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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 17**

Miscellaneous and general

*Provisions relating to offences*

**Contravention due to fault of another person**

**335.**—(1) This regulation applies where—

- (a) a contravention of a provision referred to in paragraph (6) constitutes an offence; and
- (b) a person (“A”) contravenes the provision by reason of the act or omission of another person (“B”).

(2) B may be charged with and convicted of the offence, whether or not proceedings are also brought against A.

(3) If B is convicted B is liable to the same punishment as would have been imposed on A if A had been convicted of the offence.

(4) If A is charged with the offence it is a defence for A to prove on the balance of probabilities that—

- (a) A exercised all due diligence to avoid contravening the provision; and
- (b) the contravention was due to the act or omission of B.

(5) A may not rely on the defence in paragraph (4) unless not later than seven clear days before the date of the hearing A serves on the prosecutor a notice in writing of any information held by A which identifies, or assists in identifying, B.

(6) The provisions mentioned in paragraph (1) are—

- (a) regulation 251 (compliance with standards specified in certain publications);
- (b) regulations [<sup>F1</sup>268, 268A, 269 and 269A] (offences relating to packaging and package leaflets);
- (c) regulation 273 (child resistant containers for regulated medicinal products);
- (d) regulation 275 (colouring of aspirin and paracetamol products for children);
- (e) any prohibition or requirement in Chapter 2 of Part 14 (advertising); and
- (f) regulations 305(4) and 306(7) and (8) (notices not to publish, or to cease to publish, an advertisement).

### Textual Amendments

- F1** Words in reg. 335(6)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZA** (as inserted by *The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020* (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**)

### Modifications etc. (not altering text)

- C1** Regs. 332-339 applied (with modifications) by *The Medicines for Human Use (Clinical Trials) Regulations 2004* (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

### Warranty as defence

**336.**—(1) This regulation applies where proceedings are brought against a person (“the defendant”) for an offence under these Regulations in respect of a contravention of a provision mentioned in paragraph (3).

- (2) It is a defence for the defendant to prove that—
- (a) the substance or article to which the contravention relates (the “relevant substance or article”) was sold to the defendant in the United Kingdom as—
    - (i) a substance or article which could be lawfully sold, supplied or offered for sale or supply, or
    - (ii) a substance or article which could be lawfully sold, supplied or offered for sale or supply under the name or description or for the purpose under or for which it was sold;
  - (b) the relevant substance or article was sold with a written warranty certifying a matter specified in paragraph (a), and that if the warranty were true the alleged offence would not have been committed;
  - (c) at the time of the commission of the alleged offence the defendant had no reason to believe that the matter certified in the warranty was otherwise; and
  - (d) at the time of the commission of the alleged offence the relevant substance or article was in the same state as when the defendant purchased it.
- (3) The provisions are—
- (a) regulation 251 (compliance with standards specified in certain publications);
  - (b) regulations [<sup>F2</sup>268, 268A, 269 and 269A] (offences relating to packaging and package leaflets);
  - (c) regulation 273 (child resistant containers for regulated medicinal products); and
  - (d) regulation 275 (colouring of aspirin and paracetamol products for children).
- (4) A warranty is not to be a defence under this regulation unless, no later than three clear days before the date of the hearing, the defendant sends to the prosecutor, and to the person who gave the warranty to the defendant—
- (a) a copy of the warranty;
  - (b) a notice stating that the defendant intends to rely on it; and
  - (c) the name and address of the person from whom the defendant received the warranty.
- (5) Where the defendant is an employee of the person who purchased the substance or article under the warranty, the defendant is entitled to rely on the provisions of this regulation in the same way as the employer.

(6) The person by whom the warranty is alleged to have been given is entitled to appear at the hearing and to give evidence.

(7) The court may adjourn the hearing in order to enable a person to appear and give evidence in accordance with paragraph (6).

(8) For the purposes of this regulation, a name or description entered in an invoice is to be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description without contravening a provision mentioned in paragraph (3).

(9) In the application of this regulation and regulation 337 to Scotland, references to the defendant are to be construed as references to the accused.

#### Textual Amendments

**F2** Words in reg. 336(3)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZB** (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), [reg. 1](#), **Sch. 2 para. 183**)

#### Modifications etc. (not altering text)

**C1** Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), [reg 47\(1\)](#), [Sch. 9](#) (as substituted (14.8.2012) by [S.I. 2012/1916](#), [reg. 1\(2\)](#), [Sch. 34 paras. 57\(b\)](#), **64** (with [Sch. 32](#)))

### Offences in relation to warranties and certificates

**337.**—(1) It is an offence for a defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336 (3)—

- (a) intentionally to apply a warranty given in relation to one substance or article to a different substance or article; or
- (b) intentionally to apply to one substance or article a certificate issued under regulation 330 or paragraph 19 of Schedule 31 in relation to a sample of a different substance or article.

(2) A person who intentionally or recklessly gives a purchaser a false warranty certifying a matter specified in regulation 336(2)(a) is guilty of an offence.

(3) If the defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336(3) relies successfully on a warranty given to the defendant or to the defendant's employer, proceedings for an offence under paragraph (2) may be brought in accordance with paragraph (4).

(4) Proceedings may be brought, as the prosecutor chooses—

- (a) before a court which has jurisdiction in the place where a sample of the substance or article to which the warranty relates was taken; or
- (b) before a court which has jurisdiction in the place where the warranty was given.

(5) A person guilty of an offence under this regulation is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

**Modifications etc. (not altering text)**

- C1** Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by [S.I. 2012/1916](#), reg. 1(2), Sch. 34 paras. 57(b), [64](#) (with Sch. 32))

**Offences by bodies corporate and partnerships**

**338.**—(1) If an offence under these Regulations committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, an officer of the body corporate, or a person purporting to act as an officer of the body corporate, that officer or person (as well as the body corporate) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(2) If the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and omissions of a member in connection with the member's functions of management as it applies to an officer of the body corporate.

(3) If an offence under these Regulations is—

- (a) committed by a Scottish partnership; and
- (b) proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, a partner of the partnership,

the partner (as well as the partnership) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(4) In this regulation “officer” in relation to a body corporate means a director, secretary or other similar officer of the body corporate.

**Modifications etc. (not altering text)**

- C1** Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by [S.I. 2012/1916](#), reg. 1(2), Sch. 34 paras. 57(b), [64](#) (with Sch. 32))

*Prosecutions*

**Prosecutions**

**339.**—(1) A magistrates' court in England or Wales may try an information for an offence under these Regulations that is triable only summarily if the information was laid at any time within the period of twelve months beginning with the commission of the offence.

(2) Summary proceedings in Scotland for an offence triable only summarily under these Regulations may be commenced at any time within the period of twelve months beginning with the commission of the offence (and section 136(3) of the Criminal Procedure (Scotland) Act 1995 <sup>M1</sup> applies for the purposes of this paragraph as it applies for the purposes of that section).

(3) A magistrates' court in Northern Ireland may hear and determine a complaint for an offence punishable on summary conviction under these Regulations, other than an offence which is also triable on indictment, if the complaint was made at any time within the period of twelve months beginning with the commission of the offence.

(4) A body referred to in regulation 323(2) (enforcement in England, Wales and Scotland) may not institute proceedings for an offence under these Regulations in relation to a contravention of a provision which it may or must enforce by virtue of arrangements made under that regulation unless it has given no less than 28 days' notice of its intention to do so, together with a summary of the facts on which the charges are founded, to the Secretary of State.

(5) A district council (as defined in regulation 324 (enforcement in Northern Ireland)) may not institute proceedings for an offence under these Regulations in relation to a contravention of a provision which it may or must enforce by virtue of arrangements made under regulation 324(2) unless it has given no less than 28 days' notice of its intention to do so, together with a summary of the facts on which the charges are founded, to the Minister for Health, Social Services and Public Safety.

(6) A certificate of the Secretary of State or of the Minister for Health, Social Services and Public Safety that the requirements of paragraph (4) or, as the case may be, (5) have been complied with is to be conclusive evidence that the requirements have been complied with, and a document purporting to be such a certificate is to be presumed to be such a certificate unless the contrary is proved.

**Modifications etc. (not altering text)**

**C1** Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by [S.I. 2012/1916](#), reg. 1(2), Sch. 34 paras. 57(b), 64 (with Sch. 32))

**Marginal Citations**

**M1** 1995 c. 46.

*General*

**Presumptions**

**340.**—(1) Paragraph (2) applies for the purposes of proceedings under these Regulations for an offence consisting of offering a medicinal product for sale by retail in contravention of regulation 220 (sale or supply of products not subject to general sale) or 221 (sale or supply of products subject to general sale).

(2) If it is proved that the medicinal product in question was found on a vehicle from which medicinal products are sold, it is to be presumed, unless the contrary is proved, that the person in charge of the vehicle offered the medicinal product for sale.

(3) Paragraph (4) applies for the purposes of proceedings under these Regulations for an offence consisting of a contravention of a provision within paragraph (5), where it is proved that the medicinal product in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products.

(4) It is to be presumed, unless the contrary is proved, that the person charged possessed the medicinal product for the purpose of sale or supply.

(5) The provisions within this paragraph are regulations [<sup>F3</sup>268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)] and 276 (offences: requirements relating to child safety) to the extent that they establish an offence based on possession of a medicinal product for the purpose of sale or supply.

### Textual Amendments

- F3** Words in reg. 340(5) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZC** (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 183**)

### Decisions under these Regulations

**341.**—(1) Where the licensing authority notifies a person of a decision under these Regulations, it must—

- (a) state its reasons for the decision; and
- (b) inform the person of any action the person may take under these Regulations to challenge that decision and of the time for taking that action.

(2) Paragraph (1) is without prejudice to any other provision of these Regulations concerning notification by the licensing authority.

(3) The licensing authority must publicise any decision under these Regulations to which paragraph (4) applies in such manner as it thinks fit.

(4) Those decisions are—

- (a) a decision to grant or revoke a [<sup>F4</sup>UK] marketing authorisation;
- [<sup>F5</sup>(aa) a decision to grant or revoke an EU marketing authorisation;]
- (b) a decision to grant or revoke a certificate of registration; and
- (c) a decision to grant or revoke a traditional herbal registration.

### Textual Amendments

- F4** Word in reg. 341(4)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 224(a)** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 184**)
- F5** Reg. 341(4)(aa) inserted (31.12.2020) by S.I. 2019/775, **reg. 224(b)** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 184**)

### Time limits for provision of information etc

**342.**—(1) This regulation applies if—

- (a) by any provision of these Regulations a person is required to provide—
  - (i) any information or document to the licensing authority or to the Ministers, or
  - (ii) any assistance to the licensing authority or to the Ministers; and
- (b) no time is specified in that provision within which the obligation must be performed.

(2) The obligation must be performed within such time as may be specified in a written notice given to the person by the licensing authority or the Ministers (as the case may be).

### Service of documents

**343.**—(1) A notice or other document required or authorised by any provision of these Regulations to be served on a person, or to be given or sent to a person, may be served, given or sent—

- (a) by delivering it to the person;
- (b) by sending it by post to the person's usual or last known residence or place of business in the United Kingdom;
- (c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or by sending it by post to the secretary or clerk of the body corporate at that office; or
- (d) in the case of a Scottish partnership by delivering it to a partner or by sending it by post to the address of the principal office of the partnership; or
- (e) if the person consents in writing to the use of electronic communication, by a means of electronic communication.

(2) Where a notice or other document is sent by means of electronic communication it is treated for the purposes of these Regulations as received on the day on which it is sent, unless the contrary is proved.

**Modifications etc. (not altering text)**

**C2** Reg. 343 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by [S.I. 2012/1916](#), reg. 1(2), Sch. 34 paras. 57(b), 64 (with Sch. 32))

**Payment of expenses by Ministers**

**344.**—(1) If a person enforces a provision of these Regulations in accordance with functions conferred under Part 16 (enforcement), the relevant Minister must pay such amounts as the person may reasonably require in respect of expenses incurred in the course of enforcement.

(2) In paragraph (1) “the relevant Minister” means—

- (a) in relation to enforcement in England, Wales, and Scotland, the Secretary of State; and
- (b) in relation to enforcement in Northern Ireland, the Minister for Health, Social Services and Public Safety.

**[<sup>F6</sup>Modifications to deal with serious shortages**

**344A.**—(1) The Ministers may by regulations modify the application of any of the specified provisions in circumstances where the United Kingdom, or any part of the United Kingdom, is experiencing or may experience a serious shortage of medicinal products, or of medicinal products of a specified description, arising from the withdrawal of the United Kingdom from the European Union.

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that is being or may be experienced.

(3) For the purposes of paragraph (1), the “specified provisions” are the provisions of Parts 1, 3 to 5, 10 to 13 and 16, and of the associated Schedules.

(4) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where the withdrawal of the United Kingdom from the European Union is one but not the only significant factor contributing to the shortage.

(5) No regulations under paragraph (1) may be made, or have effect, after the end of the period of two years beginning with IP completion day.

### Textual Amendments

**F6** Regs. 344A, 344B inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **225** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 185**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Regulation making powers

- 344B.**—(1) Regulations made under a power in the regulations listed in paragraph (2)—
- (a) are to be made by statutory instrument;
  - (b) may make different provision for different purposes and different areas; and
  - (c) may include incidental, supplemental, consequential, transitional, transitory or saving provisions, including consequential amendments to these Regulations.
- (2) The regulations referred to in paragraph (1) are—
- (a) regulation B17(1) and (4) (good manufacturing practice);
  - (b) regulation 50(5A) (Annex I to the 2001 Directive);
  - (c) regulation 50G(5) (orphan criteria etc);
  - (d) regulations 59(3A) and 61(7A) (post-authorisation efficacy studies);
  - (e) regulation 65C(7) (variations of UK marketing authorisations);
  - (f) regulation 102(7) (homoeopathic medicinal products);
  - (g) regulation 205A(2) (further obligations in respect of pharmacovigilance activities);
  - (h) regulation 257E (certain forms of labelling); and
  - (i) regulation 344A (modifications to deal with serious shortages).
- (3) A statutory instrument containing regulations made under the powers listed in paragraph (2) is subject to annulment in pursuance of a resolution of either House of Parliament.]

### Textual Amendments

**F6** Regs. 344A, 344B inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **225** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 185**); 2020 c. 1, **Sch. 5 para. 1(1)**

### *Immunity from civil liability*

#### Immunity from civil liability

- 345.**—(1) This regulation applies where the licensing authority makes a recommendation or requirement to which paragraph (2) applies in response to the suspected or confirmed spread of—
- (a) pathogenic agents;
  - (b) toxins;
  - (c) chemical agents; or
  - (d) nuclear radiation,
- which may cause harm to human beings.
- (2) This paragraph applies to a recommendation or requirement—



- (a) for the use of a medicinal product without an authorisation; or
  - (b) for the use of a medicinal product with an authorisation, but for a therapeutic indication that is not permitted under the authorisation.
- (3) None of the following are to be subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement—
- (a) any holder of an authorisation for the product;
  - [<sup>F7</sup>(aa) if there is no holder of an authorisation for the product but the sale or supply of the product is authorised by the licensing authority on a temporary basis under regulation 174, the person responsible for placing the product on the market in the United Kingdom;]
  - (b) any manufacturer of the product;
  - (c) any officer, servant, employee or agent of a person within [<sup>F8</sup>sub-paragraph (a), (aa) or (b);]
  - (d) any health care professional[<sup>F9</sup>; or]
  - [<sup>F10</sup>(e) any person, not being a health care professional, who administers the product in accordance with a protocol of the type mentioned in regulation 247A.]
- (4) This regulation does not apply in relation to liability under section 2 (liability for defective products) of the Consumer Protection Act 1987<sup>M2</sup> or article 5 of the Consumer Protection (Northern Ireland) Order 1987<sup>M3</sup>.
- (5) In this regulation “authorisation” means a [<sup>F11</sup>UK marketing authorisation, EU marketing authorisation], certificate of registration, traditional herbal registration or Article 126a authorisation.

#### Textual Amendments

- F7** Reg. 345(3)(aa) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **29(a)** and reg. 345(3)(aa) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **29(a)**
- F8** Words in reg. 345(3)(c) substituted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **29(b)** and words in reg. 345(3)(c) substituted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **29(b)**
- F9** Word in reg. 345(3)(d) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **29(c)** and word in reg. 345(3)(d) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **29(c)**
- F10** Reg. 345(3)(e) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **29(d)** and inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **29(d)**
- F11** Words in reg. 345(5) substituted (31.12.2020) by [S.I. 2019/775](#), **reg. 226** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 186**)

#### Marginal Citations

- M2** [1987 c.43](#). Section 2(4) was repealed in relation to England and Wales by [S.I. 2000/2771](#) article 2(1) and (3) and in relation to Scotland by [S.S.I. 2001/265](#) article 2(1) and (3).
- M3** [S.I. 1987/2049 \(N.I. 20\)](#), as amended by [2001 c.13 \(NI\)](#).

**[<sup>F12</sup>Obligation on licensing authority to maintain list of medicinal products to which derogations have applied**

**345A.**—(1) The licensing authority must publish a list of medicinal products to which the derogations described in Articles 5a, 8(2a) and (2b), 18a, 20 (second paragraph), 40(1a) and (3a), 48(3) and 104(3) of the 2001 Directive have applied.

(2) The licensing authority must update the list referred to in paragraph (1) at least every six months.]

**Textual Amendments**

**F12** Reg. 345A inserted (17.5.2023) by [The Human Medicines \(Amendment\) Regulations 2023 \(S.I. 2023/437\)](#), regs. 1(1), 5

*Review*

**[<sup>F13</sup>Review**

**346.**—(1) The Secretary of State must from time to time carry out a review of the provisions listed in paragraph (2).

(2) Those provisions are—

(a) Chapters 1, 3 and 4 of Part 3;

(b) Parts 11 and 12A;

(c) regulations—

(i) [<sup>F14</sup>18(6)],

(ii) 20(1),

[<sup>F15</sup>(*ia*) 36(4) to (7),]

(iii) 37(4)(b), (5), (6), (11) and (12),

[<sup>F16</sup>(*ia*) 42(4) and (5),]

(iv) 43(5), (6)(a) [<sup>F17</sup>and (d)], 7(c)(iii) and (vii), (8) and (10) to (14),

[<sup>F18</sup>(*iva*) 43A,]

(v) 44(1) to (6),

(vi) 59,

(vii) 60(3)(b), (9) and (10),

(viii) 61,

(ix) 63,

(x) 64(4)(b), (d) and (e), (5)(a) and (6)(c),

(xi) 65(2),

(xii) 66(5) and (6),

(xiii) 68(2)(a) and (b), (5) and (12A),

(xiv) 69(2)(a) and (b), (5) and (10),

[<sup>F19</sup>(*xiva*) 73(5A) to (5C),]

(xv) 75(2)(b) and (c),

- (xvi) 76,
- (xvii) 79,
- [<sup>F20</sup>(xviii) 82(1)(c),]
- (xviii) 85,
- (xix) 86,
- <sup>F21</sup>(xix) . . . . .
- (xx) 97,
- (xxi) 105(3)(b),
- (xxii) 107(2),
- (xxiii) 108(5),
- (xxiv) 110(8A),
- [<sup>F22</sup>(xxiv) 113(3A),]
- (xxv) 115(2)(b) and (c),
- (xxvi) 132(2),
- (xxvii) 133(5) and (6),
- (xxviii) 135(10A),
- [<sup>F23</sup>(xxviii) 142(5A) to (5C),]
- [<sup>F24</sup>(xxviii) regulations 167A [<sup>F25</sup>to 167H],]
- [<sup>F26</sup>(xxviii) regulation 174A,]
- [<sup>F27</sup>(xxviii) 213(3),]
- [<sup>F28</sup>(xxviii) 214(5C) [<sup>F29</sup>and (5D)],]
- [<sup>F27</sup>(xxviii) 217A,]
- [<sup>F27</sup>(xxviii) 218(2)(b) and (c), (3) and (5),]
- [<sup>F30</sup>(xxviii) 219 and 219A,]
- [<sup>F31</sup>(xxviii) 223(3)(b),]
- [<sup>F32</sup>(xxviii) 226A,]
- [<sup>F33</sup>(xxviii) 228(2)(d)(iv),]
- [<sup>F34</sup>(xxviii) 229(1)(db) and (dc) [<sup>F35</sup>and (2)],
- [ 233(1)(a)(ivd) and (ive),]
- <sup>F36</sup>(xxviii)
- (xxviii) 234(2)(e),]
- [<sup>F37</sup>(xxviii) regulation 247A,]
- [<sup>F38</sup>(xxviii) 248(1)(a) and (2)(a),]
- [<sup>F39</sup>(xxviii) 255A to 255C,
- (xxviii) 257A,]
- (xxix) 266(4) and (5),
- (xxx) 327(2)(g) and insofar as the provision relates to active substances paragraphs (1)(c) (iii), (iv) and (viii), (2)(a) to (f), (3), (4) and (6),

- (xxxi) 330(1) and (2),
- (xxxii) 331, and
- (xxxiii) regulation 349 insofar as it repeals section 10(7) of the Medicines Act 1968; and
- (d) Schedules—
- (i) 5 paragraphs 1(1)(b) to (d), (2)(b) to (d), 3(11)(b)(vi) to (viii), 5(2)(f) to (h),
- <sup>F40</sup>(ia) . . . . .
- (ii) 7A,
- (iii) 8 paragraphs 9A, 12, 13, 19 and 23,
- (iv) 12 paragraph 21,
- <sup>F41</sup>(ivza) 16, Part 2 entries relating to “Public Health England” and “Public Health Agency” and Part 3 entries relating to “search and rescue operations”,]
- <sup>F42</sup>(iva) 17, Part 1 items 12 and 13, Part 2 items 4a, 11 and 12, <sup>F43</sup>Part 3 item 11,] Part 4 items 11 to 13 and Part 5 items 7a and 18 <sup>F44</sup>to 20],
- (ivaa) 23, paragraph 1(a)(vii) to <sup>F45</sup>(x),]
- <sup>F46</sup>(ivab) 24 paragraph 18A,]
- <sup>F47</sup>(ivb) 22, entries relating to “Public Health England”, “Public Health Agency” and “search and rescue operations”, and]
- (v) 27 paragraphs 14 and 15.
- (3) The Secretary of State must—
- (a) set out the conclusions of a review carried out in accordance with paragraph (1) in a report; and
- (b) publish the report.
- <sup>F48</sup>(4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how—
- (a) the 2001 Directive;
- (b) Directive 2010/84/EU of the European Parliament and of the Council of 15 October 2010 amending, as regards pharmacovigilance, [Directive 2001/83/EC](#) on the Community code relating to medicinal products for human use;
- (c) Article 11 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare;
- (d) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending [Directive 2001/83/EC](#) on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products; and
- (e) Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State,
- are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).]
- (5) The report must in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these Regulations that implement those Directives in relation to the subject matter of the provisions mentioned in paragraph (2)(a), (b), (c)(i) to <sup>F49</sup>(xxxii)] and (d);

- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (6) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
- (7) Reports under this regulation are afterwards to be published at intervals not exceeding five years.]

### Textual Amendments

- F13** Reg. 346 substituted (20.8.2013) by [The Human Medicines \(Amendment\) Regulations 2013 \(S.I. 2013/1855\)](#), regs. 1(1), **31**
- F14** Word in reg. 346(2)(c)(i) substituted (E.W.S.) (1.4.2016) by [The Human Medicines \(Amendment\) Regulations 2016 \(S.I. 2016/186\)](#), regs. 1, **15(2)(a)(i)** and word in reg. 346(2)(c)(i) substituted (N.I.) (1.4.2016) by [The Human Medicines \(Amendment\) Regulations 2016 \(S.R. 2016/407\)](#), regs. 1, **15(2)(a)(i)**
- F15** Reg. 346(2)(c)(iia) inserted (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.I. 2019/62\)](#), regs. 1, **16(a)(i)** and reg. 346(2)(c)(iia) inserted (N.I.) (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.R. 2019/10\)](#), regs. 1, **16(a)(i)**
- F16** Reg. 346(2)(c)(iiaa) inserted (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.I. 2019/62\)](#), regs. 1, **16(a)(ii)** and reg. 346(2)(c)(iiaa) inserted (N.I.) (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.R. 2019/10\)](#), regs. 1, **16(a)(ii)**
- F17** Words in reg. 346(2)(c)(iv) inserted (E.W.S.) (1.4.2016) by [The Human Medicines \(Amendment\) Regulations 2016 \(S.I. 2016/186\)](#), regs. 1, **15(2)(a)(ii)** and words in reg. 346(2)(c)(iv) inserted (N.I.) (1.4.2016) by [The Human Medicines \(Amendment\) Regulations 2016 \(S.R. 2016/407\)](#), regs. 1, **15(2)(a)(ii)**
- F18** Reg. 346(2)(c)(iva) inserted (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.I. 2019/62\)](#), regs. 1, **16(a)(iii)** and reg. 346(2)(c)(iva) inserted (N.I.) (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.R. 2019/10\)](#), regs. 1, **16(a)(iii)**
- F19** Reg. 346(2)(b)(xiva) inserted (11.11.2013) by [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2013 \(S.I. 2013/2593\)](#), regs. 1(2), **8**
- F20** Reg. 346(2)(b)(xviii) inserted (11.11.2013) by [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2013 \(S.I. 2013/2593\)](#), regs. 1(2), **8**
- F21** Reg. 346(2)(c)(xixa) omitted (31.12.2020) by virtue of [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **227(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 187(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F22** Reg. 346(2)(b)(xxiva) inserted (11.11.2013) by [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2013 \(S.I. 2013/2593\)](#), regs. 1(2), **8**
- F23** Reg. 346(2)(b)(xxviii) inserted (11.11.2013) by [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2013 \(S.I. 2013/2593\)](#), regs. 1(2), **8**
- F24** Reg. 346(2)(c)(xxviii) inserted (1.1.2022) by [The Human Medicines \(Amendment\) \(Supply to Northern Ireland\) Regulations 2021 \(S.I. 2021/1452\)](#), regs. 1(2), **23**
- F25** Words in reg. 346(2)(c)(xxviii) substituted (15.4.2022) by [The Human Medicines \(Amendments Relating to the Early Access to Medicines Scheme\) Regulations 2022 \(S.I. 2022/352\)](#), regs. 1(2), **11** (with reg. 19)
- F26** Reg. 346(2)(c)(xxviii) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **30(a)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **30(a)**
- F27** Reg. 346(2)(c)(xxviii)-(xxviii) inserted (E.W.S.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/490\)](#), regs. 1(2), **9(2)(a)** and reg. 346(2)(c)(xxviii)-

- (xxviii) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **9(2)(a)**
- F28** Reg. 346(2)(c)(xxviii) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(iii)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(iii)**
- F29** Words in reg. 346(2)(c)(xxviii) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **11(2)(a)(i)** and words in reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **11(2)(a)(i)**
- F30** Reg. 346(2)(c)(xxviii) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **8** and reg. 346(2)(c)(xxviii) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **8**
- F31** Reg. 346(2)(c)(xxviii) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(iv)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(iv)**
- F32** Reg. 346(2)(c)(xxviii) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(v)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(v)**
- F33** Reg. 346(2)(c)(xxviii) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **11(2)(a)(ii)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **11(2)(a)(ii)**
- F34** Reg. 346(2)(c)(xxviii) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **6(2)(a)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **6(2)(a)**
- F35** Words in reg. 346(2)(c)(xxviii) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(v)** and words in reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(v)**
- F36** Reg. 346(2)(c)(xxviii) inserted (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **9(2)(a)** and reg. 346(2)(c)(xxviii) inserted (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **9(2)(a)**
- F37** Reg. 346(2)(c)(xxviii) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **30(b)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **30(b)**
- F38** Reg. 346(2)(c)(xxviii) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(vi)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(vi)**
- F39** Reg. 346(2)(c)(xxviii) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(vi)** and reg. 346(2)(c)(xxviii) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(vi)**
- F40** Reg. 346(2)(d)(ia) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **227(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 187(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F41** Reg. 346(2)(d)(iv) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **6(2)(b)(i)** and reg. 346(2)(d)(iv) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **6(2)(b)(i)**
- F42** Reg. 346(2)(d)(iv) substituted for reg. 346(2)(d)(iv) (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(b)(i)** and reg. 346(2)(d)(iv)

- (ivaa) substituted for reg. 346(2)(d)(iva) (N.I.) (1.4.2016) by [The Human Medicines \(Amendment\) Regulations 2016 \(S.R. 2016/407\)](#), regs. 1, **15(2)(b)(i)**
- F43** Words in reg. 346(2)(d)(iva) inserted (1.10.2017) by [The Human Medicines \(Amendment\) Regulations 2017 \(S.I. 2017/715\)](#), regs. 1, **7** and words in reg. 346(2)(d)(iva) inserted (N.I.) (1.10.2017) by [The Human Medicines \(Amendment\) Regulations 2017 \(S.R. 2017/241\)](#), regs. 1, **7**
- F44** Words in reg. 346(2)(d)(iva) inserted (1.4.2018) by [The Human Medicines \(Amendment\) Regulations 2018 \(S.I. 2018/199\)](#), regs. 1, **11(2)(b)(i)** and words in reg. 346(2)(d)(iva) inserted (N.I.) (1.4.2018) by [The Human Medicines \(Amendment\) Regulations 2018 \(S.R. 2018/64\)](#), regs. 1, **11(2)(b)(i)**
- F45** Word in reg. 346(2)(d)(ivaa) substituted (1.4.2018) by [The Human Medicines \(Amendment\) Regulations 2018 \(S.I. 2018/199\)](#), regs. 1, **11(2)(b)(ii)** and word in reg. 346(2)(d)(ivaa) substituted (N.I.) (1.4.2018) by [The Human Medicines \(Amendment\) Regulations 2018 \(S.R. 2018/64\)](#), regs. 1, **11(2)(b)(ii)**
- F46** Reg. 346(2)(d)(ivab) inserted (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.I. 2019/62\)](#), regs. 1, **16(b)(ii)** and reg. 346(2)(d)(ivab) inserted (N.I.) (9.2.2019) by [The Human Medicines \(Amendment\) Regulations 2019 \(S.R. 2019/10\)](#), regs. 1, **16(b)(ii)**
- F47** Reg. 346(2)(d)(ivb) inserted (E.W.S.) (1.4.2015) by [The Human Medicines \(Amendment\) Regulations 2015 \(S.I. 2015/323\)](#), regs. 1, **6(2)(b)(iii)** and reg. 346(2)(d)(ivb) inserted (N.I.) (1.4.2015) by [The Human Medicines \(Amendment\) Regulations 2015 \(S.R. 2015/178\)](#), regs. 1, **6(2)(b)(iii)**
- F48** Reg. 346(4) substituted (E.W.S.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/490\)](#), regs. 1(2), **9(3)** and reg. 346(4) substituted (N.I.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.R. 2014/323\)](#), regs. 1(2), **9(3)**
- F49** Word in reg. 346(5)(a) substituted (E.W.S.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/490\)](#), regs. 1(2), **9(4)** and word in reg. 346(5)(a) substituted (N.I.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.R. 2014/323\)](#), regs. 1(2), **9(4)**

*Transitional provisions, savings, amendments, repeals and revocations*

**Transitional provisions and savings**

**347.** Schedule 32 contains transitional provisions and savings.

**[<sup>F50</sup>T** **Transitional provision in relation to EU exit**

**347A.** Schedule 33A contains transitional provision in relation to the EU Exit Regulations.]

**Textual Amendments**

**F50** [Reg. 347A](#) inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **228(1)**; 2020 c. 1, Sch. 5 para. 1(1)

**Amendments to existing law**

**348.** Schedule 34 contains amendments to existing law.

**Repeals and revocations**

**349.** Schedule 35 contains repeals and revocations.

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 17.