European Union" substitute—

", where it is applying for—

(a) a COR(NI)—

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

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

(b) a COR(GB)—

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

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

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

(c) after paragraph (2) insert—

“(2A) After paragraph (5) insert—

“(5A) The application must include a statement indicating whether the certificate sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.

(5B) The applicant for the grant of a COR(GB) under the unfettered access route must provide—

(a) the application form submitted in connection with the granting of the COR(NI) which authorises the sale or supply of the product in Northern Ireland;

(b) a copy of all material submitted in support of the application for the COR(NI) which authorises the sale or supply of the product in Northern Ireland; and

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

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

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

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

(2) After paragraph (6) insert—

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

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

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

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

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

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

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

“, where it is applying for renewal of—

(a) a COR(NI) and originally granted—

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

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

(b) a COR(GB) and originally granted—

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

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

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

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

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

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

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

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