DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 8

Amendment of the Medical Devices Regulations 2002

Amendments to the Medical Devices Regulations 2002

29. The Medical Devices Regulations 2002(**1**) are amended in accordance with this Part.

Amendment of regulation 2 (interpretation)

30. In regulation 2, in paragraph (1)—

(a) for the definition of "medical device" substitute—

> ""medical device" has the meaning given in Article 2(1) of Regulation (EU) 2017/745 and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;";

(b) after the definition of "Regulation 722/2012" insert—

> ""Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;".

Amendment of regulation 2A (medical devices which are qualifying Northern Ireland goods)

31. In regulation 2A—

(a) in paragraph (1)(a), after "Northern Ireland" insert "or of Regulation (EU) 2017/745";

(b) in paragraph (2)—

(i) the words from ""qualifying Northern Ireland good"" to the end become sub-paragraph (a); and

(ii) after that sub-paragraph insert—

> "(b) "Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.".

(**1**) S.I. 2002/618, as amended by S.I. 2003/1400, 2003/1697, 2005/2759, 2909, 2007/400, 803, 2008/2936, 2009/383, 2010/557, 2012/1426, 2013/525, 2327, 2017/207, 2019/791, 1385 and 2020/1478.

Revocation and transitional provision

32. After regulation 3 (scope), insert—

"**Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745**

3ZA.—(1) Subject to paragraph (2)—

(a) Parts 2 and 3 only apply in Northern Ireland for the purposes of regulating qualifying devices.

(b) Parts 5 to 7 only apply in Northern Ireland for the purposes of regulating qualifying devices and devices within the scope of Part 4.

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph whether or not the device to which they apply is referred to in paragraph (1)—

(a) for the purposes of registration of medical devices and persons placing medical devices on the market in Northern Ireland—

(i) regulation 19 (registration of persons placing general medical devices on the market),

(ii) regulation 21B (registration of persons placing active implantable medical devices on the market), and

(iii) regulation 53 (fees in connection with the registration of devices and changes to registration details),

apply until the date which is 6 months after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745.

(b) Parts 5 to 7 apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

(3) For the purposes of paragraph (1), a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745—

(a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of Directive 93/42 or Directive 90/385, rather than Regulation (EU) 2017/745; and

(b) it is placed on the market, put into service or made available in Northern Ireland in accordance with, and subject to the requirements of and the arrangements set out in, Parts 2, 3 and 5 to 7."

Amendment of regulation 10A (UK(NI) indication: general medical devices)

33. In regulation 10A, after paragraph (3), insert—

"(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies."

Amendment of regulation 19 (registration of persons placing general medical devices on the market)

34. In regulation 19—

(a) omit paragraph (1)(a)(ii);

(b) in paragraph (1)(b) for "and custom-made devices" substitute "that are not custom-made devices";

(c) omit paragraph (2)(c);

(d) omit paragraph (5); and

(e) omit paragraph (6).

Amendment of regulation 21B (registration of persons placing active implantable medical devices on the market)

35. In regulation 21B—

(a) omit paragraph (1)(a)(ii);

(b) omit paragraph (1)(b);

(c) omit paragraph (2)(c);

(d) omit paragraph (5); and

(e) omit paragraph (6).

Amendment of regulation 24A (UK(NI) indication: active implantable medical devices)

36. In regulation 24A, after paragraph (3), insert—

"(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies."

Amendment of regulation 36A (UK(NI) indication: in vitro diagnostic medical devices)

37. In regulation 36A, after paragraph (3), insert—

"(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies."