

## Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

### Article 10

1 In the case of devices intended for clinical investigations, the manufacturer or <sup>[F1]</sup>the authorized representative established in the Community shall, at least 60 days before the commencement of the investigations, submit the statement referred to in Annex 6 to the competent authorities of the Member State in which the investigations are to be conducted.

2 The manufacturer may commence the relevant clinical investigations at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary, based on considerations of public health or public order.

<sup>[F1]</sup>Member States may, however, authorise manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the ethics committee concerned has issued a favourable opinion with respect to the investigation programme in question including its review of the clinical investigation plan.]

<sup>[F2a]</sup> The authorization referred to in the second subparagraph of paragraph 2 may be subject to approval by the competent authority.]

<sup>[F13]</sup> The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken.]

<sup>[F34]</sup> The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in point 2.3.7 of Annex 7 at the disposal of the competent authorities.

5 Clinical investigations shall be conducted in accordance with the provisions of Annex 7. The measures designed to amend non-essential elements of this Directive relating to the provisions on clinical investigation in Annex 7 shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4).]

#### 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).
- F2** Inserted by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
- F3** Inserted 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

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devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).