Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 3

ENFORCEMENT

Enforcement notices

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

I1 S. 23 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 23.