DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 7

Amendment of primary legislation

Investigatory powers under the Consumer Rights Act 2015

27.—(1) Schedule 5 to the Consumer Rights Act 2015(**1**)(investigatory powers etc) is amended in accordance with this regulation.

(2) In paragraph 8 (interpretation of Schedule 5), after the definition of "online interface order" 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."

(3) In paragraph 10 (enforcer's legislation: duties and powers mentioned in paragraph 9(1)(a)) at the end insert "regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021".

(4) In paragraph 19 (exercise of powers in Part 4), in sub-paragraph (7A)(a)(**2**), for the words from "a breach of" to the end substitute—

"a breach of—

(i) the Medical Devices Regulations 2002 (S.I. 2002/618),

(ii) regulations made under section 15(1) of the Medicines and Medical Devices Act 2021,

(iii) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

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

(5) In paragraph 30A(**3**) (power to decommission or switch off fixed medical devices)—

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

"pursuant to—

(a) the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002 (S.I. 2002/618),

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

(**1**) 2015 c.15.
(**2**) Sub-paragraph (7A) was inserted by section 41(2)(c) of the Medicines and Medical Devices Act 2021 (c.3).
(**3**) Paragraph 30A was inserted by section 41(2)(d) of the Medicines and Medical Devices Act 2021 (c.3).

(b) in sub-paragraph (2), for "medical device to which the Medical Devices Regulations 2002 apply" substitute "relevant medical device";

(c) after sub-paragraph (2), insert—

"(3) In sub-paragraph (2), "relevant medical device" means—

(a) where a domestic enforcer is acting pursuant to a duty mentioned in sub-paragraph (1)(a) or (b), any medical device to which the Medical Devices Regulations 2002 apply;

(b) where a domestic enforcer is acting pursuant to the duty mentioned in sub-paragraph (1)(c), any medical device to which Regulation (EU) 2017/745 on medical devices applies."

Amendment of the Medicines and Medical Devices Act 2021

28.—(1) The Medicines and Medical Devices Act 2021(**4**) is amended in accordance with this regulation.

(2) In section 17 (fees, information, offences), in subsection (2), for "this Part" substitute "this Chapter".

(3) In section 21 (compliance notices), after subsection (1), insert—

"(1A) In this Chapter, "medical devices provision" means a provision in—

(a) regulations under section 15(1),

(b) the Medical Devices Regulations 2002 (S.I. 2002/618),

(c) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

(d) 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."

(4) In section 34 (recovery of expenses of enforcement), in subsection (1)(a), for the words from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002 (S.I. 2002/618) (offence of breaching certain provisions in the Regulations), or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions),

in relation to a medical device, or".

(5) In section 39 (disclosure of information)—

(a) in subsection (10)(a), omit the "or" at the end;

(b) in subsection (10)(b), at the end insert—

", or

(c) contravenes any obligation or restriction created or arising by or under the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement, whether or not an obligation or restriction to which section 7A(2) of the European Union (Withdrawal) Act 2018 applies.".

(**4**) 2021 c.3.

(6) In section 42 (interpretation of Part 4), in subsection (2)—

(a) for the definition of "manufacturer" substitute—

""manufacturer" means any person who is a manufacturer for the purposes of any provision in—

(a) the Medical Devices Regulations 2002 (S.I. 2002/618), or

(b) 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) for the definition of "medical devices provision" substitute—

""medical devices provision"—

(a) in Chapter 1, has the meaning given by section 17(2), and

(b) in Chapter 3, has the meaning given by section 21(1A);".

(7) In Schedule 2 (medical devices: civil sanctions)—

(a) in paragraph 1(1) (imposition of monetary penalty)—

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

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

", or

(c) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions).";

(b) in paragraph 4 (monetary penalties: criminal proceedings and conviction)—

(i) in sub-paragraph (1)(a), from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002, or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,

may be instituted against the person in respect of the act or omission to which the notice relates before the end of the period within which the person's liability may be discharged as mentioned in paragraph 2(2) (see paragraph 3(2)(a));";

(ii) in sub-paragraph (1)(b), from "section 28" to the end substitute "the provisions mentioned in paragraph (a) in relation to that act or omission.";

(iii) in sub-paragraph (2), from "section 28" to the end substitute "any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission giving rise to the penalty.";

(c) paragraph 5 (enforcement undertakings)—

(i) in sub-paragraph (1)(a), from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002, or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,";

(ii) in sub-paragraph (2)(a), from "section 28" to the end substitute "any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission to which the undertaking relates;";

(d) in paragraph 13 (guidance as to enforcement), in sub-paragraph (1)(a), for "or regulation 60A" to the end substitute ", regulation 60A of the Medical Devices Regulations 2002 or regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021;".