Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 3

ENFORCEMENT

Enforcement notices

21 Compliance notices

(1) This section applies where the enforcement authority has reasonable grounds to suspect that a person involved in marketing or supplying a medical device is not complying with a medical devices provision.

[[F1](1A) In this Chapter, "medical devices provision" means a provision in—

(a) regulations under section 15(1),

(b) the Medical Devices Regulations 2002 (S.I. 2002/618),

(c) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

(d) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.**]**

(2) The enforcement authority may serve a notice ("a compliance notice") on the person—

(a) identifying the medical devices provision with which the person is suspected not to be complying,

(b) setting out the enforcement authority's grounds for suspecting that the person is not complying with the provision,

(c) requiring the person to comply with the provision within a specified period,

(d) requiring the person within a specified period to provide evidence to the satisfaction of the enforcement authority that the person is complying with the provision, and

(e) requiring the person within a specified period to take any other measures that may be specified in order to comply with the provision.

(3) A period specified in reliance on subsection (2)(c), (d) or (e) must be a period of at least 28 days beginning with the day on which the notice is served.

(4) The enforcement authority may vary or revoke a compliance notice.

(5) Where the person mentioned in subsection (1) is a manufacturer, a notice under subsection (2) may be served on the manufacturer or on another person who has been designated by the manufacturer to act as the manufacturer's representative (or both).

(6) In this section, "specified" means specified in the compliance notice.

Textual Amendments

F1 S. 21(1A) inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(3)**

Commencement Information

I1 S. 21 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

22 Suspension notices

(1) This section applies where the enforcement authority considers that it may be necessary to restrict the availability of a medical device in order to protect health or safety.

(2) The enforcement authority may serve on a person a notice ("a suspension notice") prohibiting the person from doing the following except with the consent of the enforcement authority—

(a) supplying the medical device;

(b) offering to supply it;

(c) agreeing to supply it;

(d) exposing it for supply;

(e) possessing it for supply.

(3) A suspension notice must—

(a) set out the enforcement authority's grounds for considering that it may be necessary to restrict the availability of the medical device to which the notice relates, and

(b) specify the period for which the notice has effect.

(4) The period may not end more than 6 months after the day on which the suspension notice is served.

(5) The enforcement authority may—

(a) reduce the period for which a suspension notice has effect, or

(b) revoke a suspension notice.

Commencement Information

I2 S. 22 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

23 Safety notices

(1) The enforcement authority may serve on a person a notice ("a safety notice") imposing on the person prohibitions or requirements that the enforcement authority considers necessary to restrict the availability of a medical device in order to protect health or safety.

(2) The prohibitions that may be imposed include prohibitions on doing any of the following except with the consent of the enforcement authority—

(a) supplying the medical device;

(b) offering to supply it;

(c) agreeing to supply it;

(d) exposing it for supply;

(e) possessing it for supply.

(3) The requirements that may be imposed include requirements to—

(a) publish, at the person's expense, one or more warnings, in such form and manner and on such occasions as may be specified in the notice, about a medical device which the person supplies or has supplied;

(b) organise or cooperate with the enforcement authority in organising in such manner as may be specified in the notice, so far as reasonably practicable, the recall of the device to the person or to any other person identified in the notice.

(4) But a requirement to organise or cooperate in the recall of a device may be imposed on a person in reliance on subsection (3)(b) only if the enforcement authority is satisfied that no alternative requirement would sufficiently protect health or safety as mentioned in subsection (1).

(5) A safety notice must set out the grounds on which the enforcement authority considers it necessary to restrict the availability of the medical device to which the notice relates.

(6) The enforcement authority may vary or revoke a safety notice.

(7) Subject to subsection (8), the enforcement authority may not serve a safety notice on a person or vary a safety notice unless the enforcement authority has given the person a reasonable opportunity to make representations about the need for, and the contents of, the proposed safety notice or, as the case may be, proposed variation.

(8) Subsection (7) does not apply where the enforcement authority considers that there is an urgent need to make the proposed safety notice or variation in order to restrict the availability of the medical device to which the proposed safety notice or variation relates.

Commencement Information

I3 S. 23 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

24 Information notices

(1) This section applies where the enforcement authority considers that a person has information which the enforcement authority needs for the purpose of deciding whether to—

(a) serve or revoke a compliance notice,

(b) serve or revoke a suspension notice, or

(c) serve, vary or revoke a safety notice.

(2) The enforcement authority may serve on the person a notice (an "information notice") requiring the person—

(a) to disclose to the enforcement authority information specified in the notice, within a period specified in the notice, or

(b) to produce records specified in the notice at a time and place specified in the notice, and to permit a person appointed by the enforcement authority to take copies of the records at that time and place.

(3) A period specified in reliance on subsection (2)(a) must be a period of at least 28 days beginning with the day on which the notice is served.

(4) A time specified in reliance on subsection (2)(b) must be at least 28 days after the notice is served.

(5) The enforcement authority may vary or revoke an information notice.

Commencement Information

I4 S. 24 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

25 Applications to set notices aside etc

(1) A person affected by a compliance, suspension or safety notice may apply to the appropriate lower court (see section 42)—

(a) to set the notice aside, or

(b) to vary it.

(2) A person on whom an information notice has been served may apply to the appropriate lower court—

(a) to set the notice aside, or

(b) to vary it as mentioned in subsection (8).

(3) An application under subsection (1) or (2) must be made within the period of 28 days beginning with the day on which the notice to which it relates is—

(a) served, or

(b) varied by the enforcement authority.

(4) The appropriate lower court may set aside a compliance, suspension, safety or information notice only if satisfied—

(a) in respect of a compliance notice, that the person on whom the notice was served is complying with each medical devices provision with which the person was suspected not to be complying,

(b) in respect of a suspension notice, that the notice is not necessary to protect health or safety,

(c) in respect of a safety notice, that the prohibitions or requirements in the notice are not necessary to protect health or safety, or

(d) in respect of an information notice, that the person on whom it has been served does not have the information or records specified in the notice.

(5) The appropriate lower court may vary a compliance notice so that it does not apply in relation to a medical devices provision specified in the notice if satisfied that the person on whom the notice was served is complying with that provision.

(6) The appropriate lower court may vary a suspension notice by reducing the period for which it is to have effect if satisfied that the period for which it would otherwise have had effect was too long.

(7) The appropriate lower court may vary a safety notice by removing a prohibition or requirement if satisfied that the prohibition or requirement is not necessary to protect health or safety.

(8) The appropriate lower court may vary an information notice so that it does not apply in relation to some of the information or records specified in the notice if satisfied that the person on whom it was served does not have that information or those records.

(9) An order of the appropriate lower court varying or setting aside a compliance, suspension, safety or information notice may contain provision delaying the coming into force of the order pending the making and determination of an appeal under section 27.

Commencement Information
I5 S. 25 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

26 Compensation

(1) A person affected by a compliance, suspension or safety notice which the appropriate lower court varies or sets aside may apply to the appropriate lower court for an order requiring the enforcement authority to pay compensation in respect of loss or damage caused by reason of the notice.

(2) An application under subsection (1) may be made at the same time as an application under section 25(1).

Commencement Information
I6 S. 26 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

27 Further appeals

(1) A person aggrieved by a decision of the appropriate lower court on an application under section 25(1) or (2) or section 26(1) may appeal against that decision to the appropriate appeals court (see section 42).

(2) An appeal under subsection (1) must be made before the end of the period of 28 days beginning with the day on which the decision to which it relates is made.

(3) The appropriate appeals court may make any order the court thinks appropriate.

Commencement Information
I7 S. 27 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

Offences

28 Offences

(1) A person commits an offence if the person breaches—
- (a) a compliance notice,
- (b) a suspension notice,
- (c) a safety notice, or
- (d) an information notice.

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

Commencement Information
I8 S. 28 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

29 Defence of due diligence

(1) It is a defence for a person charged with an offence under section 28(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 subsection (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 subsection (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 subsection (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 section to Scotland—

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

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

Commencement Information

I9 S. 29 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

30 Offences by bodies corporate

(1) Where an offence under section 28 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 subsection (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.

Commencement Information

I10 S. 30 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

PROSPECTIVE

Civil sanctions

31 Civil sanctions

Schedule 2 makes provision for and relating to civil sanctions in relation to the commission of offences to do with medical devices.

Forfeiture

32 Forfeiture of medical devices

(1) The enforcement authority may apply to the appropriate lower court (see section 42) for an order for the forfeiture of a medical device (a "forfeiture order") on the grounds that there has been a contravention of a medical devices provision in relation to the device.

(2) The appropriate lower court may make a forfeiture order if satisfied that there has been such a contravention.

(3) The enforcement authority must make reasonable efforts to give notice of the application to every person who the enforcement authority thinks is or may be entitled to the device to which the application relates.

(4) Each person claiming to be entitled to the device may—
- (a) appear at the hearing of the application, or
- (b) make written representations to the appropriate lower court in relation to the application.

(5) If the appropriate lower court decides to make a forfeiture order, the court may include in the order provision that the device to which the order relates is not to be forfeited before the appropriate time.

(6) The enforcement authority may dispose of a forfeited device in whatever way the enforcement authority thinks appropriate.

(7) But the enforcement authority may not dispose of a forfeited device before the appropriate time.

(8) In this section, the "appropriate time" is—
- (a) the end of the period within which an appeal under section 33 may be made against the order, or
- (b) if such an appeal is made, the end of the day on which the appeal is finally determined or otherwise disposed of.

(9) In this section, persons "entitled to a device" are—
- (a) if the device has not been seized by the enforcement authority, the person in possession of the device,
- (b) if the device has been seized, the person from whom it was seized, or
- (c) if different, any person to whom it belongs.

Commencement Information

I11 S. 32 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

33 Appeals against forfeiture decisions

(1) A person claiming to be entitled to a medical device which is subject to a forfeiture order may appeal against the decision to make the order.

(2) The enforcement authority may appeal against a decision of the appropriate lower court to refuse an application for a forfeiture order.

(3) An appeal under this section is to the appropriate appeals court (see section 42).

(4) An appeal under this section must be made before the end of the period of 28 days beginning with the day on which—

(a) the forfeiture order is made, or

(b) the application for a forfeiture order is refused.

(5) Subject to subsection (6), the court hearing the appeal may make any order the court thinks appropriate.

(6) If an appeal against a decision to make a forfeiture order is allowed, the court must, if the device to which the order relates has already been forfeited, order it to be returned to a person entitled to it.

(7) In this section, persons "entitled to a device" are—

(a) if the device has not been seized by the enforcement authority, the person in possession of the device,

(b) if the device has been seized, the person from whom it was seized, or

(c) if different, any person to whom it belongs.

Commencement Information

I12 S. 33 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

Recovery of expenses of enforcement

34 Recovery of expenses of enforcement

(1) This section applies where a court—

(a) convicts a person of an **[**F2offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002 (S.I. 2002/618) (offence of breaching certain provisions in the Regulations), or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions),

in relation to a medical device, or**]**

(b) makes a forfeiture order under section 32 or 33(5) in relation to a medical device.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person convicted or, as the case may be, a person from whom a device is seized or to whom it belongs to reimburse an enforcement authority for any expenditure which the authority has incurred or may incur—

(a) in connection with any seizure or detention of the device by or on behalf of the authority, or

(b) in connection with giving effect to the forfeiture order.

Textual Amendments

F2 Words in s. 34(1)(a) substituted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(4)**

Commencement Information

I13 S. 34 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

Recall of medical device by enforcement authority

35 Recall of medical device by enforcement authority

(1) This section applies where the enforcement authority considers that—

(a) it is necessary to restrict the availability of a medical device in order to protect health or safety, and

(b) the device has already been supplied or made available to members of the public.

(2) The authority may take such steps as it considers necessary to organise the return of the device to the authority or to another person (whether or not it issues a safety notice under section 23 requiring another person to organise or cooperate in organising the recall of the device).

(3) The authority may take steps in reliance on subsection (2) only if satisfied that no alternative steps that did not involve recalling the device would sufficiently protect health or safety as mentioned in subsection (1).

Commencement Information

I14 S. 35 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

Power of officer of Revenue and Customs to detain medical device

36 Power of officer of Revenue and Customs to detain medical device

(1) An officer of Revenue and Customs may seize an imported medical device and detain it for not more than two working days in order to facilitate the exercise by an enforcement authority or an officer of an enforcement authority of a function under—

(a) this Part,

(b) a medical devices provision, or

(c) Schedule 5 to the Consumer Rights Act 2015.

(2) A device seized and detained under this section must be dealt with during the period of its detention in such manner as the Commissioners for Her Majesty's Revenue and Customs may direct.

(3) In subsection (1), the reference to two working days is a reference to a period of 48 hours calculated from the time when the device in question is seized but disregarding so much of any period as falls on a Saturday or Sunday or on Christmas Day, Good Friday or a day which is a bank holiday under the Banking and Financial Dealings Act 1971 in the part of the United Kingdom where the device is seized.

Commencement Information

I15 S. 36 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

37 Offence of obstructing an officer of Revenue and Customs

(1) A person commits an offence if the person intentionally obstructs an officer of Revenue and Customs who is acting under section 36.

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

Commencement Information

I16 S. 37 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

Civil proceedings

38 Civil proceedings

(1) An obligation imposed by a medical devices provision is to be treated as a duty owed to any person who may be affected by a breach of the obligation.

(2) Accordingly, a breach of such an obligation gives rise to a right of action for breach of statutory duty.

(3) Subsections (1) and (2) are subject to—

(a) a provision to the contrary in a medical devices provision, and

(b) the defences and other incidents applying to actions for breach of statutory duty.

Commencement Information

I17 S. 38 in force at 26.5.2021 by S.I. 2021/610, **reg. 2(a)**

Status:
This version of this chapter contains provisions that are prospective.

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