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)**

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Cross Heading: Enforcement notices.