

STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Procedures for general medical devices for clinical investigations E+W+S

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in [^{F1}Great Britain] unless, before he does so, the manufacturer of the device or [^{F2}their UK responsible person] has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

- (a) subject to paragraph (3), the statement required by [^{F3}Sections 1 and 2.2] of Annex VIII [^{F4}, read with Regulation (EU) No 722/2012]; and
- (b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

[^{F5}(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.]

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a [^{F6}UK marking] otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was [^{F7}UK marked] in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or [^{F2}their UK responsible person] as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer [^{F8}or UK responsible person] (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or [^{F2}their UK responsible person] pursuant to paragraph (1), give written notice to the manufacturer or [^{F2}their UK responsible person]—

Status: There are multiple versions of this provision on screen. These apply to different geographical extents. **Skip to:** E+W+S - England, Wales and Scotland extent N.I. - Northern Ireland extent

Changes to legislation: The Medical Devices Regulations 2002, Section 16 is up to date with all changes known to be in force on or before 20 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- (a) that the relevant device may be made available for the purposes of the intended investigation; or
 - (b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.
- (6) A written notice pursuant to paragraph (5) may—
- (a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;
 - (b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.
- (7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—
- (a) further clinical use of the relevant device in the investigation is prohibited; and
 - (b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),
- unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.
- (8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or [^{F2}their UK responsible person], shall—
- (a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;
 - (b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and
 - (c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.
- (9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—
- (a) the manufacturer or [^{F2}their UK responsible person] does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or
 - (b) the manufacturer or [^{F2}their UK responsible person] does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).
- (10) No person shall conduct a clinical investigation of a relevant device—
- (a) otherwise than in accordance with Annex X; and
 - (b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),
- and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or [^{F2}their UK responsible person] shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.
- [^{F9}(11) The manufacturer, or their [^{F10}single UK responsible person], shall—
- (a) notify the Secretary of State of the end of the clinical investigation; and
 - (b) provide justification where premature termination has resulted.]

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Extent Information

- E1** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F1** Words in reg. 16(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7D\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** Words in reg. 16 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7D\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F3** Words in [reg. 16\(1\)\(a\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), [9\(a\)](#)
- F4** Words in [reg. 16\(1\)\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [6](#)
- F5** [Reg. 16\(1A\)](#) inserted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), [5](#)
- F6** Words in reg. 16(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7D\)\(c\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F7** Words in reg. 16(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7D\)\(c\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F8** Words in reg. 16(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7D\)\(d\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F9** [Reg. 16\(11\)](#) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), [9\(b\)](#)
- F10** Words in reg. 16(11) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7D\)\(e\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Procedures for general medical devices for clinical investigations **N.I.**

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in ^[F11]Northern Ireland unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

- (a) subject to paragraph (3), the statement required by ^[F12]Sections 1 and 2.2] of Annex VIII ^[F13], read with Regulation (EU) No 722/2012]; and
- (b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a CE marking otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was CE marked in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended

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investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

- (a) that the relevant device may be made available for the purposes of the intended investigation; or
- (b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(6) A written notice pursuant to paragraph (5) may—

- (a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;
- (b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—

- (a) further clinical use of the relevant device in the investigation is prohibited; and
- (b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—

- (a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;
- (b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and
- (c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.

(9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—

- (a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or
- (b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).

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- (10) No person shall conduct a clinical investigation of a relevant device—
- (a) otherwise than in accordance with Annex X; and
 - (b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.

- [^{F14}(11) The manufacturer, or their single authorised representative, shall—
- (a) notify the Secretary of State of the end of the clinical investigation; and
 - (b) provide justification where premature termination has resulted.]

Extent Information

- E2** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F11** Words in [reg. 16\(1\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 4](#)
- F12** Words in [reg. 16\(1\)\(a\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), [9\(a\)](#)
- F13** Words in [reg. 16\(1\)\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), [6](#)
- F14** [Reg. 16\(11\)](#) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), [9\(b\)](#)

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Changes to legislation:

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Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

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

- reg. 33(2)(c) inserted by [S.I. 2019/791 reg. 6\(2\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 60A excluded by [2021 c. 3 Sch. 2 para. 4](#)
- reg. 60A excluded by [2021 c. 3 Sch. 2 para. 5\(2\)](#)
- reg. 60A-60C inserted by [2021 c. 3 Sch. 3 para. 1](#)
- reg. 75(3) words inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(2\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 75(7) inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(2\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 93(4) inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(3\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 119(6) words inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(4\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 124(5) words substituted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(5\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 149(5)(e) words substituted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(2\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(1) substituted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(3\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(3) inserted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(3\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))