
Status: This version of this cross heading contains provisions that are prospective.
Changes to legislation: There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Cross Heading: Guidance as to enforcement. (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)**

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