STATUTORY INSTRUMENTS

1995 No. 449

FEES AND CHARGES

The Medical Devices (Consultation Requirements) (Fees) Regulations 1995

Made - - - -	*27th February 1995*
Laid before Parliament	*27th February 1995*
Coming into force - -	*20th March 1995*

The Secretary of State for Health, with the consent of the Treasury, in exercise of the powers conferred upon her by section 56(1) and (2) of the Finance Act 1973(**1**) and of all other powers enabling her in that behalf, hereby makes the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 and shall come into force on 20th March 1995.

(2) In these Regulations—

"Annex II" and "Annex III" mean respectively Annex II and Annex III to the Directive;

"approved manufacturer" in relation to a medicinal substance means a manufacturer who—

(a) holds a manufacturing authorisation which permits him to manufacture that substance for inclusion in an authorised medicinal product; or

(b) is permitted under the Directive to manufacture that substance for incorporation in a medical device in respect of which an EC examination certificate has been issued by a notified body which has consulted the competent body;

"authorised medicinal product" means a medicinal product in respect of which there is—

(a) a Community marketing authorisation granted by the European Commission under Council Regulation (EEC) No. 2309/93(**2**);

(b) a United Kingdom marketing authorisation granted under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**3**);

(c) a product licence which is given effect as such a United Kingdom marketing authorisation by paragraph 1 of Schedule 6 to those Regulations; or

(**1**) 1973 c. 51.
(**2**) OJ No. L 214, 24.8.1993, p. 1.
(**3**) S.I.1994/3144.

(d) any other product licence, other than a product licence of right;

"competent body" means the body which, in the United Kingdom, is the competent authority established in accordance with Council Directive 65/65/EEC(**4**); "consultation" means a consultation required either by paragraph 4.3 of Annex II or by paragraph 5 of Annex III;

"the Directive" means Council Directive 93/42/EEC(**5**);

"EC examination certificate" means either an EC design-examination certificate within the meaning of paragraph 4.3 of Annex II or an EC type-examination certificate within the meaning of paragraph 5 of Annex III;

"fee" means a fee specified in, or determined under, regulation 3;

"incorporates" means incorporates as an integral part;

"manufacturing authorisation" has the same meaning as in Article 16 of Council Directive 75/319/EEC(**6**);

"medical device" has the same meaning as in Article 1.2(a) of the Directive;

"medicinal substance" means a substance which, if used separately from a medical device, may be considered to be a medicinal product as defined in Article 1 of Council Directive 65/65/EEC;

"new medicinal substance" means a medicinal substance which is not—

(a) an authorised medicinal product for human use;

(b) an ingredient or, as the case may be, the sole active ingredient of such a product; or

(c) a substance which has been incorporated in a medical device in respect of which an EC examination certificate has been issued by a notified body which has consulted the competent body;

"notified body" has the same meaning as in Article 16 of the Directive;

"placed on the market" in relation to a medical device refers to the "placing on the market", as defined in paragraph 2(h) of Article 1 of the Directive, of that device;

"product licence" has the same meaning as in section 7 of the Medicines Act 1968(**7**);

"product licence of right" means a product licence which is a licence of right within the meaning of section 25(4) of that Act;

"put into service" in relation to a medical device refers to the "putting into service", as defined in paragraph 2(i) of Article 1 of the Directive, of that device.

(3) In these Regulations "a further consultation" means a consultation by a notified body in relation to any medical device which—

(a) may be placed on the market or put into service under an EC examination certificate which has been issued by that notified body after consultation with the competent body;

(b) is the subject of proposed changes within paragraph 4.4 of Annex II or paragraph 6 of Annex III, as the case may be, which changes, if that device is to be placed on the market or put into service, may require the issue of a supplement to an EC examination certificate which has been issued by that notified body after consultation with the competent body; or

(c) is of a similar design or type to a device which has been the subject of an unsuccessful application for an EC examination certificate where—

(**4**) OJ No. 22, 9.2.65, p. 369/65.
(**5**) OJ No. L 169, 12.7.93, p. 1.
(**6**) OJ No. L 147, 9.6.75, p. 13; Article 16.1 was replaced by Article 3(3) of Directive 89/341/EEC (OJ No. L 142, 25.5.89, p. 11).
(**7**) 1968 c. 67.

(i) the person who made that unsuccessful application makes further application for an EC examination certificate to the notified body which determined that unsuccessful application; and

(ii) within the relevant period that further application becomes the subject of consultation between that notified body and the competent body.

(4) For the purposes of paragraph (3), the relevant period means the period of 5 years which starts on the first day on which the competent body was consulted in respect of the unsuccessful application in question or, if there has been more than one such application in any particular case, in respect of the first of them.

(5) In these Regulations, unless the context requires otherwise, a reference to a numbered regulation is a reference to the regulation of these Regulations which is so numbered and a reference in a regulation to a numbered paragraph is a reference to the paragraph of that regulation which is so numbered.

Circumstances in which a fee is payable

2.—(1) Subject to paragraph (2), a notified body shall pay a fee in connection with the services and facilities provided by the Department of Health as the competent body in respect of any consultation in relation to the safety, quality and usefulness of a medicinal substance incorporated in a medical device if, in consequence of that consultation, the competent body is under a duty to express views to that notified body.

(2) No fee shall be payable in respect of the first consultation in relation to the safety, quality and usefulness of a medicinal substance incorporated in a medical device for which a product licence is held.

Fees

3.—(1) Subject to regulation 2(2) and the following paragraphs of this regulation, in respect of a consultation in relation to a medical device which incorporates a medicinal substance manufactured by—

(a) an approved manufacturer of that substance, the fee shall be £2,500;

(b) any other manufacturer, the fee shall be £7,000.

(2) Subject to the following paragraphs of this regulation, in respect of a further consultation in relation to a medical device which incorporates a medicinal substance manufactured by—

(a) an approved manufacturer of that substance, the fee shall be £625;

(b) any other manufacturer, the fee shall be £1,750.

(3) Subject to regulation 2(2) and the following paragraphs of this regulation, in respect of a consultation in relation to a medical device which incorporates more than one medicinal substance, —

(a) if each medicinal substance is manufactured by an approved manufacturer of that substance, the fee shall be £2,500;

(b) if any of those medicinal substances is not manufactured by an approved manufacturer of that substance, the fee shall be £7,000.

(4) Subject to the following paragraphs of this regulation, in respect of a further consultation in relation to a medical device which incorporates more than one medicinal substance,—

(a) if each medicinal substance is manufactured by an approved manufacturer of that substance, the fee shall be £625;

(b) if any of those medicinal substances is not manufactured by an approved manufacturer of that substance, the fee shall be £1,750.

(5) Subject to paragraph (6), in respect of a consultation in relation to a medical device which incorporates any new medicinal substance—

(a) where the competent body has not previously been consulted in relation to a medical device which incorporates that substance, the fee shall be £32,000;

(b) where it has previously been so consulted, the fee shall be £8,000.

(6) Subject to regulation 2(2), where the same notified body consults the competent body on the same occasion in relation to a number of devices which—

(a) are of similar construction and are designed to perform similar functions;

(b) incorporate medicinal substances of the same specification which are manufactured by the same manufacturer or manufacturers; and

(c) do not incorporate any other medicinal substance;

the amount of the fee in respect of that consultation shall be equal to the amount of the fee which would, but for this paragraph, be payable under the preceding paragraphs of this regulation for a consultation in relation to one of those devices. Payment and recovery of fees

4.—(1) The fee shall be paid to the Secretary of State not later than the day on which a notified body consults the competent body.

(2) All unpaid sums due on account of a fee shall be recoverable as debts due to the Crown.

Virginia Bottomley
22nd February 1995 Secretary of State for Health

We consent,

Andrew Mitchell
Timothy Kirkhope
Two of the Lords Commissioners of Her
27th February 1995 Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Annexes II and III to that Directive require the manufacturer of a medical device which incorporates a medicinal substance, or his authorised representative, to lodge an application with one of the notified bodies designated by the member States. The notified body with which an application is lodged is required to consult the competent body of a member State in order to verify the safety, quality and usefulness of the medicinal substance. A competent body which is so consulted is required to express views about the safety, quality and usefulness of the medicinal substance.

Regulation 1 contains definitions of terms used in these Regulations. Regulation 2 prescribes the circumstances in which fees are payable under these Regulations. Regulation 3 prescribes the amounts of those fees. Regulation 4 makes provision for the payment of fees and the recovery of unpaid fees.

An assessment of the cost to business of complying with these Regulations has been made, coies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.