This Statutory Instrument has been printed to correct errors in S.I. 2019/775 and S.I. 2019/791. It is being issued free of charge to all known recipients of those Statutory Instruments.

STATUTORY INSTRUMENTS

2019 No. 1385

EXITING THE EUROPEAN UNION CONSUMER PROTECTION MEDICINES

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

Made - - - - 23rd October 2019

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**1**).

In accordance with paragraph 1(3) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of these Regulations has been laid before and approved by a resolution of each House of Parliament.

Citation and commencement

1. These Regulations may be cited as the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and come into force immediately before exit day(**2**).

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

2. The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019(**3**) are amended in accordance with Schedule 1.

(**1**) 2018 c. 16.
(**2**) "Exit day" is defined in section 20 of the European Union (Withdrawal) Act 2018.
(**3**) S.I. 2019/775.

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

3. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019(**4**) are amended in accordance with Schedule 2.

Signed by authority of the Secretary of State for Health and Social Care.

Blackwood
Parliamentary Under-Secretary of State,
Department of Health and Social Care

23rd October 2019

(**4**) S.I. 2019/791.

SCHEDULE 1

Regulation 2

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

Interpretation

1. In this Schedule, "the 2012 Regulations" means the Human Medicines Regulations 2012(**5**).

Amendment of regulation 15 (amendment of regulation 18 of the 2012 Regulations – wholesale dealing in medicinal products)

2. In regulation 15(2), in inserted regulation 18(1)(c) of the 2012 Regulations(**6**), omit "for either purpose".

Amendment of regulation 17 (amendment of regulation 19 of the 2012 Regulations – exemptions from requirement for wholesale dealer's licence)

3. In regulation 17, at the end insert—

"(4) At the end insert—

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

Amendment of regulation 47 (amendment of regulation 48 of the 2012 Regulations – application of Part 5)

4. In regulation 47(2)—

(a) in sub-paragraph (a), in the inserted definition of "EU reference medicinal product", after "paragraph (b)" insert "or (c)"; and

(b) in sub-paragraph (d), in the substituted definition of "reference medicinal product"—

(i) omit the "or" at the end of paragraph (a); and

(ii) at the end of paragraph (b) insert—

"; or

(c) in relation to which an EU marketing authorisation had ceased to be in force before exit day for reasons not relating to safety, quality or efficacy.".

Amendment of regulation 56 (substitution of regulation 51 of the 2012 Regulations - applications relating to generic medicinal products)

5. In regulation 56, in paragraph (9) of substituted regulation 51 of the 2012 Regulations, after "EU reference medicinal product" insert "which falls within paragraph (b) of the definition of "reference medicinal product"".

Amendment of regulation 58 (amendment of regulation 53 of the 2012 Regulations - applications relating to similar biological medicinal products)

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

(**5**) S.I. 2012/1916; relevant amendments were made by S.I. 2019/775.
(**6**) Regulation 18 was substituted by S.I 2013/1855.

(2) In paragraph (3), for substituted paragraph (2)(a) of regulation 53 of the 2012 Regulations, substitute—

"(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) (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; but".

(3) For paragraph (4)(a), substitute—

"(a) for "Regulation 51(2)" substitute "Paragraphs (2) to (14) of regulation 51"; and".

Amendment of regulation 63 (amendment of Schedule 11 to the 2012 Regulations – advice and representations)

7.—(1) Regulation 63 is amended as follows.

(2) For paragraph (2)(a)(ii) substitute—

"(ii) at the end insert—

"and;

(d) 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.";".

(3) After paragraph (2) insert—

"(2A) In paragraph 2 (requirement to consult the appropriate committee), after sub-paragraph (2), insert—

"(2A) The licensing authority must consult the appropriate committee if the authority proposes 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.".

(2B) In paragraph 3 (exceptions to requirement to consult)—

(a) in sub-paragraph (1), after "traditional herbal registration" insert ", or to 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,"; and

(b) in sub-paragraph (1)(a), after "determined", insert "or the decision to be made".

(2C) In paragraph 5 (provisional opinion against authorisation)—

(a) after sub-paragraph (2), insert—

"(2A) If the appropriate committee is consulted under paragraph 2(2A), it may give a provisional opinion that it may be unable to advise the licensing authority to decide that the orphan criteria are met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation."; and

(b) in sub-paragraph (3), after "grant or renewal", insert ", the applicant intending to demonstrate that the orphan criteria are met in relation to a medicinal product,".

(2D) In paragraph 10 (decision of licensing authority)—

(a) omit the "or" at the end of sub-paragraph (1)(b); and

(b) at the end of sub-paragraph (1)(c) insert—

"; or

(d) decide whether to proceed with its 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,".".

(4) For paragraph (3) substitute—

"(3) In paragraph 12 (licensing authority decisions in other cases)—

(a) in sub-paragraph (1), insert ", parallel import licence" after "UK marketing authorisation" in each place it appears;

(b) in sub-paragraph (5), insert ", licence" after "the authorisation"; and

(c) after sub-paragraph (4), insert—

"(4A) This paragraph also applies if, having been consulted under paragraph 2(2A), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2A) and the licensing authority proposes to decide, against that committee's advice, 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.".".

(5) After paragraph (3) insert—

"(3A) After Part 1 insert—

"PART 1A

Paediatric Decisions

Application of this Part

13A. This Part applies to a proposed decision by the licensing authority—

(a) to refuse to agree a paediatric investigation plan (including a waiver or deferral proposed to be included in that plan), or to agree such a plan otherwise than in accordance with the request for agreement;

(b) to refuse to agree a modification to a paediatric investigation plan (including a waiver or deferral which is, or is proposed to be, included in that plan), or to agree such a modification otherwise than in accordance with the request for the modification;

(c) to impose, revoke or refuse to grant a waiver of the obligation under regulation 50A(3) 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; or

(d) to revoke a waiver which was agreed as part of an agreed paediatric investigation plan.

Opportunity to make representations

13B.—(1) If the licensing authority proposes to make a decision to which this Part applies, the licensing authority must notify the person to whom the proposed decision would be addressed ("the applicant").

(2) The applicant may, by notice in writing to the licensing authority, request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request before the end of the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant's request.

Written representations

13C.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may at the request of the applicant extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

13D.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

13E.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

13F.—(1) The licensing authority must decide whether to proceed with its proposed decision—

(a) if the applicant requested the opportunity to make written or oral representations, after receiving the appropriate committee's report under paragraph 13C or 13D or notification under paragraph 13E; or

(b) if the applicant did not request the opportunity to make written or oral representations, after the expiry of the period of time for notifying a request for that opportunity.

(2) If the appropriate committee gives a report under paragraph 13C or 13D, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 13F notification

13G.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 13F.

(2) The applicant may notify the licensing authority in writing that the applicant wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification before the end of the period of 28 days beginning with the day on which the notification is given to the applicant under paragraph 13F or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the applicant has not made any representations in accordance with paragraph 13C or 13D.".".

Amendment of regulation 139 (amendment of regulation 177 of the 2012 Regulations – application of Part 11 (pharmacovigilance) and interpretation)

8. For regulation 139(6), substitute—

"(6) In paragraph (5)—

(a) for "Schedule 33" substitute "Schedules 33 and 33A";

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

(c) after that definition, insert—

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

(d) omit the definitions of "co-ordination group", "Eudravigilance database", "Implementing Regulation" and "relevant competent authorities".".

Amendment of Schedule 6 (insertion of Schedule 12A into the 2012 Regulations)

9. In Schedule 6, in Part 8 of inserted Schedule 12A to the 2012 Regulations (periodic safety update reports), in paragraph 27 (format of periodic safety update reports)—

(a) re-number the existing paragraph as sub-paragraph (1) of paragraph 27; and

(b) insert at the end—

"(2) In this paragraph, "signal evaluation" means the process of further evaluating a validated signal taking into account all available evidence, to determine whether there are new risks causally associated with the active substance or medicinal product, or whether known risks have changed, and that process—

(a) may include non-clinical and clinical data; and

(b) must be as comprehensive as possible regarding the sources of information used for that process.".

Amendment of Schedule 7 (insertion of Schedule 33A into the 2012 Regulations)

10.—(1) Schedule 7 is amended as follows.

(2) In paragraph 5 of inserted Schedule 33A to the 2012 Regulations (list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day), after paragraph (e) insert—

"(ea) Republic of Korea;".

(3) In paragraph 57 of inserted Schedule 33A to the 2012 Regulations (temporary exemption as to the location of an appropriately qualified person for pharmacovigilance)—

(a) in sub-paragraph (2), after "regulation 182(2)(a)", insert "(obligation on holder to operate pharmacovigilance system) in respect of a relevant UK marketing authorisation or traditional herbal registration";

(b) for sub-paragraph (3) substitute—

"(3) In this paragraph—

"relevant UK marketing authorisation or traditional herbal registration" means any UK marketing authorisation or traditional herbal registration granted before, on or after exit day to a holder to whom sub-paragraph (2) applies where—

(a) that authorisation or registration is included in the same pharmacovigilance system as the UK marketing authorisation or traditional herbal registration referred to in sub-paragraph (1), and which is operated by that holder under regulation 182(1); and

(b) that pharmacovigilance system was, immediately before exit day, maintained by an appropriately qualified person responsible for pharmacovigilance to whom sub-paragraph (1)(c) applies;

"the transitional period" means the period of 21 months beginning with exit day.".

(4) After paragraph 57 of inserted Schedule 33A to the 2012 Regulations, insert—

"**Temporary exemptions in relation to the pharmacovigilance system master file**

57A.—(1) Where paragraph 57(2) applies to a holder—

(a) regulation 182(2)(b); and

(b) Part 1 of Schedule 12A,

do not, subject to sub-paragraph (2), apply to that holder for the transitional period.

(2) Sub-paragraph (1) only applies to a holder if during the transitional period—

(a) the holder maintains an EU pharmacovigilance system master file, and the pharmacovigilance system described in it is the same as the pharmacovigilance system operated for that holder's UK marketing authorisation or traditional herbal registration under regulation 182(1);

(b) that EU pharmacovigilance system master file complies with the requirements of Chapter 1 of Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council, and regulation 184(1)(b) and (2) (obligation on holder to audit pharmacovigilance system);

(c) the holder's appropriately qualified person responsible for pharmacovigilance has permanent access to that EU pharmacovigilance system master file;

(d) the holder's appropriately qualified person responsible for pharmacovigilance has permanent access to any other information concerning the compliance of the pharmacovigilance system operated under regulation 182(1) with the provisions in Part 11 of these Regulations and Schedule 12A; and

(e) the holder provides the EU pharmacovigilance system master file, and the information specified in paragraph (d), to the licensing authority if the licensing authority requests it, within such time period as the licensing authority specifies.

(3) In this paragraph—

"EU pharmacovigilance system master file" means a pharmacovigilance system master file maintained by a holder in an EEA State under Article 104 of the 2001 Directive; and

"the transitional period" means whichever is the shorter period of—

(a) the period beginning with exit day and ending with the day on which the holder's appropriately qualified person for pharmacovigilance begins to both reside and operate in the United Kingdom; or

(b) the period of 21 months beginning with exit day.".

SCHEDULE 2

Regulation 3

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Interpretation

1. In this Schedule, "the 2002 Regulations" means the Medical Devices Regulations 2002(**7**).

Amendment of regulation 3 (amendment of Part I of the 2002 Regulations)

2.—(1) Regulation 3 is amended as follows.

(2) In paragraph (6), in inserted regulation 3A of the 2002 Regulations (designated standard)—

(a) for paragraph (1), substitute—

"(1) In Parts II, III, IV, VIII and IX of these Regulations, a "designated standard" means—

(a) a technical specification which is—

(i) adopted by a recognised standardisation body, for repeated or continuous application with which compliance is not compulsory; and

(ii) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate; or

(b) a monograph of the European Pharmacopoeia (in particular on surgical sutures and on the interaction between medicinal products and materials used in devices containing medicinal products) which has been published in the Official Journal of the European Union.";

(b) in paragraph (3)(b), for "(CENLAC)" substitute, "(CENELEC)";

(c) for paragraph (8), substitute—

"(8) In this regulation—

(a) a reference to a "device" is a reference to a medical device or its accessory or an in vitro diagnostic medical device or its accessory to which these Regulations apply;

(b) a reference to "the European Pharmacopoeia" is a reference to the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia."(**8**).

(3) In paragraph (7)—

(a) in inserted regulation 4D of the 2002 Regulations (revocations, transitional and saving provisions in respect of the new national registration requirements), for paragraph (10)(b), substitute—

"(b) that is—

(i) a relevant device for the purposes of Part IV, other than a device referred to in the lists in Annex II of Directive 98/79 or a device for self-testing, which follows the procedure for CE marking in regulation 40(1); or

(ii) classified (whether or not Part IX applies in respect of the device) as belonging to Class A, referred to in Schedule 23."; and

(**7**) S.I. 2002/618; relevant amendments were made by S.I. 2019/791.
(**8**) Council of Europe (ETS No. 050), Strasbourg, 22.07.1964.

(b) in inserted regulation 4E of the 2002 Regulations (transitional provisions in respect of the European Commission's UDI database), in paragraph (7), for "Part VIII" substitute, "Part IX".

Amendment of regulation 4 (amendment of Part II of the 2002 Regulations)

3. In regulation 4(4), in inserted regulation 7A of the 2002 Regulations (registration of persons placing general medical devices on the market), after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Amendment of regulation 5 (amendment of Part III of the 2002 Regulations)

4. In regulation 5(3), in inserted regulation 21A of the 2002 Regulations (registration of persons placing active implantable medical devices on the market) after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Amendment of regulation 6 (amendment of Part IV of the 2002 Regulations)

5. In regulation 6(3), in inserted regulation 33A of the 2002 Regulations (registration etc. of persons placing in vitro diagnostic medical devices on the market) after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Amendment of regulation 7 (amendment of Part V of the 2002 Regulations)

6.—(1) Regulation 7 is amended as follows.

(2) For paragraph (4), substitute—

"(4) In regulation 48 (designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1)—

(i) omit "European Community";

(ii) for "an "EC CAB"" substitute "a "CAB"";

(c) in paragraphs (2), (4), (5), (7) and (8), for "an EC CAB", in each place it occurs, substitute "a CAB";

(d) in paragraph (6), omit "EC" in both places;

(e) in paragraphs (1), (2), (5), (7) and (8), for "the Mutual Recognition Agreements" in each place it occurs, substitute "a mutual recognition agreement".".

(3) For paragraph (5), substitute—

"(5) In regulation 49 (fees charged by UK notified bodies and EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1)—

(i) for "or EC CAB" substitute "or CAB";

(ii) in sub-paragraphs (a) and (b), for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(iii) in sub-paragraph (b), for "an EC CAB" in both places it occurs, substitute "a CAB";

(c) in paragraphs (3) and (4), for "or EC CAB" substitute "or CAB".".

Amendment of regulation 8 (amendment of Part VI of the 2002 Regulations)

7. In regulation 8, for paragraph (4), substitute—

"(4) In regulation 55(**9**) (fees payable in connection with the designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1), for "an EC CAB" substitute "a CAB";

(c) in paragraph (3)—

(i) for "an EC CAB" substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement".".

Amendment of regulation 9 (amendment of Part VII of the 2002 Regulations)

8. In regulation 9(3) (amendment of regulation 60 of the 2002 Regulations), for sub-paragraph (d), substitute—

"(d) in paragraph (4)—

(i) for "an authorised representative of a manufacturer of a device" substitute "a UK responsible person";

(ii) for "the single authorised representative of the manufacturer" substitute "a UK responsible person".".

Amendment of regulation 10 (insertion of Part VIII into the 2002 Regulations)

9.—(1) Regulation 10 is amended as follows.

(2) In inserted regulation 75 of the 2002 Regulations (common specifications)—

(a) in paragraph (3), before "Manufacturers" insert "Subject to paragraph (7),";

(b) after paragraph (6), insert—

"(7) Manufacturers of devices which fall within the groups of products listed in Schedule 16 must comply with the relevant CS for those products.".

(3) In inserted regulation 93 of the 2002 Regulations (registration of devices) after paragraph (3), insert—

"(4) The manufacturer must keep the information provided in accordance with paragraph (1) updated.".

(4) In inserted regulation 119 of the 2002 Regulations (recording and reporting adverse events that occur during clinical investigations), in paragraph (6) before "This regulation" insert "Unless a causal relationship has been established between the serious adverse event and the preceding investigational procedure,".

(5) In inserted regulation 124 of the 2002 Regulations (periodic safety update report), in paragraph (5), for "paragraph 12(2)" substitute "paragraph 2".

(**9**) Regulation 55 was amended by S.I. 2007/803, S.I. 2010/557 and S.I. 2017/207.

Amendment of regulation 11 (insertion of new Part IX into the 2002 Regulations)

10.—(1) Regulation 11 is amended as follows.

(2) In inserted regulation 149 of the 2002 Regulations (person responsible for regulatory compliance), in paragraph (5)(e), for "Chapter II" substitute "Part 1".

(3) In inserted regulation 158 of the 2002 Regulations (registration of devices)—

(a) for paragraph (1), substitute—

"(1) Before placing a device, other than a custom-made device, on the market, the manufacturer must, in accordance with the rules of the issuing entity referred to in regulation 157(2), assign a Basic UDI-DI to the device and provide it to the UDI database together with the other core data elements referred to in—

(a) Part B of Schedule 22 related to that device;

(b) paragraph 2 of Part A of Schedule 22.";

(b) after paragraph (2), insert—

"(3) The manufacturer must keep the information provided in accordance with paragraph (1) updated.".

Amendment of regulation 12 (new Schedules to the 2002 Regulations)

11.—(1) Regulation 12 is amended as follows.

(2) In inserted Schedule 19 to the 2002 Regulations (technical documentation on post-market surveillance for in vitro diagnostic medical devices), in paragraph 5—

(a) for "Article 81" substitute "regulation 189";

(b) for "Article 80" substitute "regulation 188".

(3) In inserted Schedule 24 to the 2002 Regulations (conformity assessment based on quality management system and on assessment of technical documentation - in vitro diagnostic medical devices), in paragraph 1(7)—

(a) in the heading, omit "applicable to Class C and Class D devices";

(b) omit "of Class C and D devices".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) ("the Withdrawal Act") in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c) and (d) of the Withdrawal Act) arising from the withdrawal of the UK from the European Union.

Regulation 2 and Schedule 1 amend the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) ("the Medicines Exit Regulations"). The Medicines Exit Regulations amend the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the Principal Medicines Regulations").

Paragraphs 2 and 3 amend regulations 15 and 17 of the Medicines Exit Regulations (amendment of regulations 18 and 19 of the Principal Medicines Regulations) to ensure that the requirements for a wholesale dealer's licence apply to hospitals importing human medicinal products directly from a country on an approved list, including for their own use (but not to those persons importing a medicine from such a country purely for administration to themselves or a member of their household).

Paragraph 4 amends regulation 47 of the Medicines Exit Regulations to ensure that the definition of "EU reference medicinal product" in regulation 48 of the Principal Medicines Regulations includes a medicinal product which was the subject of a marketing authorisation granted by the European Commission under Regulation (EC) No. 726/2004 which had been cancelled before exit day on grounds not relating to safety, quality or efficacy. Reference medicinal products are products in relation to which there was a full set of data supporting the application for the marketing authorisation for the product, and reliance may be placed on part of that data by subsequent applicants, for example applicants for marketing authorisations for generic versions of innovative products.

Paragraph 6 amends regulation 58 of the Medicines Exit Regulations so as to insert some missing words into regulation 53 of the Principal Medicines Regulations (biosimilar applications) relating to the time period for which biological reference medicinal products have to have been authorised before an abridged application may be made in reliance on the data supporting such reference products.

Paragraph 7 ensures that the amendments made to Schedule 11 to the Principal Medicines Regulations by regulation 63 of the Medicines Exit Regulations accommodate the process for seeking advice and making representations in relation to the new decisions conferred on the licensing authority by the Medicines Exit Regulations in relation to orphan (rare disease) medicines and paediatric medicines.

Paragraph 8 amends regulation 139(6) of the Medicines Exit Regulations (amendment of regulation 177 of the Principal Medicines Regulations) to include a definition of "signal" in relation to pharmacovigilance activities.

Paragraph 9 amends Schedule 6 to the Medicines Exit Regulations (insertion of Schedule 12A into the Principal Medicines Regulations) to provide for a definition of "signal evaluation" in paragraph 27 of inserted Schedule 12A in relation to periodic safety update reports.

Paragraph 10 amends Schedule 7 to the Medicines Exit Regulations (new Schedule 33A to the Principal Medicines Regulations - transitional provision in relation to EU Exit). The amendments—

(a) add the Republic of Korea to the list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day;

(b) ensure that the temporary exemption as to the location of an appropriately qualified person for pharmacovigilance (QPPV) applies to a holder of a UK marketing authorisation or traditional herbal registration granted before exit day, in respect of all UK marketing authorisations or registrations they hold for which there is the same QPPV; and

(c) provide a temporary exemption, subject to specified conditions, regarding the obligation to maintain and make available on request of the licensing authority a UK pharmacovigilance system master file covering all medicinal products for which the holder obtained a UK marketing authorisation.

Regulation 3 and Schedule 2 amend the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791) ("the Devices Exit Regulations"). The Devices Exit Regulations amend the Medical Devices Regulations 2002 (S.I. 2002/618) ("the Principal Devices Regulations").

Paragraph 2 makes minor amendments to regulation 3 of the Devices Exit Regulations, in particular to ensure that monographs of the European Pharmacopoeia, insofar as they relate to medical devices, are included as designated standards (i.e. standards which serve the same purpose as EU harmonised

standards and which, if followed, will lead to the device being deemed to meet certain legislative requirements).

Paragraphs 3, 4 and 5 respectively make minor amendments to regulations 7A, 21A and 33A (inserted into the Principal Devices Regulations) to ensure that information provided by manufacturers, as part of the registration obligation, is updated if the information changes after the initial registration.

Paragraphs 6, 7 and 8 make minor amendments to the Devices Exit Regulations.

Paragraphs 9 and 10 make minor amendments to various regulations inserted into the Principal Devices Regulations by the Devices Exit Regulations. In particular these amendments ensure that devices which will be subject to the regulatory regime for the first time are required to comply with certain ‘common specifications’.

Paragraph 11 makes minor amendments to Schedules 19 (technical documentation on post-market surveillance for in vitro diagnostic medical devices) and 24 (conformity assessment based on a quality management system) inserted into the Principal Devices Regulations.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sectors is foreseen.