Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 4

DISCLOSURE OF INFORMATION AND CONSEQUENTIAL ETC PROVISION

Disclosure of information

39 Disclosure of information

(1) This section applies in relation to information which the Secretary of State holds in connection with medical devices.

(2) The Secretary of State may disclose information for the purpose of warning members of the public about concerns that the Secretary of State has in relation to the safety of a medical device.

(3) The Secretary of State may disclose information to a person who provides services or exercises functions relating to medical devices for the purposes of—

(a) enabling or facilitating the exercise by the Secretary of State of a function relating to medical devices;

(b) enabling or facilitating the exercise by another person of a function relating to medical devices;

(c) enabling or facilitating the provision of a service relating to medical devices by another person.

(4) The Secretary of State may disclose information for the purposes of—

(a) civil proceedings;

(b) criminal investigations or proceedings.

(5) The Secretary of State may disclose information to a relevant person outside the United Kingdom where—

(a) the disclosure is required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of medical devices, and

(b) the Secretary of State considers that the disclosure is in the public interest.

(6) But subsection (5) does not authorise a disclosure of patient information without the consent of the individual to whom that information relates.

(7) The Secretary of State may not disclose commercially sensitive information in reliance on subsection (2), (3), (4) or (5) unless the Secretary of State—

(a) considers that it is necessary to do so for one or more of the purposes mentioned in subsection (2), (3), (4) or (5), and

(b) is satisfied that the making of the disclosure is proportionate to what is sought to be achieved by it.

(8) Where information to which this section applies is disclosed to a person in reliance on subsection (3) or (4), the person may not use or further disclose the information except—

(a) with the agreement of the Secretary of State and for a purpose mentioned in subsection (3) or (4), or

(b) in accordance with an enactment or order of a court or tribunal.

(9) Except as provided by subsection (10), the disclosure of information in accordance with this section does not breach—

(a) an obligation of confidence owed by the person making the disclosure, or

(b) any other restriction on the disclosure of the information (however imposed).

(10) Nothing in this section authorises a disclosure of information which—

(a) contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this section), **F1**...

(b) is prohibited by any of Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016 **[**F2, or**]**

[F2(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.**]**

(11) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

(12) In this section—

"commercially sensitive information" means commercial information whose disclosure the Secretary of State thinks might significantly harm the legitimate business interests of the undertaking to which it relates;

"patient information" means information (however recorded) which—

(a) relates to—

(i) the physical or mental health or condition of an individual,

(ii) the diagnosis of an individual's condition, or

(iii) an individual's care or treatment,

or is (to any extent) derived directly or indirectly from information relating to any of those matters, and

(b) identifies the individual or enables the individual to be identified (whether by itself or in combination with other information);

"relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to medical devices in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to medical devices.

Textual Amendments

F1 Word in s. 39(10)(a) omitted (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(5)(a)**

F2 S. 39(10)(c) and word inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(5)(b)**

Commencement Information

I1 S. 39 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(b)**

40 Offences relating to information

(1) A person to whom information is disclosed under section 39 commits an offence if the person uses or discloses that information in contravention of subsection (8) of that section.

(2) A person to whom information is disclosed under regulations under section 19 (information systems) commits an offence if the person uses or discloses that information in contravention of those regulations.

(3) A person guilty of an offence under subsection (1) or (2) is liable—

(a) on summary conviction in England and Wales, to imprisonment for a term not exceeding 51 weeks, to a fine or to both;

(b) on summary conviction in Scotland or Northern Ireland, to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.

(4) In relation to an offence committed before the coming into force of section 281(5) of the Criminal Justice Act 2003, the reference in subsection (3)(a) to 51 weeks is to be read as a reference to 6 months.

Commencement Information

I2 S. 40 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(b)**

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 a district council in Northern Ireland	Regulations made under section 15(1) of the Medicines and Medical Devices Act 2021
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

I3 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, CHAPTER 4.