

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 1. (See end of Document for details)

SCHEDULES

PROSPECTIVE

SCHEDULE 2

MEDICAL DEVICES: CIVIL SANCTIONS

PART 1

MONETARY PENALTIES

Imposition of monetary penalty

- 1 (1) The Secretary of State may impose a monetary penalty on a person if satisfied beyond reasonable doubt that the person has committed an offence under—
- (a) section 28 (offence of breaching enforcement notice), ^{F1}...
 - (b) regulation 60A of the Medical Devices Regulations 2002 (S.I. 2002/618) (offence of breaching certain provisions in the Regulations) [^{F2}, or]
 - [^{F2}(c) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions).]
- (2) In this Schedule “monetary penalty” means a requirement to pay to the Secretary of State a penalty of an amount determined by the Secretary of State.

Textual Amendments

- F1** Word in Sch. 2 para. 1(1)(a) omitted (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **28(7)(a)(i)**
- F2** Sch. 2 para. 1(1)(c) and word inserted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **28(7)(a)(ii)**

Notices, representations and appeals etc

- 2 (1) Where the Secretary of State proposes to impose a monetary penalty on a person, the Secretary of State must serve on the person a notice of what is proposed.
- (2) A notice under sub-paragraph (1) must offer the person the opportunity to avoid liability in relation to a monetary penalty by payment of a sum specified in the notice (which must be less than or equal to the amount of the penalty).
- (3) The person may make written representations and objections to the Secretary of State in relation to the proposed imposition of the monetary penalty.

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 1. (See end of Document for details)

- (4) After the end of the period for making such representations and objections (see paragraph 3(2)) the Secretary of State must decide whether to serve on the person a notice imposing the monetary penalty.
- (5) The Secretary of State may not impose a monetary penalty on a person if the Secretary of State is no longer satisfied as mentioned in paragraph 1(1).
- (6) A person on whom a monetary penalty is imposed may appeal against the decision to impose the penalty on the ground—
 - (a) that the decision was based on an error of fact,
 - (b) that the decision was wrong in law,
 - (c) that the amount of the penalty is unreasonable, or
 - (d) that the decision is unfair, unreasonable or wrong for any other reason.
- (7) An appeal under sub-paragraph (6) is to the First-tier Tribunal.
- (8) Where an appeal is on the ground that the appellant did not commit an offence as mentioned in paragraph 1(1), the Tribunal must allow the appeal unless satisfied beyond reasonable doubt that the appellant committed the offence in question, according to the same burden of proof as would apply if the Secretary of State were seeking to prove the matter in a criminal prosecution.

Information to be included in notices under paragraph 2

- 3 (1) A notice under paragraph 2(1) must include information as to—
 - (a) the grounds for the proposal to impose the monetary penalty;
 - (b) the effect of payment of the sum referred to in paragraph 2(2);
 - (c) the right to make representations and objections;
 - (d) the circumstances in which the Secretary of State may not impose the monetary penalty.
- (2) A notice under paragraph 2(1) must also specify—
 - (a) the period within which payment may be made so as to avoid liability for a monetary penalty, and
 - (b) the period within which representations and objections may be made.

Neither period may be more than 28 days beginning with the day on which the notice is served.
- (3) A notice under paragraph 2(4) imposing a monetary penalty must include information as to—
 - (a) the grounds for imposing the monetary penalty;
 - (b) how payment may be made;
 - (c) the period within which payment is to be made;
 - (d) any early payment discounts or late payment penalties (including interest on payments);
 - (e) rights of appeal;
 - (f) the consequences of non-payment.

The period referred to in paragraph (c) must be at least 28 days beginning with the day on which the notice is served.

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 1. (See end of Document for details)

Monetary penalties: criminal proceedings and conviction

- 4 (1) Where a notice under paragraph 2(1) is served on a person—
- (a) no criminal proceedings for an ^{F3}offence under—
 - (i) section 28,
 - (ii) regulation 60A of the Medical Devices Regulations 2002, or
 - (iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,]may be instituted against the person in respect of the act or omission to which the notice relates before the end of the period within which the person’s liability may be discharged as mentioned in paragraph 2(2) (see paragraph 3(2)(a));
 - (b) if the liability is so discharged, the person may not at any time be convicted of an offence under ^{F4}the provisions mentioned in paragraph (a) in relation to that act or omission.]
- (2) A person on whom a monetary penalty is imposed may not at any time be convicted of an offence under ^{F5}any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission giving rise to the penalty.]

Textual Amendments

- F3** Words in Sch. 2 para. 4(1)(a) substituted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **28(7)(b)(i)**
- F4** Words in Sch. 2 para. 4(1)(b) substituted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **28(7)(b)(ii)**
- F5** Words in Sch. 2 para. 4(2) substituted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **28(7)(b)(iii)**

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 1.