SCHEDULES

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:
This version of this schedule contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, SCHEDULE 3.