Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 4

DISCLOSURE OF INFORMATION AND CONSEQUENTIAL ETC PROVISION

Consequential etc provision

41 Consequential and supplementary provision

(1) In the Consumer Protection Act 1987—

(a) in section 11 (safety regulations), in subsection (7), at the end insert—

"(e) medical devices.";

(b) in section 19 (interpretation of Part 2), in subsection (1), at the appropriate place insert—

""medical device" has the same meaning as in Part 4 of the Medicines and Medical Devices Act 2021;".

(2) In the Consumer Rights Act 2015, in Schedule 5 (investigatory powers etc)—

(a) in paragraph 10 (enforcer's legislation: duties and powers mentioned in paragraph 9(1)(a)), at the appropriate place insert " regulation 61 of the Medical Devices Regulations 2002 (S.I. 2002/618) ";

(b) in the table in paragraph 11 (enforcer's legislation), at the end insert—

"The Secretary of State, a local weights and measures authority in Great Britain or	Regulations made under section 15(1) of the Medicines and Medical Devices Act 2021

a district council in Northern Ireland	
The Secretary of State, a local weights and measures authority in Great Britain or a district council in Northern Ireland	Chapter 3 of Part 4 of the Medicines and Medical Devices Act 2021”;

(c) in paragraph 19 (exercise of powers in Part 4), after sub-paragraph (7) insert—

“(7A) A domestic enforcer may exercise the power in paragraph 30A (power to decommission or switch off fixed medical devices)—

(a) if an officer of the enforcer reasonably suspects a breach of the Medical Devices Regulations 2002 (S.I. 2002/618) or of regulations made under section 15(1) of the Medicines and Medical Devices Act 2021, and

(b) for the purpose of ascertaining (by means of testing or otherwise) whether there has been such a breach.”;

(d) after paragraph 30 insert—

“30A (1) The power in sub-paragraph (2) is available to an officer of a domestic enforcer acting pursuant to the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002 (S.I. 2002/618) or to a duty in regulations made under section 15(1) of the Medicines and Medical Devices Act 2021.

(2) The officer may decommission or switch off any medical device to which the Medical Devices Regulations 2002 apply which is installed at a given location.”;

(e) in paragraph 31 (power to break open container etc)—

(i) in sub-paragraph (1), for “30” substitute “ 30A ”;

(ii) in sub-paragraph (2), for “30” substitute “ 30A ”.

(3) The Medical Devices Regulations 2002 (S.I. 2002/618) are amended in accordance with subsections (4) to (7).

(4) In regulation 2 (interpretation), in paragraph (1) omit the definition of “the 1987 Act”.

(5) Omit regulation 3B (confidentiality).

(6) In regulation 61 (enforcement and the Consumer Protection Act 1987 etc), for paragraphs (1) to (8) substitute—

“(1A) It is the duty of the Secretary of State to enforce these regulations in relation to relevant devices and devices for performance evaluation.

(1B) It is the duty of each weights and measures authority in Great Britain and each district council in Northern Ireland to enforce these regulations within its area (concurrently with the Secretary of State) in relation to relevant devices that are ordinarily intended for private use or consumption.

(1C) Nothing in this regulation authorises a weights and measures authority to bring proceedings in Scotland for an offence.”

(7) Omit—

(a) regulation 62 (compliance notices),

(b) regulation 63 (restriction notices), and

(c) regulation 64 (notification of decisions etc).

(8) As a result of the amendments made by subsections (1), (4), (6) and (7), the Medical Devices Regulations 2002 are not to be recognised as safety regulations for the purposes of the Consumer Protection Act 1987, but those amendments do not otherwise affect the continued operation of those regulations.

(9) Schedule 3 makes it an offence to breach various provisions in the Medical Devices Regulations 2002.

Commencement Information

I1 S. 41(1)-(8) in force at 26.5.2021 by S.I. 2021/610, **reg. 2(c)** (with reg. 3)

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 41.