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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 14**

**Advertising**

**CHAPTER 3**

**Monitoring of Advertising**

*Scrutiny by Ministers*

**Requirement to provide copy advertisement**

**304.**—(1) The Ministers may give a notice in writing under paragraph (2) or (3) to any person appearing to them to be concerned or likely to be concerned with the publication of advertisements relating to medicinal products.

(2) A notice under this paragraph is a notice that requires the person to whom it is given to provide the Ministers within a specified period with a copy of any advertisement that, as at the date of service of the notice, the person has published or proposes to publish and that relates to—

- (a) a specified medicinal product; or
- (b) medicinal products of a specified class or description.

(3) A notice under this paragraph is a notice that requires the person to whom it is given to provide the Ministers with a copy of any advertisement that the person proposes to publish during a specified period and that relates to—

- (a) a specified medicinal product; or
- (b) medicinal products of a specified class or description.

(4) The period specified in a notice under paragraph (3) must not exceed 12 months.

(5) A notice under paragraph (3) must specify the number of days before the proposed publication date of any advertisement by which a copy of the advertisement must be provided to the Ministers.

(6) A notice under paragraph (3) may be withdrawn by the Ministers before the expiry of the specified period.

(7) A notice under paragraph (2) or (3) may require the person to whom it is given not to publish, or further publish, during a specified period any advertisement a copy of which the person is required by the notice to provide to the Ministers.

(8) A notice under paragraph (2) or (3) must give the Ministers' reasons for giving the notice and (if appropriate) for imposing a requirement under paragraph (7).

(9) In this regulation "specified" means specified in the notice.

### **Invitation to make representations about compatibility**

**305.**—(1) This regulation applies if, having considered an advertisement a copy of which is obtained by them pursuant to a notice given under regulation 304 or by some other means, the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2.

(2) The Ministers may give a notice in writing under this regulation to any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement.

(3) A notice under this regulation must—

- (a) state that the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2;
- (b) give the reasons why they are minded to make the determination;
- (c) state that the person to whom it is given may make written representations to the Ministers within the period of 21 days beginning immediately after the date of the notice as to why the advertisement is compatible with the prohibitions imposed by Chapter 2; and
- (d) refer to the action that may be taken by the Ministers under regulation 306.

(4) A notice under this regulation may require the person to whom it is given not to publish, or to cease to publish, the advertisement.

### **Decision about compatibility**

**306.**—(1) This regulation applies if the Ministers have given a notice under regulation 305 (“the original notice”) to a person.

(2) After the end of the period of 21 days referred to in that regulation, the Ministers must give a further notice in writing (“the new notice”) to that person of their determination whether the advertisement is compatible with the prohibitions imposed by Chapter 2.

(3) In making that determination, the Ministers must take account of any representations made in accordance with that regulation.

(4) If—

- (a) the Ministers make a determination that the advertisement is compatible with the prohibitions imposed by Chapter 2; and
- (b) the original notice imposed a requirement under regulation 305(4),

the new notice must provide that the requirement no longer applies.

(5) The following provisions apply if the Ministers make a determination that the advertisement is incompatible with the prohibitions imposed by Chapter 2.

(6) The new notice must give the Ministers’ reasons for the determination.

(7) If the original notice imposed a requirement under regulation 305(4), the new notice may provide—

- (a) that the requirement is to continue to apply; or
- (b) that the requirement no longer applies.

(8) If the original notice did not impose a requirement under regulation 305(4), the new notice may require the person to whom it is given not to publish, or to cease to publish, the advertisement.

### **Corrective statement**

**307.**—(1) This regulation applies if the new notice—

- (a) maintains the application of a requirement imposed under regulation 305(4) to cease to publish the advertisement that is the subject of the notice; or
  - (b) imposes a requirement to cease to publish that advertisement.
- (2) The new notice may require the person to whom it is given to publish—
- (a) the Ministers' reasons for making the determination that the advertisement was incompatible with the prohibitions imposed by Chapter 2, either in full or in part; and
  - (b) a corrective statement concerning the advertisement.
- (3) A requirement imposed under paragraph (2)—
- (a) must specify the time within which publication must take place; and
  - (b) may specify the form of publication.

### **Offences**

**308.**—(1) A person is guilty of an offence if that person fails to comply with a requirement imposed by a notice given to that person under—

- (a) regulation 304(2) or (3);
- (b) regulation 305(4) (including such a notice as maintained under regulation 306(7)); or
- (c) regulation 306(8).

(2) A person guilty of an offence under paragraph (1) is liable—

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

(3) A person is guilty of an offence if that person fails to comply with a requirement imposed on that person under regulation 307(2).

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

### *Complaints to Ministers*

#### **Complaints to Ministers: duty to consider**

**309.**—(1) This regulation applies if a person makes a complaint to the Ministers that an advertisement that has been published, or that is proposed to be published, is incompatible with the prohibitions imposed by Chapter 2.

(2) Subject to the following provisions of this regulation and to regulation 310, the Ministers must consider the complaint unless it appears to the Ministers to be frivolous or vexatious.

(3) The Ministers are not under any duty to consider a complaint if either OFCOM or a body that appears to the Ministers to be a self-regulatory body that deals with complaints about advertisements of the type in question is already dealing with the same complaint.

(4) If the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306) they—

- (a) may consider the complaint; but
- (b) are not under any duty to do so.

(5) If the complaint is one that OFCOM would be under a duty to consider if it had been made to OFCOM (see regulation 314) the Ministers must—

- (a) investigate the complaint; or
  - (b) seek the agreement of the complainant to the complaint being referred to OFCOM.
- (6) If, within a reasonable time of being approached by the Ministers, the complainant agrees to the complaint being referred to OFCOM the Ministers must refer the complaint to OFCOM.
- (7) If, within a reasonable time of being approached by the Ministers, the complainant does not agree to the referral of the complaint, the Ministers must consider the complaint.
- (8) The Ministers must also consider the complaint if, having referred it to OFCOM, OFCOM—
- (a) decides not to consider the complaint because it appears to OFCOM to be frivolous or vexatious; or
  - (b) fails to deal adequately with the complaint within a reasonable time of the referral being made.

### **Complaints to Ministers: power to refer**

- 310.**—(1) This regulation applies if—
- (a) a person (“the complainant”) makes a complaint within paragraph (2) to the Ministers that an advertisement that has been published, or that it is proposed be published, is incompatible with the prohibitions imposed by Chapter 2; and
  - (b) the complaint does not appear to the Ministers to be frivolous or vexatious.
- (2) A complaint is within this paragraph if—
- (a) it is a complaint that the advertisement contains material prohibited by any of regulations 286 to 290, but is not a complaint that OFCOM would be under a duty to consider if it had been made to OFCOM (see regulation 314); or
  - (b) it is a complaint that the advertisement is incompatible with any of the prohibitions imposed by regulations 294 to 300.
- (3) The Ministers may—
- (a) select a body that appears to them to be a self-regulatory body that deals with complaints about advertisements of the type in question (“the appropriate body”); and
  - (b) seek the agreement of the complainant to the complaint being referred to the appropriate body.
- (4) If within a reasonable time of being approached by the Ministers the complainant agrees to the complaint being referred to the appropriate body, the Ministers must refer the complaint to that body.
- (5) If within a reasonable time of being approached by the Ministers the complainant does not agree to the referral of the complaint, the Ministers must consider the complaint.
- (6) The Ministers must also consider the complaint if, having referred it to the appropriate body—
- (a) the appropriate body decides not to consider the complaint because it appears to the body to be frivolous or vexatious; or
  - (b) the Ministers think that the appropriate body has failed to deal adequately with the complaint within a reasonable time of the referral being made.
- (7) But if the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306)—
- (a) the duties in paragraphs (4) to (6) do not apply; and
  - (b) each of those paragraphs has effect as if it conferred a power on the Ministers to act as mentioned in that paragraph.

## *Injunctions*

### **Application for injunction**

**311.**—(1) This regulation applies—

- (a) if the Ministers consider that an advertisement that has been published, or that is proposed to be published, is incompatible with the prohibitions imposed by Chapter 2; and
- (b) whether or not a complaint has been made to the Ministers or to any other person.

(2) The Ministers may apply to the court for an injunction against any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement.

(3) On the making of an application under paragraph (2), the court may grant an injunction prohibiting the publication, or further publication, of the advertisement.

(4) An injunction granted under paragraph (3) may also prohibit the publication, or further publication, of any advertisement in similar terms or likely to convey a similar impression.

(5) The court may not refuse to grant an injunction for lack of evidence that—

- (a) the publication, or proposed publication, of the advertisement has given rise to loss or damage to any person; or
- (b) the person responsible for the advertisement intended it to be incompatible with the prohibitions imposed by Chapter 2 or failed to exercise proper care to prevent it from being so incompatible.

(6) The court must give its detailed reasons in writing for its decision to grant or refuse an injunction.

(7) Where the court grants an injunction, the Ministers must as soon as is reasonably practicable provide the following in writing to each person against whom the injunction has been granted—

- (a) the court's reasons for granting the injunction;
- (b) any remedy available in the court; and
- (c) the time limit to be met for any remedy to be available.

### **Application for injunction: accuracy of factual claim**

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

- (a) an application for an injunction is made under regulation 311; and
- (b) the advertisement in question makes a factual claim about the medicinal product to which it relates.

(2) The court may require any person appearing to it to be responsible for the advertisement to provide evidence as to the accuracy of the factual claim.

(3) The court may impose a requirement under paragraph (2)—

- (a) on the application of any party to the proceedings for the injunction; or
- (b) of its own motion.

(4) In deciding whether or not to impose a requirement under paragraph (2) the court must have regard to the interests of any person who would be subject to, or affected by, the requirement.

(5) A requirement imposed under paragraph (2) must specify the time within which the evidence must be provided.

(6) If the person on whom a requirement is imposed under paragraph (2) fails to comply with it the court may infer that the factual claim is inaccurate.

- (7) A person may fail to comply with a requirement imposed under paragraph (2) by—
- (a) not providing any evidence; or
  - (b) providing evidence that the court considers inadequate.

### **Grant of injunction: publication of decision and corrective statement**

**313.**—(1) This regulation applies if the court grants an injunction under regulation 311, other than an interim injunction, in respect of an advertisement that has been published.

(2) The Ministers may by notice in writing require any person against whom the injunction has been granted to publish—

- (a) all or part of the court’s decision; and
- (b) a corrective statement concerning the advertisement in respect of which the application for the injunction was made.

(3) A requirement imposed under paragraph (2)—

- (a) must specify the time within which publication must take place; and
- (b) may specify the form of publication.

(4) If a person (“P”) fails to comply with a requirement imposed under paragraph (2) the Ministers may certify that failure to the court and the court may enquire into the matter.

(5) If the court enquires into the matter it must as part of its enquiry—

- (a) hear any witnesses produced against or on behalf of P; and
- (b) consider any statement offered in P’s defence.

(6) If having conducted its enquiry the court is satisfied that P failed without reasonable excuse to comply with a requirement imposed under paragraph (2) it may deal with P as if P were in contempt of court.

### *Complaints to OFCOM*

#### **Complaints to OFCOM**

**314.**—(1) This regulation applies if OFCOM—

- (a) receives from a person a complaint that an advertisement that contains material prohibited by any of regulations 286 to 290 (“prohibited material”) has been included in—
  - (i) a licensed service, or
  - (ii) S4C Digital or a service provided by the Welsh Authority under section 205 of the Communications Act 2003(1) (“the 2003 Act”); or
- (b) has a complaint as described in sub-paragraph (a) referred to it by the Ministers under regulation 309(5) and (6).

(2) OFCOM must consider the complaint unless—

- (a) the complaint appears to it to be frivolous or vexatious; or
- (b) paragraph (3) applies.

(3) If the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306) OFCOM—

- (a) may consider the complaint; but

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(1) 2003 c.21.

- (b) is not subject to any duty to do so.
- (4) If, having considered the complaint, OFCOM considers that the advertisement contains prohibited material it may—
- (a) in the case of an advertisement that has been included in a licensed service, give to the person who is the holder of the licence in respect of that service a direction to exclude the advertisement from the licensed service; and
  - (b) in the case of an advertisement that has been included in S4C Digital or a service provided by the Welsh Authority under section 205 of the 2003 Act, give to the Welsh Authority a direction to exclude the advertisement from S4C Digital or the service provided under section 205 of the 2003 Act.
- (5) If OFCOM gives a direction under paragraph (4), it may also give a direction to the licence holder or (as the case may be) the Welsh Authority to exclude from the service any advertisement in similar terms or likely to convey a similar impression.
- (6) In deciding whether or not to exercise its power to give a direction under paragraph (4), OFCOM must disregard any lack of evidence that—
- (a) the publication of the advertisement has given rise to loss or damage to any person; or
  - (b) the person responsible for the advertisement intended it to be incompatible with the prohibitions imposed by Chapter 2 or failed to exercise proper care to prevent it from being so incompatible.
- (7) A direction given under this regulation to a licence holder is to be treated for the purposes of the 2003 Act as a direction with respect to a matter mentioned in section 325(5) of that Act.
- (8) A direction given under this regulation to the Welsh Authority is to be treated for the purposes of the Communications Act 2003 Act as a direction with respect to a matter mentioned in paragraph 14(2) of Schedule 12 to that Act.
- (9) If OFCOM gives a direction under this regulation, it must inform the licence holder or (as the case may be) the Welsh Authority in writing of its reasons for doing so.
- (10) In this regulation—
- “licensed service” means a service in respect of which OFCOM has granted a licence under Part 1 or 3 of the Broadcasting Act 1990(2) or Part 1 or 2 of the Broadcasting Act 1996(3);
  - “S4C Digital” means the television service provided in digital form and known as S4C Digital; and
  - “Welsh Authority” means the authority whose name is, by virtue of section 56(1) of the Broadcasting Act 1990(4), Sianel Pedwar Cymru.

### *General*

#### **Public interest etc**

**315.** In exercising the functions conferred on them by this Chapter, the Ministers, the court and OFCOM must have regard, in particular, to the public interest.

#### **Civil proceedings**

**316.** In exercising the functions conferred on them by this Chapter, the Ministers may institute civil proceedings in their own name.

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(2) 1990 c.42.

(3) 1996 c.55.

(4) Section 56(1) was amended by section 406(7) of and Schedule 19(1) to the Communications Act 2003.

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**Status:** *This is the original version (as it was originally made).*

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