VALID FROM 11/04/2021

# SCHEDULES

## SCHEDULE 1

Section 1

### FURTHER PROVISION ABOUT THE COMMISSIONER FOR PATIENT SAFETY

*Principles relating to core duties*

1 (1) The Commissioner must prepare and publish a set of principles to govern the way in which the Commissioner will carry out the Commissioner's core duties.

(2) The Commissioner—

(a) may revise the principles, and

(b) must publish any revised version.

(3) The Commissioner must carry out a public consultation in preparing or revising the principles.

*Involvement of patients*

2 (1) The Commissioner must take reasonable steps to involve patients in the discharge of the Commissioner's core duties.

(2) The Commissioner must in particular take reasonable steps to—

(a) ensure that patients are aware of the Commissioner's core duties and of how they may communicate with the Commissioner, and

(b) consult patients, or persons who appear to the Commissioner to represent the interests of patients, on matters which the Commissioner proposes to consider in the discharge of the core duties.

*Supplementary functions and information*

3 (1) For the purposes of carrying out the core duties, the Commissioner may—

(a) make a report or recommendation to a relevant person;

(b) consult or receive information from patients or any other person the Commissioner thinks appropriate;

(c) request information from a relevant person;

(d) share information with a relevant person.

(2) A relevant person to whom a report or recommendation is made under sub-paragraph (1)(a) must provide a response to that report or recommendation within such period as the Commissioner may reasonably require.

(3) A relevant person must, so far as reasonably practicable, comply with a request by the Commissioner to provide information within such period as the Commissioner may reasonably require.

(4) Nothing in this Schedule authorises a disclosure of information which contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this Schedule).

(5) In this paragraph—

"data protection legislation" has the meaning given by section 3(9) of the Data Protection Act 2018;

"health care" means all forms of health care provided for individuals, whether relating to physical or mental health, and including ancillary care;

"relevant person" means—

(a) a person who exercises functions of a public nature, relating to medicines or medical devices, so far as those functions are exercisable in relation to England;

(b) any other person who, in the course of providing health care, provides services relating to medicines or medical devices in relation to England.

*Individual cases*

4 (1) The Commissioner may not exercise functions in relation to an individual case.

(2) But sub-paragraph (1) does not prevent the Commissioner considering individual cases and drawing conclusions about them for the purpose of, or in the context of, considering a general issue.

*Amendments to primary legislation*

5 (1) In Part 1 of the Table at the end of paragraph 3 of Schedule 1 to the Public Records Act 1958 (definition of public records), at the appropriate place insert— " Commissioner for Patient Safety. "

(2) In Part 3 of Schedule 1 to the House of Commons Disqualification Act 1975 (offices disqualifying for membership), at the appropriate place insert— " Commissioner for Patient Safety. "

(3) In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (other public bodies and offices: general), at the appropriate place insert— " The Commissioner for Patient Safety. "

(4) In section 71 of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc of certain health service bodies), in subsection (2), before paragraph (h) insert—

"(ga) the Commissioner for Patient Safety,".

(5) In Part 1 of Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty), in the group of entries under the heading "Health, social care and social security", at the appropriate place insert— " The Commissioner for Patient Safety. "

*Regulations about appointment and operation*

6 (1) The Secretary of State may by regulations make such provision as the Secretary of State considers appropriate with regard to the appointment and operation of the Commissioner.

(2) Regulations under sub-paragraph (1) may (among other things) contain provision for and about—

(a) the Commissioner's terms of office;

(b) remuneration or other benefits;

(c) the provision of financial or other assistance, including staff, accommodation, equipment or other facilities, for the Commissioner;

(d) requirements to prepare business plans;

(e) requirements to prepare reports;

(f) requirements to lay documents before Parliament;

(g) requirements to provide documents to the Secretary of State or other persons specified in the regulations;

(h) the conferring of functions on other persons in relation to the Commissioner;

(i) the appointment of a board to provide advice to the Commissioner.

PROSPECTIVE

## SCHEDULE 2

Section 31

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.

(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.

*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 **[**F3offence 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 **[**F4the 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 **[**F5any 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)**

## PART 2

ENFORCEMENT UNDERTAKINGS

5 (1) This paragraph applies where—

(a) the Secretary of State has reasonable grounds to suspect that a person has committed an **[**F6offence under— section 28 or regulation 60A of the Medical Devices Regulations 2002,

(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,**]**

(b) the person offers an undertaking (an "enforcement undertaking") to take specified action within a specified period,

(c) the action specified is—

(i) action to secure that the offence does not continue or recur, or

(ii) action of a description set out in supplementary regulations (see Part 4 of this Schedule), and

(d) the Secretary of State accepts the undertaking.

(2) Unless the person fails to comply with the undertaking or any part of it—

(a) the person may not at any time be convicted of an offence under **[**F7any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission to which the undertaking relates;**]**

(b) the Secretary of State may not impose on the person any monetary penalty that the Secretary of State would otherwise have power to impose by virtue of paragraph 1 in respect of that act or omission.

**Textual Amendments**

**F6** Words in Sch. 2 para. 5(1)(a) substituted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(7)(c)(i)**

**F7** Words in Sch. 2 para. 5(2)(a) substituted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(7)(c)(ii)**

## PART 3

ENFORCEMENT COSTS RECOVERY NOTICES

*Imposition of enforcement costs recovery notices*

6 (1) The Secretary of State may serve an enforcement costs recovery notice on a person on whom a monetary penalty has been imposed.

(2) For the purposes of this Schedule an "enforcement costs recovery notice" is a notice requiring the person to pay to the Secretary of State the costs incurred by the Secretary of State in relation to the monetary penalty up to the time when it was imposed.

(3) In sub-paragraph (2), "costs" includes (in particular)—

(a) investigations costs;
(b) administration costs;
(c) costs of obtaining expert advice (including legal advice).

*Information to be included in enforcement costs recovery notices*

7 (1) An enforcement costs recovery notice must specify the amount to be paid and must include information as to—
(a) the grounds for serving the notice;
(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;
(e) rights to make written representations and objections in relation to the enforcement costs recovery notice;
(f) rights of appeal;
(g) 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 enforcement costs recovery notice is served.

(2) A person required by an enforcement costs recovery notice to pay an amount to the Secretary of State may require the Secretary of State to provide a detailed breakdown of that amount.

*Appeals*

8 (1) A person served with an enforcement costs recovery notice may appeal against the decision to serve it 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 decision was unreasonable, or
(d) that any of the costs to which the notice relates were unreasonably incurred or unreasonable in amount,

or on any other grounds that are set out in supplementary regulations (see Part 4 of this Schedule).

(2) An appeal under sub-paragraph (1) is to the First-tier Tribunal.

## 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—

(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.

## 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 **[**[F8], 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**

**F8** 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.

*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.

## PART 6

INTERPRETATION

17 In this Schedule—

"enforcement costs recovery notice" has the meaning given by paragraph 6(2);

"enforcement undertaking" has the meaning given by paragraph 5(1)(b);

"monetary penalty" has the meaning given by paragraph 1(2);

"supplementary regulations" has the meaning given by paragraph 9.

PROSPECTIVE

## SCHEDULE 3

Section 41

OFFENCE OF BREACHING PROVISIONS IN THE MEDICAL DEVICES REGULATIONS 2002

### PART 1

OFFENCE

1 In the Medical Devices Regulations 2002 (S.I. 2002/618), after regulation 60 insert—

*"Offence of breaching certain provisions*

60A (1) A person commits an offence if the person contravenes a prohibition or fails to comply with a requirement in a provision of the regulations listed in the Schedule to these Regulations inserted by Schedule 3 to the Medicines and Medical Devices Act 2021.

(2) A person guilty of an offence under paragraph (1) is liable—

(a) on summary conviction in England and Wales, to imprisonment for a term not exceeding 51 weeks, to a fine or to both;

(b) on summary conviction in Scotland or Northern Ireland, to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.

(3) In respect of an offence under this regulation—

(a) a magistrates' court in England and Wales may try an information laid before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed;

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed;

(c) in Scotland, summary proceedings for the offence may be commenced before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks

is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed.

(4) For the purposes of paragraph (3)(a)(i), (b)(i) and (c)(i)—

(a) a certificate signed by or on behalf of the prosecutor and stating the date on which such evidence came to the prosecutor's knowledge is conclusive evidence of that fact, and

(b) a certificate stating that matter and purporting to be so signed is to be treated as so signed until the contrary is proved.

(5) In relation to an offence committed before the coming into force of section 281(5) of the Criminal Justice Act 2003, the reference in paragraph (2)(a) to 51 weeks is to be read as a reference to 6 months.

*Defence of due diligence*

60B (1) It is a defence for a person charged with an offence under regulation 60A(1) to show that the person took all reasonable steps and exercised all due diligence to avoid commission of the offence.

(2) If in any proceedings for such an offence the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

(a) an act or default of another person, or

(b) reliance on information given by another person,

the defendant is not, without leave of the court, entitled to rely on that defence unless the requirement in paragraph (3) is satisfied.

(3) The requirement is that at least 7 clear days before the hearing of the proceedings the defendant has served on the prosecutor a notice giving such information identifying or assisting in the identification of that other person as was then in the defendant's possession.

(4) A defendant is not entitled to rely on the defence provided by paragraph (1) by reason of the defendant's reliance on information supplied by another person unless the defendant shows that it was reasonable in all the circumstances to rely on the information, having regard in particular to—

(a) the steps which the defendant took or might reasonably have taken to verify the information, and

(b) whether the defendant had any reason to disbelieve the information.

(5) In the application of this regulation to Scotland—

(a) references to the defendant are to be read as references to the accused, and

(b) the reference in paragraph (3) to "the hearing of the proceedings" is to be read as a reference to "the trial diet".

*Offences by bodies corporate*

60C (1) Where an offence under regulation 60A(1) committed by a body corporate or a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, an officer, the officer (as well as the body corporate or partnership) commits the offence and is liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate, "officer" means—

(a) a director, manager, secretary or other similar officer of the body, or

(b) a person purporting to act in any such capacity.

(3) In paragraph (2)(a), "director", in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(4) In relation to a Scottish partnership, "officer" means—

(a) a partner, or

(b) a person purporting to act as a partner."

**PART 2**

PROVISIONS

2 In the Medical Devices Regulations 2002 (S.I. 2002/618), after the last Schedule insert, with the appropriate number, the following Schedule—

"SCHEDULE Regulation 60A

PROVISIONS BREACH OF WHICH IS AN OFFENCE UNDER REGULATION 60A

The regulations referred to in regulation 60A(1) are—

| ***Regulation*** | ***Description*** |
|---|---|
| 8(1), (2) | Essential requirements for general medical devices |
| 10(1) to (5) | CE marking of general medical devices |
| 11 | CE marking of general medical devices within scope of more than one Directive |
| 13(1) to (4) | Procedures for affixing a CE marking to general medical devices |
| 14(1), (2), (5) | Procedures for systems and procedure packs, and for devices to be sterilised before use |
| 15 | Procedures for custom-made general medical devices |
| 16(1), (4), (7), (10) | Procedures for general medical devices for clinical investigation |

| | |
|---|---|
| 17(1), (2) | Manufacturers etc and conformity assessment procedures for general medical devices |
| 19 | Registration of persons placing general medical devices on the market |
| 22 | Essential requirements for active implantable medical devices |
| 24 | CE marking of active implantable medical devices |
| 25 | CE marking of active implantable medical devices within scope of more than one Directive |
| 27 | Procedures for affixing a CE marking to active implantable medical devices |
| 28 | Procedures for custom-made active implantable medical devices |
| 29(1), (3), (6), (7), (9) | Procedures for active implantable medical devices for clinical investigations |
| 30(1) | Manufacturers etc and conformity assessment procedures for active implantable medical devices |
| 34 | Essential requirements for in vitro diagnostic medical devices |
| 36(1) to (5) | CE marking of in vitro diagnostic medical devices |
| 37 | CE marking of in vitro diagnostic medical devices within scope of more than one Directive |
| 38 | In vitro diagnostic medical devices not ready for use |
| 40 | Procedures for affixing a CE marking to in vitro diagnostic medical devices |
| 41(1), (2), (3) | Manufacturers etc and conformity assessment procedures for in vitro diagnostic medical devices |
| 43 | Devices for performance evaluation |
| 44 | Registration of manufacturers etc of in vitro diagnostic medical devices and devices for performance evaluation |
| 50(1)(a) and (b), (2), (3) | Products incorrectly marked with a notified body or conformity assessment body number |
| 51(1), (2) | Products incorrectly marked with a CE marking” |

**Status:**
Point in time view as at 11/02/2021.

**Changes to legislation:**
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021.