DRAFT STATUTORY INSTRUMENTS

# 2021 No.

# The Medical Devices (Northern Ireland Protocol) Regulations 2021

## PART 9

## Amendments of other secondary legislation

### Amendment of the Blood Safety and Quality Regulations 2005

**38.** In the Blood Safety and Quality Regulations 2005(**1**), in regulation 2 (scope of the regulations), in paragraph (3), at the end insert "and 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 the Human Tissue (Quality and Safety for Human Application) Regulations 2007

**39.** In the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**2**), in regulation 2 (extent and application)—

(a) in paragraph (3)(c), omit the "or" at the end; and

(b) in paragraph (3)(d), at the end insert—

", or

(e) 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 the Legislative and Regulatory Reform (Regulatory Functions) Order 2007

**40.**—(1) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007(**3**) is amended as follows.

(2) In Part 2 of the Schedule, in the section headed "Medicines", after "Human Medicines Regulations 2012", insert—

"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

Medical Devices (Northern Ireland Protocol) Regulations 2021".

(**1**) S.I. 2005/50; regulation 2 was amended by S.I. 2019/4.
(**2**) S.I. 2007/1523; regulation 2 was amended by S.I. 2012/1916, 2018/335, and 2019/481.
(**3**) S.I. 2007/3544, to which there are amendments not relevant to these Regulations.

(3) In Part 3 of the Schedule, in the section headed "Public health and safety", after "The Personal Protective Equipment (Enforcement) Regulations 2018", insert "The Medical Devices (Northern Ireland Protocol) Regulations 2021".

### Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

**41.** In the Medicines (Products for Human Use) (Fees) Regulations 2016(**4**), in regulation 10(5) (fee for advice for other purposes)—

(a) in paragraph (a), omit the "or" at the end; and

(b) in paragraph (b), at the end insert—

"; or

(c) obtaining an EU technical documentation assessment certificate or EU type-examination certificate of the type mentioned in section 5 of Annex IX and section 6 of Annex X of 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, for a medical device incorporating that product or a product of that type."

### Amendment of the Economic Growth (Regulatory Functions) Order 2017

**42.** In the Economic Growth (Regulatory Functions) Order 2017(**5**), in Part 3 of the Schedule, in the section headed "Medicines", after "Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004", insert—

"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

Medical Devices (Northern Ireland Protocol) Regulations 2021".

### Amendment of the Market Surveillance (Northern Ireland) Regulations 2021

**43.**—(1) The Market Surveillance (Northern Ireland) Regulations 2021(**6**) are amended as follows.

(2) In regulation 6 (enforcer's legislation), at the end insert—

"(rr) regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021."

(3) In Schedule 1 (investigatory powers)—

(a) in paragraph 1 (interpretation of terms used in this schedule), at the end insert—

""Regulation (EU) 2017/745 on medical devices" 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."

(b) in paragraph 16 (power to decommission or switch off any medical device)—

(i) in sub-paragraph (1), for the words from "pursuant to" to the end substitute—

(**4**) S.I. 2016/190, amended by S.I. 2019/775; there are other amending instruments but none is relevant.
(**5**) S.I. 2017/267, to which there are amendments not relevant to these Regulations.
(**6**) S.I. 2021/

"pursuant to—

(a) the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002,

(b) a duty in regulations made under section 15(1) of the Medicines and Medical Devices Act 2021, or

(c) the duty in regulation 26(1) or (2) of the Medical Devices (Northern Ireland Protocol) Regulations 2021.";

(ii) in sub-paragraph (2), after "Medical Devices Regulations 2002" insert "or Regulation (EU) 2017/745 on medical devices";

(iii) in sub-paragraph (3)(a)(ii), after "Medicines and Medical Devices Act 2021;", omit "and";

(iv) after sub-paragraph (3)(a)(ii) insert—

"(iii) the Medical Devices (Northern Ireland Protocol) Regulations 2021;

(iv) Regulation (EU) 2017/745 on medical devices; and".