STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VI

Fees charged by the Secretary of State

Interpretation of Part VI

52.—(1) In this Part[F1]...—

[[F2]"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;**]**

[[F2]"authorised medicinal product" means a medicinal product in respect of which a marketing authorisation has been granted;**]**

[[F2]"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;**]**

[[F2]"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;**]**

[[F2]"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

(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;**]**

[F2"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;**]**

"Group A device" means a Class I medical device, a Class IIa medical device, or a Class IIb medical device which is neither an implantable device nor a long term invasive medical device;

"Group B device" means a Class IIb medical device which is either an implantable medical device or a long term invasive medical device, or a Class III medical device, or an active implantable medical device; and "half day" means a period of three and a half hours.

[F2"incorporates" means incorporates as an integral part;**]**

[F2"marketing authorisation" has the meaning given by regulation 8 of the Human Medicines Regulations 2012;**]**

[F2"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;**]**

[F2"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;**]**

[F2"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;**]**

[F2"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;**]**

[[F2]"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**]**

[[F2]"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.**]**

(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42, and in the event of a dispute over the classification of a device, the Secretary of State shall determine the classification of the device in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42.

Textual Amendments

F1 Words in reg. 52(1) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **15**

F2 Words in reg. 52(1) inserted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **7**

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medical Devices Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Pt. 8 inserted by S.I. 2019/791 reg. 10 (This amendment not applied to legislation.gov.uk. Reg. 10 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 54)
- Pt. 9 inserted by S.I. 2019/791 reg. 11 (This amendment not applied to legislation.gov.uk. Reg. 11 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 55)
- Sch. 3 inserted by 2021 c. 3 Sch. 3 para. 2
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(2)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(2)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) heading words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 2A(1A) inserted by S.I. 2024/221 reg. 11(b)
- reg. 3ZA(2)(a)(aa) substituted for reg. 3ZA(2)(a) by S.I. 2024/221 reg. 12(c)(ii)
- reg. 4D(10)(b) substituted by S.I. 2019/791, reg. 3(7) (as amended) by S.I. 2019/1385 Sch. 2 para. 2(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
- reg. 4E(7) words substituted by S.I. 2019/791, reg. 3(7) (as amended) by S.I. 2019/1385 Sch. 2 para. 2(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
- reg. 6(d) inserted by S.I. 2019/791 reg. 4(2) (This amendment not applied to legislation.gov.uk. Reg. 4(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 10)
- reg. 33(1)(c) inserted by S.I. 2019/791 reg. 6(2)(a) (This amendment not applied to legislation.gov.uk. Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 33(2)(c) inserted by S.I. 2019/791 reg. 6(2)(b) (This amendment not applied to legislation.gov.uk. Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 34D inserted by S.I. 2024/221 reg. 17
- reg. 60A excluded by 2021 c. 3 Sch. 2 para. 4
- reg. 60A excluded by 2021 c. 3 Sch. 2 para. 5(2)
- reg. 60A-60C inserted by 2021 c. 3 Sch. 3 para. 1

- reg. 75(3) words inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(2)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 75(7) inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(2)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 93(4) inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(3) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 119(6) words inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(4) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 124(5) words substituted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(5) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 149(5)(e) words substituted by S.I. 2019/791, reg. 11 (as amended) by S.I. 2019/1385 Sch. 2 para. 10(2) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(1) substituted by S.I. 2019/791, reg. 11 (as amended) by S.I. 2019/1385 Sch. 2 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(3) inserted by S.I. 2019/791, reg. 11 (as amended) by S.I. 2019/1385 Sch. 2 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))