Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Article 8

Safeguard clause

1 Where a Member State ascertains that the devices referred to in Article 4 (1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

a failure to meet the essential requirements referred to in Article 3;

b incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;

c shortcomings in the standards themselves.

[[F1]2 The Commission shall enter into consultation with the Parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

a the measures are justified:

(i) it shall immediately so inform the Member State which took the measures and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the Parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the advisory procedure referred to in Article 6(2);

(ii) when necessary in the interests of public health, appropriate measures designed to amend non-essential elements of this Directive relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4);

b the measures are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorised representative.**]**

3 Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4 The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Textual Amendments

F1 Substituted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).