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)**

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 21.