
Status: This version of this part contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, PART 5. (See end of Document for details)

SCHEDULES

PROSPECTIVE

SCHEDULE 2

MEDICAL DEVICES: CIVIL SANCTIONS

PART 5

GENERAL AND SUPPLEMENTAL

Guidance as to enforcement

- 13 (1) The Secretary of State must prepare and publish guidance as to—
- (a) the sanctions that may be imposed on a person who commits an offence under section 28 [^{F1}, regulation 60A of the Medical Devices Regulations 2002 or regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021;]
 - (b) the action that the Secretary of State may take in relation to such a person;
 - (c) the circumstances in which the Secretary of State is likely to take any such action.
- (2) The guidance must include guidance about the Secretary of State's use of the power to impose a monetary penalty, with information as to—
- (a) the circumstances in which such a penalty may not be imposed;
 - (b) the amount of such a penalty;
 - (c) the matters likely to be taken into account by the Secretary of State in determining that amount (including, where relevant, any discounts for voluntary reporting of non-compliance);
 - (d) how liability for such a penalty may be discharged and the effect of discharge;
 - (e) rights to make representations and objections and rights of appeal in relation to such a penalty.
- (3) The guidance must include guidance about the Secretary of State's use of the power to serve an enforcement costs recovery notice, with information as to—
- (a) the circumstances in which such a notice may not be served;
 - (b) the amount that a person may be required to pay;
 - (c) the matters likely to be taken into account by the Secretary of State in determining that amount;
 - (d) how liability for the costs to which the notice relates may be discharged and the effect of discharge;

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- (e) rights to make representations and objections and rights of appeal in relation to those costs.
- (4) The guidance must include guidance about the Secretary of State's use of the power to accept an enforcement undertaking.
- (5) Where appropriate, the Secretary of State must revise guidance published under this paragraph and publish the revised guidance.
- (6) Before publishing guidance or revised guidance under this paragraph, the Secretary of State must consult—
 - (a) the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland, and
 - (b) any other persons the Secretary of State considers appropriate.
- (7) The Secretary of State must have regard to the guidance or revised guidance published under this paragraph in exercising functions under this Schedule.

Textual Amendments

- F1** Words in [Sch. 2 para. 13\(1\)\(a\)](#) substituted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **28(7)(d)**

Pre-commencement consultation

- 14 If, before the day on which this Schedule comes into force, any consultation was undertaken which, had it been undertaken after that day, would to any extent have satisfied the requirements of section 45 or paragraph 13, those requirements are to that extent to be taken to have been satisfied.

Reports on use of civil sanctions

- 15 (1) The Secretary of State must from time to time publish reports about the use made by the Secretary of State of powers under this Schedule.
- (2) Each report must, in particular, specify—
- (a) the cases in which a monetary penalty was imposed, or an enforcement costs recovery notice was served, during the period to which the report relates (other than cases in which the penalty or notice was overturned on appeal);
 - (b) the cases in which liability for a monetary penalty was discharged as mentioned in paragraph 2(2);
 - (c) the cases in which an enforcement undertaking was accepted.
- (3) This paragraph does not require the Secretary of State to include in a report any information which, in the Secretary of State's opinion, it would be inappropriate to include on the ground that doing so—
- (a) would or might be unlawful, or
 - (b) might adversely affect any current investigation or proceedings.

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Disclosure of information

- 16 (1) Information may be disclosed to the Secretary of State for the purpose of the exercise by the Secretary of State of any powers conferred on the Secretary of State under or by virtue of this Schedule if the information is held by or on behalf of—
- (a) a police officer or an officer of Revenue and Customs,
 - (b) the Crown Prosecution Service,
 - (c) a procurator fiscal, or
 - (d) the Public Prosecution Service for Northern Ireland.
- (2) It does not matter for the purposes of sub-paragraph (1) whether the information was obtained before or after this Schedule comes into force.
- (3) Subject to sub-paragraphs (4) and (5), the disclosure of information under this paragraph is not to be taken to breach any restriction on the disclosure of information (however imposed).
- (4) Nothing in this paragraph authorises a disclosure of information which would contravene the data protection legislation (but in determining whether a disclosure would do so, take into account the power conferred by this paragraph).
- (5) Nothing in this paragraph authorises a disclosure of information which would contravene Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016.
- (6) This paragraph does not affect a power to disclose information that exists apart from this paragraph.

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