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 the Medical Devices Regulations 2002**

**3.** The Medical Devices Regulations 2002(**1**) are amended in accordance with regulations 4 to 16.

**Amendment of regulation 2 in relation to England, Scotland and Wales (interpretation)**

**4.** In regulation 2(1)(**2**), insert at the appropriate place—

""*statistical review*" means a review of the statistical sections of the written notice which a manufacturer or their UK responsible person submits to the Secretary of State pursuant to regulation 16(1) or 29(1) in respect of an intended clinical investigation of a relevant device;".

**Amendment of regulation 16 in relation to England, Scotland and Wales (procedures for general medical devices for clinical investigations)**

**5.** After regulation 16(1)(**3**), insert—

"(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

(a) obtain advice on regulatory requirements relating to an intended clinical investigation; or

(b) obtain a statistical review in relation to an intended clinical investigation.".

**Amendment of regulation 29 in relation to England, Scotland and Wales (procedures for active implantable medical devices for clinical investigations)**

**6.** After regulation 29(1)(**4**), insert—

"(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

(**1**) S.I. 2002/618; relevant amending instruments are 2003/1697, 2007/400, 2007/803, 2008/2936, 2010/557, 2012/1426, 2013/525, 2013/2327, 2017/207, 2019/791, 2020/1478, 2021/873 and 2021/910.
(**2**) Amended by S.I. 2003/1697, 2007/400, 2008/2936, 2012/1426, 2013/2327, 2019/791, 2021/873, 2021/910 and section 41(4) of the Medicines and Medical Devices Act 2021 (c. 3).
(**3**) Relevant amending instruments are S.I. 2008/2936, 2013/2327 and 2019/791.
(**4**) Relevant amending instruments are S.I. 2013/2327 and 2019/791.

(a) obtain advice on regulatory requirements relating to an intended clinical investigation; or

(b) obtain a statistical review in relation to an intended clinical investigation.".

**Amendment of regulation 52 (interpretation of Part VI)**

**7.** In regulation 52(1)(**5**), 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

(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

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

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.".

**Amendment of regulation 53 in relation to England, Scotland and Wales (fees in connection with the registration of devices and changes to registration details)**

**8.** In regulation 53(**6**), for "£100" substitute "£240".

**Amendment of regulation 53 in relation to Northern Ireland (fees in connection with the registration of devices and changes to registration details)**

**9.** In regulation 53(**7**), for "£100" substitute "£240".

(**6**) Amended by S.I. 2017/207 and 2019/791.
(**7**) Amended by S.I. 2020/1478.

**Amendment of regulation 54 in relation to England, Scotland and Wales (fees payable in connection with the designation of approved bodies)**

**10.**—(1) Regulation 54(**8**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "£2,063" substitute "£8,918", and

(b) in sub-paragraph (b), for "£8,252" substitute "£35,672".

(3) For paragraph (2), substitute—

"(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 45(4) must, in connection with that application for a variation, pay to the Secretary of State—

(a) in respect of an extension to the scope of the body's designation to carry out tasks under Part 2, Part 3 or Part 4, which extends the body's designation in relation to a Part under which they have already been designated, a fee of £12,571;

(b) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and where the Secretary of State considers that an additional assessment of the body's procedures is required, a fee of £18,212.".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£15,904" substitute "£58,341",

(b) for sub-paragraph (b), substitute—

"(b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection, a fee of £45,675, plus the amounts specified in paragraph (3A); and",

(c) in sub-paragraph (c), for "£4,404" substitute "£10,072".

(5) In paragraph (3A)—

(a) in sub-paragraph (a)(i), for "£361.20" substitute "£631", and

(b) in sub-paragraph (a)(ii), for "£90.30" substitute "£171".

(6) In paragraph (3C)—

(a) in sub-paragraph (a), for "£8,252" substitute "£35,672",

(b) in sub-paragraph (b) for "£15,904" substitute "£58,341", and

(c) after sub-paragraph (b), insert ", plus the amounts specified in paragraph (3A).".

(7) In paragraph (3D)—

(a) in sub-paragraph (a), for "£2,586" substitute "£18,583",

(b) in sub-paragraph (b), for "£3,876" substitute "£22,789", and

(c) after sub-paragraph (b), insert ", plus the amounts specified in paragraph (3A).".

(8) In paragraph (3E), for "£532" substitute "£1,297".

(9) After paragraph (3E), insert—

"(3F) Where, pursuant to regulation 45(7)(a) or 45(7)(b), the Secretary of State conducts an on-site assessment of a subsidiary of the body, the body must pay to the Secretary of State a fee of £22,789, plus the costs and expenses referred to in paragraph (3A)."

(10) For paragraph (5) substitute—

"(5) In this regulation—

(**8**) Relevant amending instruments are S.I. 2019/791 and 2021/873.

"Regulation (EU) No 920/2013" means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices; and

"subsidiary" is to be construed in accordance with section 1159 of the Companies Act 2006.".

**Amendment of regulation 55 in relation to England, Scotland and Wales (fees payable in connection with the designation etc. of conformity assessment bodies)**

**11.**—(1) Regulation 55(**9**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "£2,063" substitute "£8,918", and

(b) in sub-paragraph (b), for "£8,252" substitute "£35,672".

(3) For paragraph (2), substitute—

"(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) must, in connection with that application for a variation, pay to the Secretary of State—

(a) in respect of an extension to the scope of the body's designation to carry out tasks arising out of a mutual recognition agreement that were not previously within the scope of the body's designation, a fee of £12,571; or

(b) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and which requires the Secretary of State to undertake an additional assessment of the body's procedures, a fee of £18,212.".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£15,904" substitute "£58,341", and

(b) in sub-paragraphs (b) and (d), for "£4,404" substitute "£10,072".

(5) In paragraph (3A), for "£15,904" substitute "£58,341".

(6) In paragraph (3B), for "£4,404" substitute "£10,072".

(7) In paragraph (3D)—

(a) in sub-paragraph (a)(i), for "£361.20" substitute "£631", and

(b) in sub-paragraph (a)(ii), for "£90.30" substitute "£171".

**Amendment of regulation 55 in relation to Northern Ireland (fees payable in connection with the designation etc. of conformity assessment bodies)**

**12.**—(1) Regulation 55(**10**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "£2,063" substitute "£8,918", and

(b) in sub-paragraph (b), for "£8,252" substitute "£35,672".

(3) For paragraph (2), substitute—

(**9**) Relevant amending instruments are S.I. 2007/803, 2017/207 and 2019/791.
(**10**) Amended by S.I. 2020/1478.

"(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) must, in connection with that application for a variation, pay to the Secretary of State—

(a) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out tasks arising out of a UK mutual recognition agreement that were not previously within the scope of the body's designation, a fee of £12,571; or

(b) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and which requires the Secretary of State to undertake an additional assessment of the body's procedures, a fee of £18,212.".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£15,904" substitute "£58,341", and

(b) in sub-paragraphs (b) and (d), for "£4,404" substitute "£10,072".

(5) In paragraph (3A), for "£15,904" substitute "£58,341".

(6) In paragraph (3B), for "£4,404" substitute "£10,072".

(7) In paragraph (3D)—

(a) in sub-paragraph (a)(i), for "£361.20" substitute "£631", and

(b) in sub-paragraph (a)(ii), for "£90.30" substitute "£171".

**Amendment of regulation 56 in relation to England, Scotland and Wales (fees payable in relation to clinical investigation notices)**

**13.**—(1) In regulation 56(1)(**11**)—

(a) in sub-paragraph (a)(i), for "£2,920" substitute "£5,711",

(b) in sub-paragraph (a)(ii), for "£3,570" substitute "£11,069",

(c) in sub-paragraph (b)(i), for "£3,820" substitute "£7,472", and

(d) in sub-paragraph (b)(ii), for "£5,040" substitute "£15,627".

(2) After regulation 56(3A), insert—

"(3B) A person who requests a meeting with the Secretary of State in respect of an intended clinical investigation under regulation 16(1A) or 29(1A) must pay the following fees in advance of the meeting—

(a) £906 for a regulatory advice meeting under regulation 16(1A)(a) or 29(1A)(a); and

(b) £782 for a statistical review meeting under regulation 16(1A)(b) or 29(1A)(b).".

**New regulation 56B**

**14.** After regulation 56A (fees in connection with approval of coronavirus test devices), insert—

"**Circumstances in which a fee is payable in relation to a consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device**

**56B.**—(1) Subject to paragraph (2), the fee payable by an approved body in respect of a consultation or further consultation with the Secretary of State in relation to the safety,

(**11**) Amended by S.I. 2019/791.

quality and usefulness of a medicinal substance incorporated in a device is the fee specified in regulation 56C.

(2) No fee is payable if it is the first time the Secretary of State has been consulted by any approved body in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device if the medicinal substance is an authorised medicinal product.".

**New regulation 56C**

**15.** After regulation 56B (circumstances in which a fee is payable in relation to a consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device), insert—

"**Fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device**

**56C.**—(1) Subject to regulation 56B(2) and paragraph (3), the fee in respect of a consultation in relation to a device which incorporates one or more medicinal substances is—

(a) £4,550 if each medicinal substance is manufactured by an approved manufacturer of that substance;

(b) £10,604 if any of the medicinal substances are not manufactured by an approved manufacturer of that substance.

(2) Subject to paragraph (3), the fee in respect of a further consultation in relation to a device which incorporates one or more medicinal substances is—

(a) £900 if each medicinal substance is manufactured by an approved manufacturer of that substance;

(b) £2,451 if any of the medicinal substances are not manufactured by an approved manufacturer of that substance.

(3) In relation to a device which incorporates a new medicinal substance, the fee is—

(a) £46,526 for a consultation; and

(b) £11,551 for a further consultation.

(4) Where an approved body consults the Secretary of State in relation to more than one device at the same time and those devices—

(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 fee payable for that consultation is the fee which would be payable under this regulation for a consultation in relation to one of those devices.

(5) Any fee payable under this regulation must be paid to the Secretary of State not later than the day on which an approved body consults the Secretary of State.".

**New regulation 56D**

**16.** After regulation 56C (fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device), insert—

"**Fees payable in connection with pre-consultation meetings**

**56D.**—(1) The fee payable by a person other than an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that person making an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(2) The fee payable by an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that body consulting the Secretary of State in relation to an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(3) The fee payable is—

(a) £824, if the advice provided at that meeting consists of advice in connection with—

(i) quality development only, or

(ii) safety development only;

(b) £1,044, if the advice provided at that meeting consists of advice in connection with—

(i) quality and safety development only, or

(ii) clinical development only;

(c) £1,429, if the advice provided at that meeting consists of advice in connection with—

(i) quality and clinical development only, or

(ii) safety and clinical development only;

(d) £1,813, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

(4) Any fee payable under this regulation must be paid within 14 days following written notice from the Secretary of State requiring payment of that fee ".