Status: This version of this cross heading contains provisions that are prospective. Changes to legislation: There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Cross Heading: Enforcement undertakings. (See end of Document for details)

# SCHEDULES

PROSPECTIVE

### SCHEDULE 2

## MEDICAL DEVICES: CIVIL SANCTIONS

## PART 4

#### POWER TO MAKE SUPPLEMENTARY PROVISION ETC BY REGULATIONS

# Enforcement undertakings

11 Supplementary regulations may make provision of any of the following sorts in relation to an enforcement undertaking—

- (a) provision as to the procedure for entering into an undertaking;
- (b) provision as to the terms of an undertaking;
- (c) provision as to publication of an undertaking by the Secretary of State;
- (d) provision as to variation of an undertaking;
- (e) provision as to circumstances in which a person may be regarded as having complied with an undertaking;
- (f) provision as to monitoring by the Secretary of State of compliance with an undertaking;
- (g) provision as to certification by the Secretary of State that an undertaking has been complied with;
- (h) provision for appeals against refusal to give such certification;
- (i) in a case where a person has given inaccurate, misleading or incomplete information in relation to an undertaking, provision for the person to be regarded as not having complied with it;
- (j) in a case where a person has complied partly but not fully with an undertaking, provision for that part-compliance to be taken into account in the imposition of any criminal or other sanction on the person.

# Status:

This version of this cross heading contains provisions that are prospective.

# Changes to legislation:

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