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."