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(**1**).

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."(**2**).

(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

(**1**) S.I. 2002/618; relevant amendments were made by S.I. 2019/791.
(**2**) 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(**3**) (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".

(**3**) 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".