STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III

Active Implantable Medical Devices

Procedures for active implantable medical devices for clinical investigations

29.—(1) No person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in the United Kingdom unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

(a) subject to paragraph (2), the statement required by Section 2.2 of Annex 6; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.1 and 3.2 of Annex 6.

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(3) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(4) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

(a) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, that the relevant device may be made available for the purposes of the intended investigation; or

(b) if the ethics committee opinion required under Section 2.2 of Annex 6 is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(5) A written notice pursuant to paragraph (4) may—

(a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

(b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(6) Where a written notice pursuant to paragraph (4) in respect of a relevant device has been withdrawn by the Secretary of State—

(a) further clinical use of the relevant device in the investigation is prohibited; and

(b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(7) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—

(a) take all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1, and the first paragraph of Section 3.2, of Annex 6;

(b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and

(c) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation.

(8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(b) are met, amongst other reasons, if—

(a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (7); or

(b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1).

(9) No person shall conduct a clinical investigation of a relevant device—

(a) otherwise than in accordance with Annex 7; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex 7.