STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VI

Fees charged by the Secretary of State

Fees payable in relation to clinical investigation notices

56.—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

(a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—

(i) a fee, if the device is a Group A device, of £1,600, or

(ii) a fee, if the device is a Group B device, of £2,100; or

(b) in all other cases—

(i) a fee, if the device is a Group A device, of £2,200, or

(ii) a fee, if the device is a Group B device, of £3,000.

(2) Except where paragraph (3) applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or his authorised representative has previously given such notice in relation to that device.

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

(a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;

(b) a change to the number of patients or devices forming the basis of the proposed trial;

(c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;

(d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or

(e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

(4) A fee under this regulation—

(a) shall be payable when the notice to which it relates is given to the Secretary of State; and

(b) shall accompany that notice when it is given.