Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021 and paragraphs 8F(1) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2023 No.

MEDICAL DEVICES HEALTH AND SAFETY FEES AND CHARGES

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

Made - - - -	***
Coming into force - -	*1st April 2023*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8C of, and paragraphs 1(1)(ab) and 7(2)(**1**) of Schedule 4 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**2**), and sections 15(1), 16(1)(i), 17(1)(a) and 43 of the Medicines and Medical Devices Act 2021(**3**), after having considered the matters in section 15(2) to (4) of the Medicines and Medical Devices Act 2021.

The Secretary of State has carried out a public consultation in accordance with section 45(1) of the Medicines and Medical Devices Act 2021.

In accordance with section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021 and paragraphs 8F(1)(**4**) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

The Treasury have consented to the making of these Regulations as required by paragraphs 3(1) and 10 of Schedule 4 to the European Union (Withdrawal) Act 2018.

(**1**) The powers in paragraphs 1(1)(ab) and 7(2) of Schedule 4 to the European Union (Withdrawal) Act 2018 are exercisable by the "appropriate authority". See paragraph 2 of that Schedule, which defines "appropriate authority" for the purposes of paragraph 1 of that Schedule. See also paragraph 8 of that Schedule, which defines "appropriate authority" for the purposes of paragraph 7 of that Schedule.

(**2**) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). Section 8C was inserted by section 21 of the 2020 Act, and paragraph 1(1)(ab) of Schedule 4 by section 28 of the 2020 Act. Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

(**3**) 2021 c. 3. The Medicines and Medical Devices Act 2021 was amended by the Health and Care Act 2022 (c. 31).

(**4**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.

PART 1

Preliminary and Revocation

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023.

(2) These Regulations come into force on 1st April 2023.

(3) Any amendment or revocation made by these Regulations has the same extent and application as the provision amended, subject as follows.

(4) In Part 2—

(a) regulations 4 to 6, 8, 10, 11, 13 apply in relation to England, Scotland and Wales;

(b) regulations 14 to 16 extend and apply in relation to England, Scotland and Wales;

(c) regulations 9 and 12 apply in relation to Northern Ireland.

(5) In Part 4, regulation 23 extends and applies to Northern Ireland.

Revocation

2. The Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**5**) are revoked.

PART 2

Amendment of the Medical Devices Regulations 2002

Amendment of the Medical Devices Regulations 2002

3. The Medical Devices Regulations 2002(**6**) 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)(**7**), 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)(**8**), 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—

(**5**) S.I. 1995/449, amended by S.I. 2005/2759, 2007/803, 2008/530, 2012/1916 and 2016/190.
(**6**) 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.
(**7**) 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).
(**8**) Relevant amending instruments are S.I. 2008/2936, 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 29 in relation to England, Scotland and Wales (procedures for active implantable medical devices for clinical investigations)

6. After regulation 29(1)(**9**), 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 52 (interpretation of Part VI)

7. In regulation 52(1)(**10**), 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;

(**9**) Relevant amending instruments are S.I. 2013/2327 and 2019/791.
(**10**) Amended by S.I. 2003/1697.

(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 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(**11**), 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(**12**), for "£100" substitute "£240".

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(**13**) 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",

(**11**) Amended by S.I. 2017/207 and 2019/791.
(**12**) Amended by S.I. 2020/1478.
(**13**) Relevant amending instruments are S.I. 22019/791 and 2021/873.

(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—

"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(**14**) 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".

(**14**) Relevant amending instruments are S.I. 2007/803, 2017/207 and 2019/791.

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(**15**) 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, 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)(**16**)—

(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).".

(**15**) Amended by S.I. 2020/1478.
(**16**) Amended by S.I. 2019/791.

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, 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 ".

Part 3

Amendment of the Blood Safety and Quality Regulations 2005

Amendment of the Blood Safety and Quality Regulations 2005

17.—(1) Regulation 22 (fees) of the Blood Safety and Quality Regulations 2005(**17**) is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (a), for "£3,074" substitute "£3,381",

(b) in sub-paragraph (b), for "£518" substitute "£570", and

(c) in sub-paragraph (c), for "£463" substitute "£509".

(**17**) S.I. 2005/50; relevant amending instruments are S.I. 2005/2898, 2006/2013, 2008/525, and 2010/554.

(3) In paragraph (2A)(b), for "£492" substitute "£967".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£2,583" substitute "£3,552", and

(b) in sub-paragraph (b), for "£1,292" substitute "£1,776".

(5) In paragraph (3A), for "£683" substitute "£751".

(6) In paragraph (3C)(c), for "£492" substitute "£967".

(7) In paragraph (5)—

(a) in sub-paragraph (a), for "£2,583" substitute "£3,552", and

(b) in sub-paragraph (b), for "£1,292" substitute "£1,776".

(8) In paragraph (5B)—

(a) in sub-paragraph (a), for "£2,583" substitute "£3,552", and

(b) in sub-paragraph (b), for "£1,292" substitute "£1,776".

(9) In paragraph (5C)—

(a) in sub-paragraph (a), for "£2,583" substitute "£3,552", and

(b) in sub-paragraph (b), for "£1,292" substitute "£1,776".

(10) In paragraph (5E), for "£10,000" substitute "£11,000".

Part 4

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

18. The Medical Devices (Northern Ireland Protocol) Regulations 2021(**18**) are amended in accordance with regulations 19 to 25.

Amendment of regulation 7 (registration of custom-made devices)

19. In regulation 7(5), for "£100" substitute "£240".

Amendment of regulation 16 (clinical investigation fees)

20. In regulation 16(5)—

(a) in sub-paragraph (a), for "non-invasive class IIb device" substitute "class IIb device, which is neither an implantable device nor a long-term invasive device" and

(b) in sub-paragraph (b), for "an invasive class IIb device or class III device" substitute "a class IIb device, which is either an implantable device or a long-term invasive device or a class III device".

New regulation 17A (advice in relation to intended clinical investigations)

21. After regulation 17 (clinical investigations not carried out for a purpose specified in Article 62(1)) insert—

(**18**) S.I. 2021/905.

"**Advice in relation to intended clinical investigations**

17A.—(1) A manufacturer or sponsor may request a meeting with the Secretary of State in advance of an application being submitted under Article 70(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.

(2) A person who requests a meeting with the Secretary of State under paragraph (1), must pay the following fees in advance of that meeting—

(a) £906 for a regulatory advice meeting under paragraph (1)(a); and

(b) £782 for a statistical review meeting under paragraph (1)(b).

(3) In this regulation, "statistical review" means a review of the statistical sections of the application which a sponsor intends to submit to the Secretary of State under Article 70(1) in respect of an intended clinical investigation."

Amendment of regulation 19 (fees payable in connection with the designation of notified bodies)

22.—(1) Regulation 19 is amended as follows.

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

(3) In paragraph (6)—

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

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

New Part 4A

23. After Part 4 insert—

"Part 4A

Fees for consultation in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device

Interpretation of Part 4A

19A. In this Part—

"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 a relevant conformity assessment certificate for a device incorporating that medicinal substance and that certificate was issued by a notified body under Regulation (EU) 2017/745 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 12.1 of Annex I;

"consultation" means a consultation required by section 5.2 or 5.4 of Annex IX or section 6 of Annex X;

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

(a) may be placed on the market or put into service in accordance with Regulation (EU) 2017/745 and which is the subject of a relevant conformity assessment certificate issued by that notified body after consultation with the Secretary of State;

(b) is the subject of proposed changes within section 5(f) of Annex IX, and if that device is to be placed on the market or put into service, those changes may require the issue of a supplement to a relevant conformity assessment certificate previously issued by that notified 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 a relevant conformity assessment certificate where—

(i) the person who made that unsuccessful application makes a further application for a relevant conformity assessment 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 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 (General interpretation provisions) 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 a relevant conformity assessment certificate has been issued by a notified 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 section 12.1 of Annex I;

"relevant conformity assessment certificate" means either an EU technical documentation assessment certificate issued in accordance with Annex IX or an EU type-examination certificate issued in accordance with Annex X;

"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 section 12.1 of Annex I; 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.

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

19B.—(1) Subject to paragraph (2), the fee payable by a notified body in respect of a consultation or further consultation with the Secretary of State in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device is the fee specified in regulations 19C.

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

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

19C.—(1) Subject to regulation 19B(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 a notified 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 the notified body consults the Secretary of State.

Fees for pre-consultation meetings

19D.—(1) The fee payable by a person other than a notified 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 a relevant conformity assessment certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(2) The fee payable by a notified body with whom the Secretary of State holds a meeting in order to provide scientific advice to that body with a view to that body consulting the Secretary of State in relation to an application for a relevant conformity assessment 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.".

Amendment of Schedule 1 (fees for clinical investigations)

24.—(1) Schedule 1 is amended as follows.

(2) For the heading to Table 1 substitute—

"Clinical investigation of a class I device, class IIa device or class IIb device, which is neither an implantable device nor a long-term invasive device.".

(3) In the second column (Fee) in Table 1 (Clinical investigation of a class I device, class IIa device or non-invasive class IIb device)—

(a) in entry 1, for "£3,820" substitute "£7,472", and

(b) in entry 2, for "£2,920" substitute "£5,711".

(4) For the heading to Table 2 substitute—

"Clinical investigation of a class IIb device, which is either an implantable device or a long-term invasive device, or a class III device.".

(5) In the second column (Fee) in Table 2 (Clinical investigation of an invasive class IIb device or class III device)—

(a) in entry 1, for "£5,040" substitute "£15,627", and

(b) in entry 2, for "£3,570" substitute "£11,069".

Amendment of Schedule 2 (fees in connection with the designation of notified bodies)

25.—(1) Schedule 2 is amended as follows.

(2) In the first column (Application) in Table 1 (Application fees)—

(a) for entry 4, substitute—

"4. For an extension of the scope of the designation under Article 46(1) which extends the body's designation to carry out tasks included in an Annex that was not previously within the body's designation";

(b) after entry 4, insert—

"5. For an extension of the scope of the designation under Article 46(1) which extends the body's designation to carry out 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".

(3) In the second column (Fee) in Table 1 (Application fees)—

(a) in entry 1, for "£8,252" substitute "£35,672",

(b) in entry 2, for "£2,063" substitute "£8,918",

(c) in entry 3, for "£8,252" substitute "£35,672",

(d) in entry 4, for "£6,504" substitute "£12,571", and

(e) in entry 5, insert "£18,212".

(4) In the second column (Fee) in Table 2 (Fees for assessments and reviews)—

(a) in entry 1, for "£15,904" substitute "£58,341",

(b) in entry 2, for "£10,160" substitute "£45,675",

(c) in entry 3, for "£4,404" substitute "£10,072",

(d) in entry 4, for "£3,876" substitute "£22,789", and

(e) in entry 5—

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

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

Signed by the authority of the Secretary of State for Health and Social Care

Name
Parliamentary Under Secretary of State,
Date Department of Health and Social Care

We consent

Name
Name
Two Lords Commissioners of His Majesty's
Date Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices Regulations 2002 ("the 2002 Regulations"), the Blood Safety and Quality Regulations 2005 ("the 2005 Regulations") and the Medical Devices (Northern Ireland Protocol) Regulations 2021 ("the 2021 Regulations"). They also revoke and restate the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the 1995 Regulations").

The fee amounts specified in these Regulations are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 13 August 2022. A summary of the consultation responses and the Government's response to the consultation are published on the MHRA's website (www.mhra.gov.uk).

Part 1 revokes the 1995 Regulations. Regulations 7 and 14 to 16 and regulation 23 restate, with amendments and fee increases, the 1995 Regulations in the 2002 and 2021 Regulations.

Part 2 amends the 2002 Regulations. Regulations 4 to 6 introduce new optional services provided by the Secretary of State in relation to intended clinical investigations of medical devices. Regulations 8 to 12 increase existing fees payable to the Secretary of State in connection with the registration of devices and the designation of approved bodies and conformity assessment bodies. Regulation 13 increases fees payable to the Secretary of State in connection with clinical investigations and inserts fees for the new services provided by regulations 5 and 6.

Part 3 amends the 2005 Regulations. Regulation 17 amends regulation 22 of the 2005 Regulations to increase the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation, and haemovigilance.

Part 4 amends the 2021 Regulations. Regulations 19, 22 and 25 revise and increase existing fees in the 2021 Regulations payable to the Secretary of State in connection with the registration of custom-made devices and the designation of notified bodies. Regulations 20, 21 and 24 revise and increase the fees for clinical investigation applications and introduce new fees for advice provided by the Secretary of State in relation to an intended clinical investigation.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.