SCHEDULE 2 Regulation 3

Amendments to EU tertiary legislation

PART 1

Amendments to Commission Decision 2002/364/EC

1. In Article 1 (which relates to the adoption of common technical specifications), at the end, insert "as that Annex applied before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

2. Omit Article 2 (which relates to the addressees of the Decision).

3. In the Annex (which contains common technical specifications for in vitro diagnostic medical devices)—

(a) in point 3.1.4—

(i) for "CE marking" substitute "UK or CE marking",

(ii) for "CE marked" substitute "UK or CE marked";

(b) in point 3.1.8.—

(i) for "CE marked" substitute "UK or CE marked,",

(ii) for "notified body" substitute "approved body";

(c) in point 3.4.1—

(i) for "CE marking" substitute "UK or CE making",

(ii) for "CE marked" substitute "UK or CE marked";

(d) in Table 1, in the row marked Diagnostic sensitivity, for "Notified Body" in each place substitute "Approved Body".

PART 2

Amendments to Commission Regulation (EU) No 207/2012

4. In Article 1 (which relates to the scope of the Regulation), before the first paragraph insert—

"In this Regulation a reference to an Annex to Directive 90/385/EEC or to an Annex to Directive 93/42/EEC is to be construed as a reference to those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

5. In Article 3 (which relates to the provision of instructions for use in an electronic form)—

(a) in paragraph 1(a), for "Directive 90/385/EEC" substitute "Part 3 of the Medical Devices Regulations 2002";

(b) in paragraph 1(b), (c) and (e) for "Directive 93/42/EEC" substitute "Part 2 of the Medical Devices Regulations 2002";

(c) in paragraph 1(d), for "Directives 90/385/EEC and 93/42/EEC", substitute "Part 3 or Part 2 of the Medical Devices Regulations 2002".

6. In Article 7 (which relates to access to instructions for use through a website)—

(a) in paragraph 2(e), for "Directive 95/46/EC" substitute "the Data Protection Act 2018(**1**) and the UK GDPR".

(b) after paragraph 2 insert—

"**3.** In this Article "the UK GDPR" has the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(10) and (14) of that Act).".

7. For Article 8 (which relates to review of obligations by a notified body) substitute—

"Except for medical devices of Class I, as defined in Annex IX to Directive 93/42, the fulfilment of the obligations laid down in Articles 4 to 7 of this Regulation must be reviewed by an approved body during the applicable conformity assessment procedure for the medical device in question, as set out in Part 2 or Part 3 of the Medical Devices Regulations 2002. The review must be based on a specific sampling method adapted to the class and the complexity of the product.".

8. In Article 10 (which relates to the commencement and applicability of the Regulation) omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

PART 3

Amendments to Commission Regulation (EU) No 722/2012

9. In Article 2 (which relates to interpretation), in the stem of the paragraph, for "Directive 90/385/EEC and Directive 93/42/EEC" substitute "the Medical Devices Regulations 2002".

10. In Article 3 (which relates to risk analysis and risk management), for paragraph 1, substitute—

"**1.** Before lodging an application for a conformity assessment for the purpose of complying with regulation 13 or regulation 27 of the Medical Devices Regulations 2002, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or their UK responsible person must carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.".

11. In Article 4 (which relates to verification of the fitness of notified bodies, which are now approved bodies)—

(a) for paragraph 1 substitute—

"The Secretary of State must verify on a regular basis that approved bodies designated under Part 5 of the Medical Devices Regulations 2002 have up-to-date knowledge and expertise of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices with the provisions of those Regulations and with the particular requirements of Annex I to this Regulation.";

(b) omit paragraph 2.

12. In Article 5 (which relates to conformity assessment procedures)—

(a) in paragraph 1, for "Directive 90/385/EEC or Directive 93/42/EEC" substitute "Part 3 or Part 2 of the Medical Devices Regulations 2002";

(b) in paragraph 2, for "Notified bodies" substitute "Approved bodies";

(c) in paragraph 3—

(i) in the first sub-paragraph, for "Notified bodies" substitute "Approved bodies";

(ii) in the second sub-paragraph, for "notified bodies" substitute "approved bodies";

(**1**) 2018 c. 12.

(d) for paragraphs 4 to 6 substitute—

"**4.** Before issuing a design-examination certificate or a type-examination certificate the approved body must inform the Secretary of State of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.

5. The Secretary of State may submit comments on the summary evaluation report referred to in paragraph 4 within the following deadlines:

(a) in relation to medical devices using starting materials for which a TSE certificate of suitability as referred to in paragraph 3 has been submitted, within four weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4;

(b) in relation to medical devices using starting materials for which a TSE certificate of suitability has not been submitted, within 12 weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4.

6. The approved bodies must—

(a) give due consideration to any comments received in accordance with paragraph 5;

(b) provide an explanation as regards this consideration, including any due justification not to take account of one or more of the comments received, along with their final decisions to the Secretary of State.";

(e) in paragraph 7—

(i) for "notified body" substitute "approved body",

(ii) for "paragraphs 1-6" substitute "paragraphs 1 to 3".

13. Omit Articles 6 (which relates to the obligation on Member States to ensure compliance with the requirements of the Regulation), 7 (which relates to certificates issued before 29th August 2013) and 8 (which relates to the repeal of an earlier piece of EU legislation).

14. In Article 9 (which relates to entry into force and application) omit "This Regulation is binding in its entirety and directly applicable in all Member States".

15. In Annex I (which relates to risk assessment, management and evaluation of notified bodies which have now become approved bodies)—

(a) in section 1.2, in the fifth paragraph, for "European or" to the end of that paragraph, substitute "international scientific committees or bodies.";

(b) in section 1.2.5.2, in the second paragraph, omit "European or";

(c) in section 2—

(i) for the heading substitute "EVALUATION BY APPROVED BODIES",

(ii) for "notified bodies referred to in Article 4" substitute "approved bodies referred to in Article 4";

(d) in section 2.1—

(i) for the heading substitute "Information of the Approved Body regarding changes and new information",

(ii) for "notified body", in both places it occurs, substitute "approved body";

(e) in section 2.2—

(i) for "an EC", in both places it occurs, substitute "a",

(ii) for "Article 9(8) of Directive 90/385/EEC or Article 11(11) of Directive 93/42/EEC" substitute "regulation 18(3) or regulation 31(3) of the Medical Devices Regulations 2002",

(iii) for "notified body" substitute "approved body";

(f) in section 2.3—

(i) for "a notified body" substitute "an approved body",

(ii) for "this notified body" substitute "this approved body".

16. In Annex II (which relates to summary evaluation reports)—

(a) in the table headed "Details relating to the submitting notified body"—

(i) for the heading substitute "Details relating to the submitting approved body",

(ii) in entry 1 for "notified body" substitute "approved body",

(iii) in entry 2 for "Notified body" substitute "Approved body",

(iv) in entry 10, for the stem substitute—

"Confirmation that the submitting approved body has been designated by the Secretary of State for the conformity assessment of";

(b) in the box headed "Notified Body Statement"—

(i) for the heading substitute "Approved Body Statement",

(ii) for "Council Directive 90/385/EEC" substitute "Part 3 of the Medical Devices Regulations 2002",

(iii) for "Council Directive 93/42/EEC" substitute "Part 2 of the Medical Devices Regulations 2002".

PART 4

Amendments to Commission Implementing Regulation 920/2013

17. In Article 1(a) (definitions), for "Article 1(2)(c) of Directive 90/385/EEC or medical devices and their accessories as defined in Article 1(2) of Directive 93/42", substitute "regulation 2(1) of the Medical Devices Regulations 2002".

18. For Article 1(c) substitute—

"(c) "approved body" has the same meaning as in regulation 2(1) of the Medical Devices Regulations 2002;".

19. For Article 1(d) substitute—

"(d) "accreditation" means an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific activity;".

20. Omit Article 1(e) and 1(f).

21. In Article 1(g), for "designating authority" substitute "Secretary of State".

22. In Article 1(i), for "a designating authority's" substitute "the Secretary of State's".

23. After Article 1insert—
"Article 1a

In this Regulation, any reference to Annex 8 to Directive 90/385 or to Annex XI to Directive 93/42 is to be construed as a reference to those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

24. In Article 3 (which relates to the procedure for the designation of notified bodies, now of approved bodies)—

(a) In its heading, for "notified" substitute "approved";

(b) in paragraph 1, in the first sub-paragraph, for "a notified body" substitute "an approved body";

(c) in paragraph 1, in the second sub-paragraph—

(i) for "notified" substitute "approved",

(ii) for "used in the New Approach Notified Designated Organisations Information System and subdivisions of those fields." substitute "found in Guidance: UK approved bodies for medical devices https://www.gov.uk/publications/medical-devices-uk-approved-bodies-for-medical-devices.";

(d) in paragraph 2—

(i) in the first sub-paragraph, for "The designating authority of the Member State where the conformity assessment body is established" substitute "The Secretary of State";

(ii) omit the second sub-paragraph.

(e) omit paragraphs 3 to 6;

(f) in paragraph 7 omit the first sub-paragraph.

25. In Article 4(extension of renewal of designation)—

(a) in paragraph 1, for "notified" substitute "approved";

(b) in paragraph 2, for "notified" substitute "an approved";

(c) for paragraph 5, substitute—

"**5.** An approved body, within the meaning of regulation A45(1)(b) of the Medical Devices Regulations 2002, whose designation does not have a stated validity period or has a validity period exceeding five years, is to be subject to a renewal within five years of IP completion day".

26. In Article 5 (surveillance and monitoring)—

(a) in paragraph 1—

(i) for "notified" in each place it occurs, substitute "approved",

(ii) in the first sub-paragraph, for "designating authority of the Member State where the notified body is established" substitute "Secretary of State",

(iii) in the third sub-paragraph, for "That designating authority" substitute "The Secretary of State";

(b) in paragraph 2, for "designating authorities", substitute "Secretary of State";

(c) in paragraph 3—

(i) for the first sub-paragraph substitute—

"The Secretary of State shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. The Secretary of State shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from outside the United Kingdom, which might indicate the non-fulfilment of the obligations by an approved body or its deviation from common or best practice.",

(ii) in the second sub-paragraph, for "designating authority of the Member State where the notified body is established" substitute "Secretary of State".

27. For Article 6 (investigation of competence of notified bodies) substitute—

"**Investigation of the competence of an approved body**

The Secretary of State may investigate cases regarding the competence of an approved body or the fulfilment of the requirements and responsibilities to which an approved body is subject under the Medical Devices Regulations 2002.".

28. Omit Articles 7 (exchange of experience on investigation and supervision of conformity assessment bodies) and 8 (operating of designated authorities).

29. For Article 9 (co-operation with accrediting bodies) substitute (without changing the numbering or heading)—

"Where designation is based on accreditation within the meaning of Regulation (EC) No 765/2008, the Secretary of State shall ensure that the accreditation body that has accredited a particular approved body is kept informed of incident reports and other information that relate to matters under the control of the approved body when the information may be relevant for the assessment of the performance of the approved body. The Secretary of State must ensure that the accreditation body in charge of the accreditation of a particular conformity assessment body is kept informed of findings relevant for the accreditation. The accreditation body shall inform the Secretary of State of its findings.".

30. In Article 10 (which relates to entry into force and application), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

31. In Annex I (which relates to interpretation of the conformity assessment body criteria) —

(a) in section 1.3(b)—

(i) for "authorised representative" substitute "UK responsible person",

(ii) omit "Union";

(b) omit section 1.5.

32. In Annex II (the application form to be submitted when applying for designation as an approved body) —

(a) in the title for "notified" substitute "an approved";

(b) in the fourth line of the application form, for "EU Notified" substitute "Approved";

(c) in the table of documents to be submitted—

(i) in box 4 omit from ",either within the Member State" to the end,

(ii) in box 15 for "the designating authority" to the end substitute "the Secretary of State",

(iii) in boxes 17 and 18 for "notified body", substitute "approved body",

(iv) in box 31 for "notified" in each place it occurs substitute "approved",

(v) in box 41 for "Communications from regulatory authorities including competent authorities and designating authorities" substitute "Communications from the Secretary of State or other regulatory authorities".