STATUTORY INSTRUMENTS

2021 No. 905

MEDICAL DEVICES CONSUMER PROTECTION

The Medical Devices (Northern Ireland Protocol) Regulations 2021

Made - - - -	*26th July 2021*
Coming into force - -	*27th July 2021*

The Secretary of State, in exercise of the powers conferred by section 8C of, and paragraph 1(1)(ab) of Schedule 4, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**1**), makes the following Regulations.

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 8F(1)(**2**) and 12(1) of Schedule 7 to that Act.

The Treasury has consented to the making of these Regulations as required by paragraph 3(1) of Schedule 4 to that Act.

PART 1

Preliminary

Citation and commencement

1.—(1) These Regulations may be cited as the Medical Devices (Northern Ireland Protocol) Regulations 2021.

(2) These Regulations come into force on the day after the day on which they are made.

Commencement Information

I1 Reg. 1 in force at 27.7.2021, see **reg. 1(2)**

(**1**) 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 that Act. Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

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

Extent and application

2.—(1) Parts 1, 4, 5, 7 and 8 extend to England and Wales, Scotland and Northern Ireland.

(2) Parts 2, 3 and 6 extend to Northern Ireland only.

(3) Any amendment made by Part 9 has the same extent as the provision amended.

(4) In Part 8—

(a) Regulations 30, and 32 to 37 apply in relation to Northern Ireland only;

(b) Regulation 31 applies in relation to Great Britain only.

Commencement Information

I2 Reg. 2 in force at 27.7.2021, see **reg. 1(2)**

Interpretation

3.—(1) In these Regulations—

"Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC(**3**);

"ethics committee" means a research ethics committee recognised or established by, or on behalf of, the Scottish Ministers, the Welsh Ministers, the Department of Health in Northern Ireland or the Health Research Authority(**4**).

(2) Unless otherwise defined in these Regulations, terms used have the same meaning as in Regulation (EU) 2017/745.

(3) In these Regulations a reference to—

(a) an Article is a reference to an Article of Regulation (EU) 2017/745;

(b) an Annex is a reference to an Annex to Regulation (EU) 2017/745.

Commencement Information

I3 Reg. 3 in force at 27.7.2021, see **reg. 1(2)**

Scope

4. These Regulations apply to all devices to which Regulation (EU) 2017/745 applies.

Commencement Information

I4 Reg. 4 in force at 27.7.2021, see **reg. 1(2)**

(**3**) OJ No. L 117, 05.05.2017, p. 1., amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020, OJ No. L 130, 24.04.2020, p.18.

(**4**) The Health Research Authority is established by section 109 of the Care Act 2014 (c.23).

PART 2

Making available on the market and putting into service under Regulation (EU) 2017/745

Reprocessing of single-use devices

5. The reprocessing and further use of single-use devices is permitted only when it is carried out in accordance with Article 17.

Commencement Information
I5 Reg. 5 in force at 27.7.2021, see **reg. 1(2)**

Requirement on health institutions to provide information relating to implanted devices

6. A health institution which has implanted a device to which Article 18 applies, must make available to the patient in whom the device has been implanted—

(a) the implant card for the device bearing the health institution's identity, and

(b) the information provided by the manufacturer with the device pursuant to Article 18(1), by any means that allow rapid access to that information.

Commencement Information
I6 Reg. 6 in force at 27.7.2021, see **reg. 1(2)**

Registration of custom-made devices

7.—(1) A manufacturer who makes custom-made devices available on the market in Northern Ireland must register that type of device with the Secretary of State.

(2) Registration—

(a) must take place within 28 days beginning with the day on which that type of device is first made available on the market, and

(b) requires the manufacturer to submit to the Secretary of State the information specified in paragraph (3).

(3) The information to be submitted to the Secretary of State is—

(a) the name, business address and contact details of the manufacturer of the device;

(b) if an authorised representative has been designated by the manufacturer, the authorised representative's name, business address, contact details and evidence of that designation;

(c) a description of the type of device concerned.

(4) The manufacturer must ensure that the information submitted to the Secretary of State remains up to date.

(5) The fee payable to the Secretary of State for registering a device or amending the registration of a device under this regulation is **[**[F1]£240**]**.

(6) This regulation does not apply before 1st September 2021 in respect of any class IIa or class IIb non-implantable devices made available on the market by a manufacturer who is not established in the United Kingdom.

F1 Sum in reg. 7(5) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **19**

Commencement Information
I7 Reg. 7 in force at 27.7.2021, see **reg. 1(2)**

Certificates of free sale - fee

8. A manufacturer or authorised representative who requests a certificate of free sale from the Secretary of State under Article 60(1), must pay to the Secretary of State a fee of £75.

Commencement Information
I8 Reg. 8 in force at 27.7.2021, see **reg. 1(2)**

Retention of documentation relating to conformity assessments and custom-made devices

9.—(1) The liquidator or trustee in bankruptcy of a manufacturer, or of an authorised representative, must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, information to which section 8 of Annex IX applies, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is—

(a) in the case of information relating to an implantable device, 15 years after the last device was placed on the market, and

(b) in any other case, 10 years after the last device was placed on the market.

Commencement Information
I9 Reg. 9 in force at 27.7.2021, see **reg. 1(2)**

UK(NI) indication

10.—(1) This regulation applies if the CE marking is affixed in accordance with Article 20 on the basis of a certificate issued by a notified body established in the United Kingdom.

(2) The CE marking must be accompanied by the UK(NI) indication.

(3) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.

(4) The manufacturer must affix the UK(NI) indication—

(a) visibly, legibly and indelibly, and

(b) before placing the device on the market or putting the device into service.

(5) A person may only make available on the market or put into service a device to which this regulation applies if the manufacturer has affixed the UK(NI) indication in accordance with this regulation.

(6) In this regulation, "the UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020(**5**).

Commencement Information
I10 Reg. 10 in force at 27.7.2021, see **reg. 1(2)**

PART 3

Clinical investigations under Regulation (EU) 2017/745

Ethical review of clinical investigations

11.—(1) A sponsor proposing to conduct a clinical investigation of a device in Northern Ireland must apply to an ethics committee for an ethical review of the proposed clinical investigation.

(2) The sponsor must submit to the Secretary of State a copy of the opinion of the ethics committee as soon as it becomes available and before the clinical investigation is started.

Commencement Information
I11 Reg. 11 in force at 27.7.2021, see **reg. 1(2)**

Prior authorisation of clinical investigations by the Secretary of State

12.—(1) A clinical investigation to which Article 70(7)(a) applies must not start unless—

(a) it has been authorised by the Secretary of State, and

(b) a favourable opinion in respect of the clinical investigation has been issued by an ethics committee.

(2) For the purposes of paragraph (1)(a) and subject to paragraph (3), the Secretary of State must notify the sponsor of whether the clinical investigation is authorised within—

(a) 65 days of the validation date provided for in Article 70(5), if the Secretary of State decides to consult experts for advice on whether the clinical investigation should be authorised, or

(b) 45 days of the validation date in any other case.

(3) If the Secretary of State requests additional information from the sponsor under Article 70(6), the expiry of the periods in paragraph (2) is suspended from the date of the first request until such time as the additional information has been received.

Commencement Information
I12 Reg. 12 in force at 27.7.2021, see **reg. 1(2)**

(**5**) S.I. 2020/1460.

Arbitration following the refusal of a clinical investigation application

13.—(1) A sponsor notified of a refusal under Article 70(3), 71(4), or 78(10) may, within 28 days of being notified, apply to the Institute to appoint an adjudicator to review the refusal.

(2) The adjudicator must provide a report to the Secretary of State and the sponsor setting out any recommendations in respect of the disputed refusal.

(3) The Secretary of State must take the report of the adjudicator into account and decide whether to—

(a) confirm or alter the grounds for the refusal of the application,

(b) authorise the clinical investigation, or

(c) in the case of a refusal under Article 70(3), proceed to consider the application under Article 70.

(4) The Secretary of State must notify the sponsor of the decision in paragraph (3).

(5) The sponsor must pay any fees, costs or expenses of the Institute and its appointed adjudicator that are payable in connection with the application made under paragraph (1).

(6) In this regulation, "Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

Commencement Information
I13 Reg. 13 in force at 27.7.2021, see **reg. 1(2)**

Damage compensation in relation to clinical investigations

14. A sponsor of a clinical investigation must hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability in the event of injury or death attributable to participation in the clinical investigation.

Commencement Information
I14 Reg. 14 in force at 27.7.2021, see **reg. 1(2)**

Retention of documentation relating to clinical investigations

15.—(1) The liquidator or trustee in bankruptcy of a sponsor of a clinical investigation or of a sponsor's legal representative or contact person under Article 62(2), must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, any of the documentation referred to in Annex XV, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is—

(a) in the case of documentation relating to the clinical investigation of a device that was subsequently placed on the market—

(i) if the device was an implantable device, 15 years after the last device was placed on the market, and

(ii) if the device was not an implantable device, 10 years after the last device was placed on the market;

(b) in any other case, 10 years after the clinical investigation ended.

Commencement Information
I15 Reg. 15 in force at 27.7.2021, see **reg. 1(2)**

Clinical investigation fees

16.—(1) The sponsor of a clinical investigation must pay the relevant fee for—

(a) an application submitted to the Secretary of State under Article 70(1);

(b) a notification to the Secretary of State of a substantial modification under Article 75(1).

(2) The relevant fee is payable when the application or notification to which it relates is made to the Secretary of State.

(3) If a sponsor fails to pay the relevant fee, the Secretary of State may reject the application, reject the notification or suspend the clinical investigation until the fee is paid.

(4) Fees for clinical investigations are set out in Schedule 1.

(5) In this regulation, "the relevant fee" means—

(a) for a clinical investigation of a class I device, class IIa device or **[**F2class IIb device, which is neither an implantable device nor a long-term invasive device**]**, the fee in table 1 in Schedule 1, and

(b) for a clinical investigation of **[**F3a class IIb device, which is either an implantable device or a long-term invasive device or a class III device**]**, the fee in table 2 in Schedule 1.

F2 Words in reg. 16(5)(a) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **20(a)**
F3 Words in reg. 16(5)(b) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **20(b)**

Commencement Information
I16 Reg. 16 in force at 27.7.2021, see **reg. 1(2)**

Clinical investigations not carried out for a purpose specified in Article 62(1)

17.—(1) The provisions in paragraph (2) apply to clinical investigations of custom-made devices carried out for a purpose other than one of the purposes specified in Article 62(1), in addition to the provisions specified in Article 82(1).

(2) The provisions are—

(a) those of Article 62(4) not already specified in Article 82(1);

(b) Article 62(5) and (7);

(c) Article 63 except—

(i) in paragraph (2)(e), not the words "include the Union-wide unique single identification number of the clinical investigation referred to in Article 70(1) and"; and

(ii) in paragraph (6), not the words "in the electronic system on clinical investigations referred to in Article 73";

(d) Articles 64 to 69;

(e) Article 70 except—

(i) in paragraph (1), not the first sentence of the second subparagraph;

(ii) in paragraph (2), not the final sentence of the paragraph, and in the first sentence the words "data in the electronic system referred to in Article 73" to the end are to be read "documentation and submit the updated documentation to the Secretary of State";

(iii) in paragraph (3), in the first subparagraph, not the words "by means of the electronic system referred to in Article 73"; and

(iv) paragraphs (8) and (9);

(f) Article 71;

(g) Article 72;

(h) Article 75 except in paragraph (1), not the words "by means of the electronic system referred to in Article 73";

(i) Article 76 except—

(i) in paragraph (3), not the words "by means of the electronic system referred to in Article 73"; and

(ii) in paragraph (4), not the words "through the electronic system referred to in Article 73";

(j) Article 77 except—

(i) in paragraphs (1) and (7), not the words "through the electronic system referred to in Article 73";

(ii) paragraph (4);

(iii) in paragraph (5), not the second sentence of the second subparagraph;

(iv) paragraph (6); and

(v) in paragraph (7), in the second subparagraph, the words "entered into the electronic system pursuant to paragraph (5) of this Article" are to be read "submitted pursuant to paragraph (5) of this Article";

(k) Article 80 except—

(i) in paragraphs (2) and (3), not the words "by means of the electronic system referred to in Article 73"; and

(ii) paragraphs (4) and (5);

(l) Annex XV except section 3.1.1 in Chapter II.

Commencement Information

I17 Reg. 17 in force at 27.7.2021, see **reg. 1(2)**

[F4Advice 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.**]**

F4 Reg. 17A inserted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **21**

PART 4

Notified bodies designated under Regulation (EU) 2017/745

Notified bodies

18.—(1) The Secretary of State is the appointed authority responsible for notified bodies under Article 35.

(2) In the event of restriction, suspension, or withdrawal of a designation, the notified body must provide the Secretary of State with any documents requested for the purposes of enabling the Secretary of State to exercise the functions of the authority responsible for notified bodies under Article 46(6).

Commencement Information

I18 Reg. 18 in force at 27.7.2021, see **reg. 1(2)**

Fees payable in connection with the designation of notified bodies

19.—(1) Fees in connection with the designation of notified bodies are set out in Schedule 2.

(2) The applicant must pay the Secretary of State the fee specified in table 1 in Schedule 2 for an application—

(a) for initial designation as a notified body under Article 38;

(b) for reassessment under Article 44(10);

(c) to extend the scope of a designation under Article 46(1).

(3) A notified body designated by the Secretary of State under Article 42 that submits a summary evaluation report to the Secretary of State in accordance with Article 5(4) of Regulation (EU) 722/2012, must pay to the Secretary of State a fee of **[**F5£1,297**]**.

(4) A fee specified in table 1 in Schedule 2 or paragraph (3) is payable when the application or submission to which it relates is made to the Secretary of State.

(5) If an applicant fails to pay a fee specified in table 1 in Schedule 2 or paragraph (3), the Secretary of State may reject the application or submission to which it relates.

(6) If the Secretary of State conducts an assessment or review listed in table 2 in Schedule 2, the fee payable by the conformity assessment body is—

(a) the fee specified for that assessment or review in table 2 in Schedule 2,

(b) an amount for time spent by each member of staff to undertake the assessment or review at a rate—

(i) for the time spent on site, of **[**F6£631**]** per half day (period of less than a half day counting as a half day) up to a maximum of 2 half days on any one date, and

(ii) for the time spent travelling to and from the site, of **[**F7£171**]** per hour,

(c) the actual costs of travel, accommodation and subsistence, and

(d) out of pocket expenses.

(7) A fee under paragraph (6) is payable within one month of receipt by the conformity assessment body of a written notice from the Secretary of State requiring payment of the fee.

(8) If a conformity assessment body fails to pay a fee under paragraph (6), the Secretary of State may—

(a) refuse to designate the body under Article 42;

(b) if the body has already been designated, suspend, restrict, or fully or partially withdraw, the designation.

(9) In this regulation, "Regulation (EU) 722/2012" means Commission Regulation (EU) No 722/2012 of 8th August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin(**6**).

F5 Sum in reg. 19(3) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **22(2)**

F6 Sum in reg. 19(6)(b)(i) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **22(3)(a)**

F7 Sum in reg. 19(6)(b)(ii) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **22(3)(b)**

Commencement Information

I19 Reg. 19 in force at 27.7.2021, see **reg. 1(2)**

[F8Part 4A

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

F8 Pt. 4A inserted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **23**

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;

(**6**) OJ No. L 212, 09.08.2012, p. 3.

"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 medicinal 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.**]**

PART 5

General provision about language requirements and fees

Language requirements

20. Where Regulation (EU) 2017/745 provides for the UK in respect of Northern Ireland to determine the language requirements for information and documentation, such information and documentation must be written in English.

Commencement Information

I20 Reg. 20 in force at 27.7.2021, see **reg. 1(2)**

Unpaid fees

21. All unpaid sums due by way of, or on account of, any fees payable under these Regulations are recoverable as debts due to the Crown.

Commencement Information

I21 Reg. 21 in force at 27.7.2021, see **reg. 1(2)**

Waivers, reductions and refunds

22. The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under these Regulations;

(b) refund the whole or part of any fee paid pursuant to these Regulations.

Commencement Information

I22 Reg. 22 in force at 27.7.2021, see **reg. 1(2)**

PART 6

Enforcement

Offence of breaching certain provisions

23.—(1) A person commits an offence if the person contravenes a prohibition or fails to comply with a requirement in a provision of the regulations listed in Table 1 or the Articles listed in Table 2 in Schedule 3 to these Regulations.

(2) A person guilty of an offence under paragraph (1) is liable on summary conviction to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.

(3) In respect of an offence under this regulation, a magistrates' court in Northern Ireland may hear and determine any complaint made before the earlier of—

(a) the end of the period of 1 year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(b) the end of the period of 3 years beginning with the day on which the offence was committed.

(4) For the purposes of paragraph (3)(a)—

(a) a certificate signed by or on behalf of the prosecutor and stating the date on which such evidence came to the prosecutor's knowledge is conclusive evidence of that fact, and

(b) a certificate stating that matter and purporting to be so signed is to be treated as so signed until the contrary is proved.

Commencement Information

I23 Reg. 23 in force at 27.7.2021, see **reg. 1(2)**

Defence of due diligence

24.—(1) It is a defence for a person charged with an offence under regulation 23(1) to show that the person took all reasonable steps and exercised all due diligence to avoid commission of the offence.

(2) If in any proceedings for such an offence the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

(a) an act or default of another person, or

(b) reliance on information given by another person,

the defendant is not, without leave of the court, entitled to rely on that defence unless the requirement in paragraph (3) is satisfied.

(3) The requirement is that at least 7 clear days before the hearing of the proceedings the defendant has served on the prosecutor a notice giving such information identifying or assisting in the identification of that other person as was then in the defendant's possession.

(4) A defendant is not entitled to rely on the defence provided by paragraph (1) by reason of the defendant's reliance on information supplied by another person unless the defendant shows that it was reasonable in all the circumstances to rely on the information, having regard in particular to—

(a) the steps which the defendant took or might reasonably have taken to verify the information, and

(b) whether the defendant had any reason to disbelieve the information.

Commencement Information

I24 Reg. 24 in force at 27.7.2021, see **reg. 1(2)**

Offences by bodies corporate

25.—(1) Where an offence under regulation 23(1) committed by a body corporate or a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, an officer, the officer (as well as the body corporate or partnership) commits the offence and is liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate, "officer" means—

(a) a director, manager, secretary or other similar officer of the body, or

(b) a person purporting to act in any such capacity.

(3) In paragraph (2)(a), "director", in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(4) In relation to a Scottish partnership, "officer" means—

(a) a partner, or

(b) a person purporting to act as a partner.

Commencement Information

I25 Reg. 25 in force at 27.7.2021, see **reg. 1(2)**

Enforcement

26.—(1) It is the duty of the Secretary of State to enforce these Regulations and Regulation (EU) 2017/745.

(2) It is the duty of each district council in Northern Ireland to enforce these Regulations and Regulation (EU) 2017/745 within its area (concurrently with the Secretary of State) in relation to devices that are ordinarily intended for private use or consumption.

Commencement Information

I26 Reg. 26 in force at 27.7.2021, see **reg. 1(2)**

PART 7

Amendment of primary legislation

Investigatory powers under the Consumer Rights Act 2015

27.—(1) Schedule 5 to the Consumer Rights Act 2015(**7**)(investigatory powers etc) is amended in accordance with this regulation.

(2) In paragraph 8 (interpretation of Schedule 5), after the definition of "online interface order" insert—

> ""Regulation (EU) 2017/745 on medical devices" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC."

(3) In paragraph 10 (enforcer's legislation: duties and powers mentioned in paragraph 9(1)(a)) at the end insert "regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021".

(4) In paragraph 19 (exercise of powers in Part 4), in sub-paragraph (7A)(a)(**8**), for the words from "a breach of" to the end substitute—

"a breach of—

(i) the Medical Devices Regulations 2002 (S.I. 2002/618),

(ii) regulations made under section 15(1) of the Medicines and Medical Devices Act 2021,

(iii) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

(iv) Regulation (EU) 2017/745 on medical devices, and".

(5) In paragraph 30A(**9**) (power to decommission or switch off fixed medical devices)—

(a) in sub-paragraph (1), for the words from "pursuant to" to the end substitute—

"pursuant to—

(a) the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002 (S.I. 2002/618),

(b) a duty in regulations made under section 15(1) of the Medicines and Medical Devices Act 2021, or

(c) the duty in regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021.";

(b) in sub-paragraph (2), for "medical device to which the Medical Devices Regulations 2002 apply" substitute "relevant medical device";

(c) after sub-paragraph (2), insert—

"(3) In sub-paragraph (2), "relevant medical device" means—

(**7**) 2015 c.15.
(**8**) Sub-paragraph (7A) was inserted by section 41(2)(c) of the Medicines and Medical Devices Act 2021 (c.3).
(**9**) Paragraph 30A was inserted by section 41(2)(d) of the Medicines and Medical Devices Act 2021 (c.3).

(a) where a domestic enforcer is acting pursuant to a duty mentioned in sub-paragraph (1)(a) or (b), any medical device to which the Medical Devices Regulations 2002 apply;

(b) where a domestic enforcer is acting pursuant to the duty mentioned in sub-paragraph (1)(c), any medical device to which Regulation (EU) 2017/745 on medical devices applies."

Commencement Information

I27 Reg. 27 in force at 27.7.2021, see **reg. 1(2)**

Amendment of the Medicines and Medical Devices Act 2021

28.—(1) The Medicines and Medical Devices Act 2021(**10**) is amended in accordance with this regulation.

(2) In section 17 (fees, information, offences), in subsection (2), for "this Part" substitute "this Chapter".

(3) In section 21 (compliance notices), after subsection (1), insert—

"(1A) In this Chapter, "medical devices provision" means a provision in—

(a) regulations under section 15(1),

(b) the Medical Devices Regulations 2002 (S.I. 2002/618),

(c) the Medical Devices (Northern Ireland Protocol) Regulations 2021, or

(d) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC."

(4) In section 34 (recovery of expenses of enforcement), in subsection (1)(a), for the words from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002 (S.I. 2002/618) (offence of breaching certain provisions in the Regulations), or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions),

in relation to a medical device, or".

(5) In section 39 (disclosure of information)—

(a) in subsection (10)(a), omit the "or" at the end;

(b) in subsection (10)(b), at the end insert—

", or

(c) contravenes any obligation or restriction created or arising by or under the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement, whether or not an obligation or restriction to which section 7A(2) of the European Union (Withdrawal) Act 2018 applies.".

(**10**) 2021 c.3.

(6) In section 42 (interpretation of Part 4), in subsection (2)—

(a) for the definition of "manufacturer" substitute—

""manufacturer" means any person who is a manufacturer for the purposes of any provision in—

(a) the Medical Devices Regulations 2002 (S.I. 2002/618), or

(b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;";

(b) for the definition of "medical devices provision" substitute—

""medical devices provision"—

(a) in Chapter 1, has the meaning given by section 17(2), and

(b) in Chapter 3, has the meaning given by section 21(1A);".

(7) In Schedule 2 (medical devices: civil sanctions)—

(a) in paragraph 1(1) (imposition of monetary penalty)—

(i) in paragraph (a), omit the "or" at the end;

(ii) in paragraph (b), at the end insert—

", or

(c) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021 (offence of breaching certain provisions).";

(b) in paragraph 4 (monetary penalties: criminal proceedings and conviction)—

(i) in sub-paragraph (1)(a), from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002, or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,

may be instituted against the person in respect of the act or omission to which the notice relates before the end of the period within which the person's liability may be discharged as mentioned in paragraph 2(2) (see paragraph 3(2)(a));";

(ii) in sub-paragraph (1)(b), from "section 28" to the end substitute "the provisions mentioned in paragraph (a) in relation to that act or omission.";

(iii) in sub-paragraph (2), from "section 28" to the end substitute "any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission giving rise to the penalty.";

(c) paragraph 5 (enforcement undertakings)—

(i) in sub-paragraph (1)(a), from "offence under" to the end substitute—

"offence under—

(i) section 28,

(ii) regulation 60A of the Medical Devices Regulations 2002, or

(iii) regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021,";

(ii) in sub-paragraph (2)(a), from "section 28" to the end substitute "any of the provisions mentioned in sub-paragraph (1)(a) in respect of the act or omission to which the undertaking relates;";

(d) in paragraph 13 (guidance as to enforcement), in sub-paragraph (1)(a), for "or regulation 60A" to the end substitute ", regulation 60A of the Medical Devices Regulations 2002 or regulation 23 of the Medical Devices (Northern Ireland Protocol) Regulations 2021;".

Commencement Information
I28 Reg. 28 in force at 27.7.2021, see **reg. 1(2)**

PART 8

Amendment of the Medical Devices Regulations 2002

Amendments to the Medical Devices Regulations 2002

29. The Medical Devices Regulations 2002(**11**) are amended in accordance with this Part.

Commencement Information
I29 Reg. 29 in force at 27.7.2021, see **reg. 1(2)**

Amendment of regulation 2 (interpretation)

30. In regulation 2, in paragraph (1)—

(a) for the definition of "medical device" substitute—

""medical device" has the meaning given in Article 2(1) of Regulation (EU) 2017/745 and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;";

(b) after the definition of "Regulation 722/2012" insert—

""Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;".

Commencement Information
I30 Reg. 30 in force at 27.7.2021, see **reg. 1(2)**

(**11**) S.I. 2002/618, as amended by S.I. 2003/1400, 2003/1697, 2005/2759, 2909, 2007/400, 803, 2008/2936, 2009/383, 2010/557, 2012/1426, 2013/525, 2327, 2017/207, 2019/791, 1385 and 2020/1478.

Amendment of regulation 2A (medical devices which are qualifying Northern Ireland goods)

31. In regulation 2A—

(a) in paragraph (1)(a), after "Northern Ireland" insert "or of Regulation (EU) 2017/745";

(b) in paragraph (2)—

(i) the words from ""qualifying Northern Ireland good"" to the end become sub-paragraph (a); and

(ii) after that sub-paragraph insert—

"(b) "Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.".

Commencement Information

I31 Reg. 31 in force at 27.7.2021, see **reg. 1(2)**

Revocation and transitional provision

32. After regulation 3 (scope), insert—

"**Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745**

3ZA.—(1) Subject to paragraph (2)—

(a) Parts 2 and 3 only apply in Northern Ireland for the purposes of regulating qualifying devices.

(b) Parts 5 to 7 only apply in Northern Ireland for the purposes of regulating qualifying devices and devices within the scope of Part 4.

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph whether or not the device to which they apply is referred to in paragraph (1)—

(a) for the purposes of registration of medical devices and persons placing medical devices on the market in Northern Ireland—

(i) regulation 19 (registration of persons placing general medical devices on the market),

(ii) regulation 21B (registration of persons placing active implantable medical devices on the market), and

(iii) regulation 53 (fees in connection with the registration of devices and changes to registration details),

apply until the date which is 6 months after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745.

(b) Parts 5 to 7 apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

(3) For the purposes of paragraph (1), a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745—

(a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of Directive 93/42 or Directive 90/385, rather than Regulation (EU) 2017/745; and

(b) it is placed on the market, put into service or made available in Northern Ireland in accordance with, and subject to the requirements of and the arrangements set out in, Parts 2, 3 and 5 to 7."

Commencement Information
I32 Reg. 32 in force at 27.7.2021, see **reg. 1(2)**

Amendment of regulation 10A (UK(NI) indication: general medical devices)

33. In regulation 10A, after paragraph (3), insert—

"(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies."

Commencement Information
I33 Reg. 33 in force at 27.7.2021, see **reg. 1(2)**

Amendment of regulation 19 (registration of persons placing general medical devices on the market)

34. In regulation 19—

(a) omit paragraph (1)(a)(ii);

(b) in paragraph (1)(b) for "and custom-made devices" substitute "that are not custom-made devices";

(c) omit paragraph (2)(c);

(d) omit paragraph (5); and

(e) omit paragraph (6).

Commencement Information
I34 Reg. 34 in force at 27.7.2021, see **reg. 1(2)**

Amendment of regulation 21B (registration of persons placing active implantable medical devices on the market)

35. In regulation 21B—

(a) omit paragraph (1)(a)(ii);

(b) omit paragraph (1)(b);

(c) omit paragraph (2)(c);

(d) omit paragraph (5); and

(e) omit paragraph (6).

Commencement Information
I35 Reg. 35 in force at 27.7.2021, see **reg. 1(2)**

Amendment of regulation 24A (UK(NI) indication: active implantable medical devices)

36. In regulation 24A, after paragraph (3), insert—

"(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies."

Commencement Information
I36 Reg. 36 in force at 27.7.2021, see **reg. 1(2)**

Amendment of regulation 36A (UK(NI) indication: in vitro diagnostic medical devices)

37. In regulation 36A, after paragraph (3), insert—

"(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies."

Commencement Information
I37 Reg. 37 in force at 27.7.2021, see **reg. 1(2)**

PART 9

Amendments of other secondary legislation

Amendment of the Blood Safety and Quality Regulations 2005

38. In the Blood Safety and Quality Regulations 2005(**12**), in regulation 2 (scope of the regulations), in paragraph (3), at the end insert "and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC".

Commencement Information
I38 Reg. 38 in force at 27.7.2021, see **reg. 1(2)**

Amendment of the Human Tissue (Quality and Safety for Human Application) Regulations 2007

39. In the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**13**), in regulation 2 (extent and application)—

(**12**) S.I. 2005/50; regulation 2 was amended by S.I. 2019/4.
(**13**) S.I. 2007/1523; regulation 2 was amended by S.I. 2012/1916, 2018/335, and 2019/481.

(a) in paragraph (3)(c), omit the "or" at the end; and

(b) in paragraph (3)(d), at the end insert—

", or

(e) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC."

Commencement Information

I39 Reg. 39 in force at 27.7.2021, see **reg. 1(2)**

Amendment of the Legislative and Regulatory Reform (Regulatory Functions) Order 2007

40.—(1) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007(**14**) is amended as follows.

(2) In Part 2 of the Schedule, in the section headed "Medicines", after "Human Medicines Regulations 2012", insert—

"Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Medical Devices (Northern Ireland Protocol) Regulations 2021".

(3) In Part 3 of the Schedule, in the section headed "Public health and safety", after "The Personal Protective Equipment (Enforcement) Regulations 2018", insert "The Medical Devices (Northern Ireland Protocol) Regulations 2021".

Commencement Information

I40 Reg. 40 in force at 27.7.2021, see **reg. 1(2)**

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

41. In the Medicines (Products for Human Use) (Fees) Regulations 2016(**15**), in regulation 10(5) (fee for advice for other purposes)—

(a) in paragraph (a), omit the "or" at the end; and

(b) in paragraph (b), at the end insert—

"; or

(c) obtaining an EU technical documentation assessment certificate or EU type-examination certificate of the type mentioned in section 5 of Annex IX and section 6 of Annex X of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, for a medical device incorporating that product or a product of that type."

(**14**) S.I. 2007/3544, to which there are amendments not relevant to these Regulations.
(**15**) S.I. 2016/190, amended by S.I. 2019/775; there are other amending instruments but none is relevant.

Commencement Information

I41 Reg. 41 in force at 27.7.2021, see **reg. 1(2)**

Amendment of the Economic Growth (Regulatory Functions) Order 2017

42. In the Economic Growth (Regulatory Functions) Order 2017(**16**), in Part 3 of the Schedule, in the section headed "Medicines", after "Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004", insert—

"Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Medical Devices (Northern Ireland Protocol) Regulations 2021".

Commencement Information

I42 Reg. 42 in force at 27.7.2021, see **reg. 1(2)**

Amendment of the Market Surveillance (Northern Ireland) Regulations 2021

43.—(1) The Market Surveillance (Northern Ireland) Regulations 2021(**17**) are amended as follows.

(2) In regulation 6 (enforcer's legislation), at the end insert—

"(rr) regulation 26 of the Medical Devices (Northern Ireland Protocol) Regulations 2021."

(3) In Schedule 1 (investigatory powers)—

(a) in paragraph 1 (interpretation of terms used in this schedule), at the end insert—

""Regulation (EU) 2017/745 on medical devices" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC."

(b) in paragraph 16 (power to decommission or switch off any medical device)—

(i) in sub-paragraph (1), for the words from "pursuant to" to the end substitute—

"pursuant to—

(a) the duty in regulation 61(1A) or (1B) of the Medical Devices Regulations 2002,

(b) a duty in regulations made under section 15(1) of the Medicines and Medical Devices Act 2021, or

(c) the duty in regulation 26(1) or (2) of the Medical Devices (Northern Ireland Protocol) Regulations 2021.";

(ii) in sub-paragraph (2), after "Medical Devices Regulations 2002" insert "or Regulation (EU) 2017/745 on medical devices";

(**16**) S.I. 2017/267, to which there are amendments not relevant to these Regulations.
(**17**) S.I. 2021/858

(iii) in sub-paragraph (3)(a)(ii), after "Medicines and Medical Devices Act 2021;", omit "and";

(iv) after sub-paragraph (3)(a)(ii) insert—

"(iii) the Medical Devices (Northern Ireland Protocol) Regulations 2021;

(iv) Regulation (EU) 2017/745 on medical devices; and".

Commencement Information

I43 Reg. 43 in force at 27.7.2021, see **reg. 1(2)**

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

Nadhim Zahawi
Parliamentary Under-Secretary of State,
Department of Health and Social Care

26th July 2021

We consent

Alan Mak
David Rutley
Two Lords Commissioners of Her Majesty's
Treasury

21st July 2021

SCHEDULE 1

Regulation 16

Fees for clinical investigations

Commencement Information

I44 Sch. 1 in force at 27.7.2021, see **reg. 1(2)**

Table 1

[F9Clinical 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]

Activity	*Fee*
1. Application submitted under Article 70(1)	[F10£7,472]
2. Application re-submitted under Article 70(1) where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application under Article 71(4)	[F11£5,711]
3. Notification of a substantial modification under Article 75(1)	£207

F9 Sch. 1 Table 1 heading substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **24(2)**

F10 Sum in Sch. 1 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **24(3)(a)**

F11 Sum in Sch. 1 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **24(3)(b)**

Table 2

[F12Clinical investigation of a class IIb device, which is either an implantable device or a long-term invasive device, or a class III device]

Activity	*Fee*
1. Application submitted under Article 70(1)	[F13£15,627]
2. Application re-submitted under Article 70(1) where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application under Article 71(4)	[F14£11,069]
3. Notification of a substantial modification under Article 75(1)	£331

F12 Sch. 1 Table 2 heading substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **24(4)**
F13 Sum in Sch. 1 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **24(5)(a)**
F14 Sum in Sch. 1 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **24(5)(b)**

SCHEDULE 2

Regulation 19

Fees in connection with the designation of notified bodies

Commencement Information
I45 Sch. 2 in force at 27.7.2021, see **reg. 1(2)**

Table 1

Application fees

Application	*Fee*
1. For initial designation submitted under Article 38	**[**[F15]£35,672**]**
2. For initial designation re-submitted under Article 38 where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application	**[**[F16]£8,918**]**
3. For reassessment under Article 44(10)	**[**[F17]£35,672**]**
[[F18]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**]**	**[**[F19]£12,571**]**
[[F20]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**]**	**[**[F21]£18,212**]**

F15 Sum in Sch. 2 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(3)(a)**
F16 Sum in Sch. 2 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(3)(b)**

F17 Sum in Sch. 2 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(3)(c)**
F18 Words in Sch. 2 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(2)(a)**
F19 Sum in Sch. 2 Table 1 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(3)(d)**
F20 Words in Sch. 2 Table 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), **25(2)(b)**
F21 Sch. 2 Table 1 sum inserted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(3)(e)**

Table 2

Fees for assessments and reviews

Activity	*Fee*
1. On-site assessment under Article 39(4) in connection with an application for initial designation under Article 38, or an application for reassessment under Article 44(10)	**[**F22£58,341**]**
2. On-site audit as part of an annual reassessment under Article 44(4)	**[**F23£45,675**]**
3. Observed audit of notified body personnel under Article 44(5)	**[**F24£10,072**]**
4. On-site assessment of a subsidiary	**[**F25£22,789**]**
5. ‘For-cause’ review under Article 44(7) to—	(a) **[**F26£18,583**]**
(a) review assessments by the notified body, including clinical evaluation documentation;	(b) **[**F27£22,789**]**
(b) otherwise verify compliance with the requirements of Regulation (EU) 2017/745 or address a particular issue	

F22 Sum in Sch. 2 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(4)(a)**
F23 Sum in Sch. 2 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(4)(b)**
F24 Sum in Sch. 2 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(4)(c)**
F25 Sum in Sch. 2 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(4)(d)**
F26 Sum in Sch. 2 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(4)(e)(i)**
F27 Sum in Sch. 2 Table 2 substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **25(4)(e)(ii)**

SCHEDULE 3

Regulation 23

Provisions breach of which is an offence under regulation 23

Commencement Information

I46 Sch. 3 in force at 27.7.2021, see **reg. 1(2)**

Table 1

Regulation	*Title of the regulation*
5	Reprocessing of single-use devices
6	Requirement on health institutions relating to implanted devices
7	Provision of information relating to custom-made devices
9	Retention of documentation relating to conformity assessments and custom-made devices
10	UK(NI) indication
11	Ethical review of clinical investigations
12(1)	Prior authorisation of clinical investigations by the Secretary of State
14	Damage compensation in relation to clinical investigations
15	Retention of documentation relating to clinical investigations

Table 2

Article	*Title of the article*
5(1) to (3), (5)	Placing on the market and putting into service
6(1)-(3)	Distance sales
7	Claims
9(3), (4)	Common specifications
10 (except in paragraph 14, only the first sub-paragraph)	General obligations on manufacturers
11(1), (3), (6)	Authorised representative
12	Change of authorised representative
13	General obligations of importers
14	General obligations of distributors
15	Person responsible for regulatory compliance

Article	*Title of the article*
16(3), (4)	Cases in which obligations of manufacturers apply to importers, distributors or other persons.
17(1)	Single-use devices and their reprocessing
18(1)	Implant card and information to be supplied to the patient with an implanted device
21(2)	Devices for special purposes
22(1), (3) to (5)	Systems and procedure packs
23(1)	Parts and components
25(1), (2)	Identification within the supply chain
32(1), (2)	Summary of safety and clinical performance
52(1) to (4), (6) to (11), (13)	Conformity assessment procedures
53(3)	Involvement of notified bodies in conformity assessment procedures
58(1)	Voluntary change of notified body
62(1), (2) (only the first sub-paragraph), (3) (only the first sub-paragraph), (4), (5), (7)	General requirements regarding clinical investigations conducted to demonstrate conformity of devices
82(1)	Requirements regarding other clinical investigations
84	Post-market surveillance plan
85	Post-market surveillance report
86	Periodic safety update report
89(1), (3) (only the second sub-paragraph),(5), (8)	Analysis of serious incidents and field safety corrective actions
94 (only the final paragraph)	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for the implementation in respect of Northern Ireland of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017) ("Regulation (EU) 2017/745"). Article 5(4) of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement between the United Kingdom and the European Union ("the Protocol") provides that the EU law listed in Annex 2 to the Protocol will apply to and in the UK, in respect

of Northern Ireland. Regulation (EU) 2017/745 is listed in Annex 2 and applied from 26 May 2021. Section 7A of the European Union (Withdrawal) Act 2018 gives effect to Regulation (EU) 2017/745 in domestic law.

Part 2 of these Regulations makes supplementary provision in relation to placing devices on the market and putting devices into service in Northern Ireland under Regulation (EU) 2017/745.

Part 3 makes provision in relation to clinical investigations in Northern Ireland under Regulation (EU) 2017/745. Regulation 16 and Schedule 1 set out the fees for making applications and notifying of substantial modifications.

Part 4 of these Regulations makes provision in relation to notified bodies. It provides that the Secretary of State is the authority responsible for notified bodies under Article 35 of Regulation (EU) 2017/745. Regulation 19 and Schedule 2 set out the fees for making applications and for on-site assessments and reviews.

Part 5 makes general provision about language requirements and the fees imposed by these Regulations.

Part 6 deals with enforcement. Regulation 23 makes it a criminal offence to breach a prohibition or requirement in a provision listed in Table 1 or Table 2 in Schedule 3. Table 1 lists regulations in these Regulations and Table 2 lists Articles in Regulation (EU) 2017/745. Regulation 26 confers duties on the Secretary of State and each district council in Northern Ireland to enforce these Regulations and Regulation (EU) 2017/745.

Part 7 amends the Consumer Rights Act 2015 and the Medicines and Medical Devices Act 2021.

Part 8 amends the Medical Devices Regulations 2002. Regulation 32 revokes parts of the Medical Devices Regulations 2002 as they apply to Northern Ireland, and makes transitional provision. The Medical Devices Regulations 2002 implemented Directives 90/385/EEC and 93/42/EEC, which are repealed by Regulation (EU) 2017/745. Regulations 33, 36 and 37 insert provision about the size of the UK(NI) indication. The requirement to affix the UK(NI) indication is imposed by Article 7(3) of the Protocol.

Part 9 makes consequential amendments to other pieces of secondary legislation.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sector is foreseen. The Explanatory Memorandum is published alongside these Regulations on www.legislation.gov.uk.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021.