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;

(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)**

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, Paragraph 13.