

# Medicines and Medical Devices Act 2021

# **2021 CHAPTER 3**

## PART 4

MEDICAL DEVICES

## **CHAPTER 3**

### ENFORCEMENT

#### Enforcement notices

### 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—

*Changes to legislation:* There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 25. (See end of Document for details)

- (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**

II S. 25 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 25.