SCHEDULE 2

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

Amendment of regulation 3(7)

9. In regulation 3(7)—

(a) omit regulation 4B and 4C as inserted by regulation 3(7);

(b) in regulation 4D as inserted by regulation 3(7)—

(i) in each place "exit day" occurs substitute "IP completion day";

(ii) in paragraph (1), for "the day on which" substitute "when";

(iii) for paragraph (2)(a) substitute—

"(a) that is a relevant device for the purposes of Part II; and";

(iv) in paragraph (2)(b) omit "(whether or not Part II applies in respect of the device)";

(v) for paragraph (3)(a) substitute—

"(a) that is a relevant device for the purposes of Part II; and";

(vi) in paragraph (3)(b) omit "(whether or not Part II applies in respect of the device)";

(vii) in paragraph (4) omit ", with the modifications in paragraph (5)—";

(viii) omit paragraph (5);

(ix) in paragraph (6) for "the day on which" substitute "when";

(x) omit paragraph (7);

(xi) in paragraph (8) for "the day on which" substitute "when";

(xii) for paragraph (9)(a) substitute—

"(a) that is a relevant device for the purposes of Part IV, or";

(xiii) for paragraph (10) substitute—

"(10) Regulation 33A does not apply until the day that is 12 months after IP completion day in respect of a device or accessory that is a relevant device for the purposes of Part IV which follows the procedure in regulation 40(1).";

(xiv) in paragraph (11) omit the words from ", with the following modifications" to the end;

(xv) omit paragraph (12);

(c) omit regulation 4E as inserted by regulation 3(7);

(d) omit regulation 4F as inserted by regulation 3(7);

(e) omit regulation 4G as inserted by regulation 3(7);

(f) in regulation 4H(2) as inserted by regulation 3(7) for "exit day" substitute "IP completion day";

(g) in regulation 4J as inserted by regulation 3(7) omit paragraphs (2) and (3);

(h) in regulation 4K as inserted by regulation 3(7) omit paragraphs (2), (3) and (4);

(i) in regulation 4L as inserted by regulation 3(7)—

(i) omit paragraphs (2) and (3);

(ii) in paragraph (4) for "UK notified bodies" substitute "approved bodies";

(j) in regulation 4M as inserted by regulation 3(7) omit paragraph (2);

(k) in regulation 4N as inserted by regulation 3(7), for the opening words substitute—

"Where regulation 7 applies for the purposes of regulation 4D(2)(b) or (3)(b), Directives 2003/12 and 2005/50 apply with the following modifications—;";

(l) in regulation 4O as inserted by regulation 3(7), omit paragraph (2);

(m) in regulation 4P as inserted by regulation 3(7), omit paragraph (2);

(n) omit regulation 4Q as inserted by regulation 3(7);

(o) omit regulation 4R as inserted by regulation 3(7);

(p) omit regulation 4S as inserted by regulation 3(7);

(q) in regulation 4T as inserted by regulation 3(7)—

(i) in paragraph (1), for "Parts IV and IX" substitute "Part IV";

(ii) in paragraph (2)(a) omit "or 69";

(iii) in paragraph (3) omit "or VIII";

(iv) in paragraph (4)—

(aa) in sub-paragraph (b) omit "or 69";

(bb) in sub-paragraph (c) omit "or to "accessory for a medical device" in regulation 69";

(cc) in sub-paragraph (d) for the words from "the practical application of that definition" to "regulation 137.", substitute "the practical application of that definition, as having the meaning given to it in regulation 2;";

(dd) in sub-paragraph (e) omit "or to "accessory for an *in vitro* diagnostic medical device" in regulation 137".