STATUTORY INSTRUMENTS

2023 No. 377

The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023

PART 2

Amendment of the Medical Devices Regulations 2002

Amendment of regulation 52 (interpretation of Part VI)

7. In regulation 52(1)(**1**), insert at the appropriate place—

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

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

(b) holds an examination certificate for a device incorporating that medicinal substance and that certificate was issued by an approved body or notified body after consultation with the Secretary of State in respect of that substance;

“authorised medicinal product” means a medicinal product in respect of which a marketing authorisation has been granted;

“clinical development” means the conduct of studies of a medicinal substance in human subjects in order to—

(a) discover or verify the effects of such a substance,

(b) identify any adverse reaction to such a substance, or

(c) study absorption, distribution, metabolism and excretion of such a substance,

with the object of ascertaining the safety or efficacy of that substance, as required to verify the safety and usefulness of the substance in accordance with section 7.4 of Annex I of Directive 93/42 and section 10 of Annex I of Directive 90/385;

“consultation” means a consultation required by—

(a) section 4.3 of Annex II of Directive 93/42 or Directive 90/385; or

(b) section 5 of Annex III of Directive 93/42 or Directive 90/385;

“examination certificate” means—

(a) a design-examination certificate within the meaning of sections 4.3 and 4.4 of Annex II of Directive 93/42 or Directive 90/385, issued by an approved body;

(b) a type-examination certificate within the meaning of sections 5 and 6 of Annex III of Directive 93/42 or Directive 90/385, issued by an approved body;

(c) an EC design-examination certificate within the meaning of sections 4.3 and 4.4 of the version of Annex II of Directive 93/42 or Directive 90/385 that existed immediately before IP completion day, issued by a notified body; or

(**1**) Amended by S.I. 2003/1697.

(d) an EC type-examination certificate within the meaning of sections 5 and 6 of the version of Annex III of Directive 93/42 or Directive 90/385 that existed immediately before IP completion day), issued by a notified body;

"further consultation" means a consultation by an approved body in relation to any device which—

(a) may be placed on the market or put into service in accordance with Part 2 or 3 and which is the subject of an examination certificate issued by that approved body after consultation with the Secretary of State;

(b) is the subject of proposed changes within section 4.4 of Annex II of Directive 93/42 or Directive 90/385 or section 6 of Annex III of Directive 93/42 or Directive 90/385 and if that device is to be placed on the market or put into service, those changes may require a supplement to the examination certificate previously issued by that approved body after consultation with the Secretary of State; or

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

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

(ii) within the relevant period that further application becomes the subject of consultation between that approved body and the Secretary of State;

"incorporates" means incorporates as an integral part;

"marketing authorisation" has the meaning given by regulation 8 of the Human Medicines Regulations 2012;

"medicinal substance" means a substance which, if used separately from a device, may be considered to be a medicinal product, as defined in Schedule 1 to the Medicines (Products for Human Use) Fees Regulations 2016;

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

(a) an authorised medicinal product;

(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 device in respect of which an examination certificate has been issued by an approved body which has consulted the Secretary of State;

"quality development" means the chemical, pharmaceutical and biological testing required in order to verify the quality of a medicinal substance in accordance with paragraph 7.4 of Annex I of Directive 93/42 and section 10 of Annex I of Directive 90/385;

"relevant period" means the period of 5 years which starts on the first day on which the Secretary of State was consulted in respect of the unsuccessful application or, if there has been more than one such application in any particular case, in respect of the first of them;

"safety development" means the toxicological and pharmacological testing required in order to verify the safety of a medicinal substance in accordance with paragraph 7.4 of Annex I of Directive 93/42 and section 10 of Annex I of Directive 90/385; and

"scientific advice" means advice in connection with the quality, safety or clinical development for a medicinal substance incorporated, or to be incorporated, in a device.".