

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 4. (See end of Document for details)

SCHEDULES

PROSPECTIVE

SCHEDULE 2

MEDICAL DEVICES: CIVIL SANCTIONS

PART 4

POWER TO MAKE SUPPLEMENTARY PROVISION ETC BY REGULATIONS

Supplementary regulations: general

- 9 (1) The Secretary of State may by regulations (“supplementary regulations”)—
- (a) make provision specified in paragraphs 10 to 12 supplementing that made by this Schedule;
 - (b) make provision that is consequential on or incidental to that made by this Schedule;
 - (c) make transitional, transitory or saving provision in relation to earlier supplementary regulations.
- (2) Regulations made under sub-paragraph (1) may—
- (a) make different provision for different purposes;
 - (b) make different provision for different areas;
 - (c) make provision for all cases to which the power applies or for those cases subject to specified exceptions or for any specified cases or descriptions of case.

Monetary penalties and costs

- 10 (1) Supplementary regulations may make provision of any of the following sorts in relation to the power of the Secretary of State to impose a monetary penalty under paragraph 1 or costs under paragraph 6—
- (a) provision for early payment discounts;
 - (b) provision for the payment of interest or other financial penalties for late payment;
 - (c) provision for enforcement.
- (2) Provision made by virtue of sub-paragraph (1)(b) must secure that the interest or other financial penalties for late payment do not in total exceed the amount of the penalty or costs to which the interest or other financial penalties relate.
- (3) Provision made by virtue of sub-paragraph (1)(c) may include—

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- (a) provision for the Secretary of State to recover the penalty or costs, and any interest or other financial penalty for late payment, as a civil debt;
- (b) provision for the penalty or costs, and any interest or other financial penalty for late payment, to be recoverable, on the order of a court, as if payable under a court order.

Enforcement undertakings

- 11 Supplementary regulations may make provision of any of the following sorts in relation to an enforcement undertaking—
- (a) provision as to the procedure for entering into an undertaking;
 - (b) provision as to the terms of an undertaking;
 - (c) provision as to publication of an undertaking by the Secretary of State;
 - (d) provision as to variation of an undertaking;
 - (e) provision as to circumstances in which a person may be regarded as having complied with an undertaking;
 - (f) provision as to monitoring by the Secretary of State of compliance with an undertaking;
 - (g) provision as to certification by the Secretary of State that an undertaking has been complied with;
 - (h) provision for appeals against refusal to give such certification;
 - (i) in a case where a person has given inaccurate, misleading or incomplete information in relation to an undertaking, provision for the person to be regarded as not having complied with it;
 - (j) in a case where a person has complied partly but not fully with an undertaking, provision for that part-compliance to be taken into account in the imposition of any criminal or other sanction on the person.

Appeals

- 12 (1) Supplementary regulations may make provision of any of the following sorts in relation to an appeal in respect of the imposition of a requirement or the service of a notice under this Schedule—
- (a) provision suspending the requirement or notice pending determination of the appeal (and providing for time during which the requirement or notice is suspended not to be taken into account in calculating any period of time relating to the requirement or notice);
 - (b) provision as to the powers of the tribunal to which the appeal is made.
- (2) Provision made by virtue of sub-paragraph (1)(b) may (among other things) include provision conferring on the tribunal to which the appeal is made—
- (a) power to withdraw the requirement or notice;
 - (b) power to confirm the requirement or notice;
 - (c) power to take any steps that the Secretary of State could take in relation to the act or omission giving rise to the requirement or notice;
 - (d) power to remit the decision whether to confirm the requirement or notice, or any matter relating to that decision, to the Secretary of State.

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