SCHEDULE 2

Amendments to EU tertiary legislation

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".