STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 14

Advertising

CHAPTER 1

General

Interpretation

277.—(1) In this Part—

"court" means the High Court or, in Scotland, the Court of Session;

[[F1]"holder of a temporary authorisation" means, where there is in force in relation to a medicinal product an authorisation by the licensing authority on a temporary basis under regulation 174 (but not an authorisation, certificate or registration as mentioned in regulation **[**[F2]281(1)(a) to (e)**]**), the person who is responsible for placing that product on the market in the United Kingdom;**]**

"injunction" (except in regulation 313) includes an interim injunction;

"OFCOM" means the Office of Communications;

"person qualified to prescribe or supply medicinal products" includes—

(a) persons who, in the course of their profession or in the course of a business, may lawfully—

(i) prescribe medicinal products,

(ii) sell medicinal products by retail, or

(iii) supply medicinal products in circumstances corresponding to retail sale; and

(b) employees of such persons;

"publication", in relation to an advertisement, means the dissemination or issue of that advertisement—

(a) orally;

(b) in writing;

(c) by means of an electronic communications network within the meaning of the Communications Act 2003 [M1]; or

(d) in any other way,

and includes causing or procuring such publication by or on behalf of another person, and "publish" has a corresponding meaning.

(2) In the application of this Part to Scotland—

(a) references to an injunction are to be read as references to an interdict; and

(b) references to an interim injunction are to be read as references to an interim interdict.

Textual Amendments

F1 Words in reg. 277(1) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **16** and words in reg. 277(1) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **16**

F2 Words in reg. 277(1) substituted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **10** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **10**

Marginal Citations

M1 2003 c.21.

Functions of the Ministers

278. A function of the Ministers under this Part may be exercised by either of them acting alone or both of them acting jointly (and references in this Part to "the Ministers" are to be read accordingly).

CHAPTER 2

Requirements relating to advertising

General

Products without a marketing authorisation etc

[F3279.—(1) A person may not publish an advertisement in Great Britain for a medicinal product unless one of the following is in force for the product—

(a) a UKMA(GB) or UKMA(UK);

[F4(aa) an authorisation by the licensing authority on a temporary basis under regulation 174;**]**

(b) a COR(GB) or COR(UK); or

(c) a THR(GB) or THR(UK).

(2) A person may not publish an advertisement in Northern Ireland for a medicinal product unless one of the following is in force for the product—

(a) a UKMA(NI) or UKMA(UK);

[F5(aa) an authorisation by the licensing authority on a temporary basis under regulation 174;**]**

(b) a COR(NI) or COR(UK);

(c) a THR(NI) or THR(UK);

(d) an EU marketing authorisation; or

(e) an Article 126a authorisation.

(3) A person may not publish an advertisement in the whole United Kingdom for a medicinal product unless, in relation to that product—

(a) one of the authorisations or registrations specified in paragraph (1) is in force in Great Britain; and

(b) one of the authorisations or registrations specified in paragraph (2) is in force in Northern Ireland.**]**

Textual Amendments

F3 Reg. 279 substituted (31.12.2020) by S.I. 2019/775, **reg. 211** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 167**)

F4 Reg. 279(1)(aa) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **11(a)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350, regs. 1(3), **11(a)**

F5 Reg. 279(2)(aa) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **11(b)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **11(b)**

General principles

280.—(1) A person may not publish an advertisement for a medicinal product with a **[**F6UK marketing authorisation, EU marketing authorisation,**]** traditional herbal registration or Article 126a authorisation unless the advertisement complies with the particulars listed in the summary of the product characteristics.

[F7(1A) Where an advertisement mentioned in paragraph (1) relates to a product in relation to which there is a separate authorisation or registration in force in Great Britain and in Northern Ireland, it may not be published in the whole United Kingdom unless it complies with the particulars listed in the summary of the product characteristics in each of those authorisations or registrations (as the case may be).**]**

(2) A person may not publish an advertisement for a medicinal product unless the advertisement encourages the rational use of the product by presenting it objectively and without exaggerating its properties.

(3) A person may not publish an advertisement for a medicinal product that is misleading.

[F8(4) A person may not publish an advertisement for a medicinal product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174 (but not an authorisation, certificate or registration as mentioned in regulation **[**F9281(1)(a) to (e)**]**), unless it is published as part of a campaign that has been approved by the Ministers.**]**

Textual Amendments

F6 Words in reg. 280(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 212(a)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(b)**)

F7 Reg. 280(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 212(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(c)**)

F8 Reg. 280(4) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **18** and reg. 280(4) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **18**

F9 Words in reg. 280(4) substituted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs.

1(3), **12** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **12**

Duties of authorisation holders and registration holders

281.—(1) This regulation applies to a person who holds—

(a) a **[**F10UK**]** marketing authorisation for a medicinal product;

(b) a certificate of registration for a medicinal product;

(c) a traditional herbal registration for a medicinal product; F11...

(d) an Article 126a authorisation for a medicinal product **[**F12; or

(e) an EU marketing authorisation for a medicinal product.**]**

[F13(1A) Paragraphs (3) to (5) apply to the holder of a temporary authorisation in relation to a medicinal product.**]**

(2) The person must establish a scientific service to compile and collate all information relating to the product (whether received from medical sales representatives employed by that person or from any other source).

(3) The person must ensure that any medical sales representative who promotes the product is given sufficient training, and has sufficient scientific knowledge, to enable the representative to provide information about the product that is as precise and complete as possible.

(4) The person must retain—

(a) a sample of any advertisement for which the person is responsible relating to the product; and

(b) a statement indicating the persons to whom the advertisement is addressed, the method of its publication and the date when it was first published.

(5) The person must, if required to do so by notice given to the person by the Ministers, within the period specified in that notice—

(a) provide a copy of the sample and statement mentioned in paragraph (4) to the Ministers;

(b) supply such other information as the Ministers may request for the purposes of their functions under this Part; or

(c) provide such assistance as the Ministers may request for those purposes.

Textual Amendments

F10 Word in reg. 281(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **213(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Word in reg. 281(1)(c) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 213(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 169**)

F12 Reg. 281(1)(e) and word inserted (31.12.2020) by S.I. 2019/775, **reg. 213(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 169**)

F13 Reg. 281(1A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **19** and reg. 281(1A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **19**

Advertising to the public

Application of regulations 283 to 292

282. Regulations 283 (products for the purpose of inducing abortions) to 292 (exception for approved vaccination campaigns) apply to advertisements wholly or mainly directed at members of the public

Products for the purpose of inducing abortions

283. A person may not publish an advertisement that is likely to lead to the use of a medicinal product for the purpose of inducing an abortion.

Prescription only medicines

284.—(1) A person may not publish an advertisement that is likely to lead to the use of a prescription only medicine.

(2) This regulation is subject to **[**F14regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.) and**]** regulation 292 (exception for approved vaccination campaigns).

Textual Amendments

F14 Words in reg. 284(2) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **20** and words in reg. 284(2) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **20**

[F15Medicines with differing classification status in Great Britain and Northern Ireland

284A. In the case of a medicinal product for sale or supply in Great Britain where the product concerned is not a prescription only medicine in Great Britain but is either—

(a) a prescription only medicine in Northern Ireland; or

(b) not authorised for sale or supply in Northern Ireland,

any advertisement to the public must include a statement that the medicinal product is not available without a prescription, or is not available for sale or supply, in Northern Ireland (as the case may be).**]**

Textual Amendments

F15 Reg. 284A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **213A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 170**)

Narcotic and psychotropic substances

285.—(1) A person may not publish an advertisement relating to a medicinal product that—

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) contains a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

(2) This regulation is subject to **[**F16regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.) and**]** regulation 292 (exception for approved vaccination campaigns).

Textual Amendments

F16 Words in reg. 285(2) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **21** and words in reg. 285(2) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **21**

Material relating to diagnosis

286.—(1) A person may not publish an advertisement relating to a medicinal product that states, or implies, that a medical consultation or surgical operation is unnecessary.

(2) A person may not, in particular, publish an advertisement relating to a medicinal product that offers to provide a diagnosis or suggest a treatment by post or by means of an electronic communications network within the meaning of the Communications Act 2003.

(3) A person may not publish an advertisement relating to a medicinal product that might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.

Material about effects of medicinal product

287.—(1) A person may not publish an advertisement relating to a medicinal product that suggests that the effects of taking the medicinal product—

(a) are guaranteed;

(b) are better than or equivalent to those of another identifiable treatment or medicinal product; or

(c) are not accompanied by any adverse reaction.

(2) A person may not publish an advertisement relating to a medicinal product that uses in terms that are misleading or likely to cause alarm pictorial representations of—

(a) changes in the human body caused by disease or injury; or

(b) the action of the medicinal product on the human body.

(3) A person may not publish an advertisement relating to a medicinal product that refers in terms that are misleading or likely to cause alarm to claims of recovery.

(4) A person may not publish an advertisement relating to a medicinal product that suggests that—

(a) the health of a person who is not suffering from any disease or injury could be enhanced by taking the medicinal product; or

(b) the health of a person could be affected by not taking the medicinal product.

(5) Paragraph (4)(b) is subject to **[**F17regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.) and**]** regulation 292 (exception for approved vaccination campaigns).

Textual Amendments

F17 Words in reg. 287(5) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **22** and words in reg. 287(5) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **22**

Material about status of medicinal product

288. A person may not publish an advertisement relating to a medicinal product that suggests that—

(a) it is a foodstuff, cosmetic or other consumer product that is not a medicinal product; or

(b) its safety or efficacy is due to the fact that it is natural.

Recommendations by scientists etc

289. A person may not publish an advertisement relating to a medicinal product that refers to a recommendation by—

(a) scientists;

(b) health care professionals; or

(c) persons who because of their celebrity could encourage use of the medicinal product.

Advertisements directed at children

290. A person may not publish an advertisement relating to a medicinal product that contains any material that is directed principally at children.

Form and content of advertisement

291.—(1) A person may not publish an advertisement relating to a medicinal product unless it is presented so that—

(a) it is clear that it is an advertisement; and

(b) the product is clearly identified as a medicinal product.

(2) A person may not publish an advertisement relating to a medicinal product unless it includes—

(a) the name of the medicinal product;

(b) if the medicinal product contains only one active ingredient, the common name of the active ingredient;

(c) the information necessary for the correct use of the medicinal product; and

(d) an express and clear invitation to read carefully the instructions on the package or in the package leaflet (as the case may be).

(3) This regulation is subject to regulation 296 (exception for advertisements intended as a reminder).

(4) Paragraph (2) is subject to regulation 301 (advertisements for registered homoeopathic medicinal products).

[[F18](5) Paragraph (2)(d) is subject to regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.).**]**

Textual Amendments

F18 Reg. 291(5) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **23** and reg. 291(5) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **23**

[F19Campaigns relating to the suspected or confirmed spread of pathogenic agents etc.

291A.—(1) Regulations 284 (prescription only medicines), 285 (narcotic and psychotropic substances), 287(4)(b) (material about effects of a medicinal product) and 291(2)(d) (form and content of advertisement) do not apply to an advertisement as part of a campaign that—

(a) relates to the use of a medicinal product in response to the suspected or confirmed spread of—

(i) pathogenic agents,

(ii) toxins,

(iii) chemical agents, or

(iv) nuclear radiation; and

(b) has been approved by the Ministers.

(2) Before approving a campaign that relates to—

(a) all or any area of Scotland, the Ministers must consult the Scottish Ministers;

(b) all or any areas of Wales, the Ministers must consult the Welsh Ministers.**]**

Textual Amendments

F19 Reg. 291A inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **24** and reg. 291A inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **24**

Exception for approved vaccination campaigns

292. Regulations 284 (prescription only medicines), 285 (narcotic and psychotropic substances) and 287(4)(b) (material about effects of medicinal products) do not apply to an advertisement as part of a vaccination campaign that—

(a) relates to a medicinal product that is a vaccine or serum; and

(b) has been approved by the Ministers.

Prohibition of supply to the public for promotional purposes

Prohibition of supply to the public for promotional purposes

293.—**[**F20(1) The holder of **[**F21either a temporary authorisation or**]**—

(a) in the case of a medicinal product for sale or supply in Great Britain, a UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK); or

(b) in the case of a medicinal product for sale or supply in Northern Ireland, a UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation or Article 126a authorisation,

may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.**]**

(2) A person who carries on a medicines business may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.

(3) This regulation applies regardless of whether the promotional purpose is that of the seller or supplier or of a third party.

(4) In this regulation "medicines business" means a business that consists in whole or in part of manufacturing, selling or supplying medicinal products.

Textual Amendments

F20 Reg. 293(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 214** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 171**)

F21 Words in reg. 293(1) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **13** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **13**

Advertising to persons qualified to prescribe or supply etc

General requirements

294.—(1) This regulation applies to an advertisement that—

(a) relates to a medicinal product; and

(b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not publish an advertisement to which this regulation applies unless—

(a) subject to **[**F22paragraphs (2C) and (3),**]** it contains the particulars set out in paragraphs 1 to 8 of Schedule 30; and

(b) in the case of a written advertisement, it is in accordance with paragraph 9 of that Schedule.

[F23(2A) By way of an exception to paragraph (2), in the case of an advertisement that relates to a pharmacy medicine or a medicinal product subject to general sale, a person may publish the advertisement if it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30; and

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a website address that corresponds to that statement.

(2B) The website at the address mentioned in paragraph (2A)(c) must make available—

(a) the particulars set out in paragraphs 1 to 8 of Schedule 30; or

(b) a copy of the summary of the product characteristics.**]**

[F24(2C) Paragraph 1 of Schedule 30 does not apply in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174.**]**

(3) In the case of an advertisement that is not a written advertisement, those particulars may alternatively be made available in written form to all persons to whom the advertisement is made available.

(4) This regulation—

(a) does not apply to an advertisement to which regulation 295 (abbreviated advertisements) applies;

(b) does not apply to oral representations made by medical sales representatives to which regulation 299 (medical sales representatives) applies; and

(c) is subject to regulations 296 (exception for advertisements intended as a reminder) and 301 (advertisements for registered homoeopathic medicinal products).

[F25(5) In the case of an advertisement which relates to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.**]**

Textual Amendments

F22 Words in reg. 294(2)(a) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **26(2)** and words in reg. 294(2)(a) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **26(2)**

F23 Reg. 294(2A)(2B) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **24(2)** and reg. 294(2A)(2B) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **24(2)**

F24 Reg. 294(2C) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **26(3)** and reg. 294(2C) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **26(3)**

F25 Reg. 294(5) inserted (31.12.20200 by S.I. 2019/775, **reg. 214A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 172**)

Abbreviated advertisements

295.—(1) This regulation applies to an abbreviated advertisement that—

(a) relates to a medicinal product; and

(b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not issue an abbreviated advertisement to which this regulation applies unless it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply);

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a web site address that corresponds to that statement; and

[F26(d) the name and address of the holder **[**F27of either the temporary authorisation or**]**—

(i) in the case of a medicinal product for sale or supply in Great Britain, of the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK) for the medicinal product, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, the name and address of the holder of the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation, or Article 126a authorisation for the medicinal product,

or the business name and address of the part of the holder's business that is responsible for the sale or supply of the medicinal product.**]**

(3) The web site at the address mentioned in sub-paragraph (2)(c) must make available—

(a) the particulars set out in Schedule 30; or

(b) a copy of the summary of the product characteristics.

(4) In this regulation, "abbreviated advertisement" means an advertisement, other than a loose insert, that—

(a) does not exceed 420 square centimetres in size; and

(b) appears in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply medicinal products.

[F28(4A) In the application of this regulation to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.**]**

(5) This regulation is subject to regulation 301 (advertisements for registered homoeopathic medicinal products).

Textual Amendments

F26 Reg. 295(2)(d) substituted (31.12.2020) by S.I. 2019/775, **reg. 215(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**)

F27 Words in reg. 295(2)(d) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **14** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **14**

F28 Reg. 295(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 215(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**)

Exception for advertisements intended as a reminder

296. Regulations 291 (form and content of advertisement) and 294 (general requirements) do not apply to an advertisement relating to a medicinal product if the advertisement is intended solely as a reminder of the product and consists solely of—

(a) in the case of a product other than a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name or trademark; and

(b) in the case of a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name, invented name or trademark or the scientific name of the stock or stocks from which it is derived.

Written material accompanying promotions

297.—(1) A person may not as part of the promotion of a medicinal product send or deliver any written material to a person qualified to prescribe or supply medicinal products unless the material—

(a) **[**[F29]subject to paragraph (1A),**]** contains particulars in accordance with all the paragraphs of Schedule 30; and

(b) states the date on which it was drawn up or last revised.

[[F30](1A) Paragraph 1 of Schedule 30 does not apply in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174.**]**

(2) A person may not include any information in written material to which paragraph (1) applies unless it—

(a) is accurate;

(b) is up-to-date;

(c) can be verified; and

(d) is sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the product to which it relates.

(3) A person may not include any illustrative material in written material to which paragraph (1) applies unless—

(a) the illustrative material is accurately reproduced; and

(b) the written material indicates the precise source of the illustrative material.

(4) In this regulation "illustrative material" means a quotation, table or any other illustrative material taken from a medical journal or other scientific work.

Textual Amendments

F29 Words in reg. 297(1)(a) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **28(2)** and words in reg. 297(1)(a) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **28(2)**

F30 Reg. 297(1A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **28(3)** and reg. 297(1A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **28(3)**

Free samples for persons qualified to prescribe or supply medicinal products

298.—(1) A person ("the supplier") may not supply a free sample of a medicinal product to another person ("the recipient") unless the following conditions are met.

(2) Condition A is that the recipient—

(a) is qualified to prescribe medicinal products; and

(b) receives the sample for the purpose of acquiring experience in dealing with the product in question.

(3) Condition B is that the sample is supplied to the recipient—

(a) on an exceptional basis; and

(b) in response to a request from, and signed and dated by, the recipient.

(4) Condition C is that, taking the year in which the sample is supplied as a whole, only a limited number of samples of the product in question are supplied to the recipient in that year.

(5) Condition D is that the sample—

[F31(a) is no larger than the smallest presentation of the product that is available for sale—

(i) in the case of a medicinal product for sale or supply in Great Britain, in Great Britain, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, in Northern Ireland;**]**

(b) is marked "free medical sample – not for resale" or bears a similar description; and

(c) is accompanied by a copy of the summary of the product characteristics.

(6) Condition E is that the sample does not contain—

(a) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

(7) Condition F is that the supplier maintains an adequate system of control and accountability in relation to the supply of free samples.

Textual Amendments

F31 Reg. 298(5)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 215A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 174**)

Medical sales representatives

299.—(1) This regulation applies in relation to the promotion by a medical sales representative of medicinal products to persons qualified to prescribe or supply such products.

(2) During each visit for promotional purposes the representative must give to, or have available for, each person visited a copy of the summary of the product characteristics for each product promoted.

(3) The representative must report all information, with particular reference to any adverse reactions, that—

(a) is received from persons visited for promotional purposes; and

(b) relates to the use of a product promoted,

to the scientific service established in accordance with regulation 281(2) by the holder of the **[**[F32]UK marketing authorisation, EU marketing authorisation**]** certificate of registration, traditional herbal registration or Article 126a authorisation for the product.

Textual Amendments

F32 Words in reg. 299(3) substituted (31.12.2020) by S.I. 2019/775, **reg. 217** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 176**); 2020 c. 1, **Sch. 5 para. 1(1)**

Inducements and hospitality

300.—(1) A person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer, or promise any gift, pecuniary advantage or benefit unless it is—

(a) inexpensive; and

(b) relevant to the practice of medicine or pharmacy.

(2) A person may not provide hospitality at a meeting or event held for the purposes of the promotion of a medicinal product unless—

(a) the hospitality is strictly limited to the main purposes of the meeting or event; and

(b) the person to whom it is provided or offered is a health care professional.

(3) Nothing in this regulation shall prevent any person providing hospitality at an event held for purely professional or scientific purposes provided that—

(a) the hospitality is strictly limited to the main scientific objective of the event; and

(b) the person to whom it is provided or offered is a health care professional.

(4) A person qualified to prescribe or supply medicinal products may not solicit or accept any gift, pecuniary advantage, benefit or hospitality that is prohibited by this regulation.

(5) In this regulation "hospitality" includes—

(a) sponsorship of a person's attendance at a meeting or event; and

(b) the payment of travelling or accommodation expenses.

(6) This regulation does not apply in relation to measures or trade practices relating to prices, margins or discounts that were in existence on 1st January 1993.

Homoeopathic medicinal products

Advertisements for registered homoeopathic medicinal products

301.—(1) A person may not publish an advertisement relating to a homoeopathic medicinal product to which a certificate of registration relates unless the advertisement meets the following conditions.

(2) Condition A is that the advertisement does not mention any specific therapeutic indications.

(3) Condition B is that the advertisement does not contain any details other than those mentioned in Schedule 28 (labelling requirements for registrable homoeopathic medicinal products).

(4) Nothing in regulation 291(2) (form and content of advertisement), 294 (general requirements) or 295 (abbreviated advertisements) requires an advertisement relating to a homoeopathic medicinal product to which a certificate of registration relates to contain any detail not specified in Schedule 28.

Traditional herbal medicinal products

Advertisements for traditional herbal medicinal products

302. A person may not publish an advertisement relating to a herbal medicinal product to which a traditional herbal registration relates unless it contains—

(a) the words "Traditional herbal medicinal product for use in"; followed by

(b) a statement of one or more therapeutic indications for the product consistent with the terms of the registration; followed by

(c) the words "exclusively based on long standing use".

Offences

Offences

303.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Chapter.

(2) A breach of a provision in this Chapter includes any—

(a) contravention by any person of any prohibition in this Chapter; and

(b) failure by any person to comply with any requirement or obligation in this Chapter.

(3) A person guilty of an offence under this regulation other than one to which paragraph (4) applies 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.

(4) This paragraph applies to an offence consisting of a breach of—

(a) regulation 298(1) (free samples);

(b) regulation 299(2) or (3) (medical sales representatives); or

(c) regulation 300(4) (solicitation or acceptance of inducements or hospitality).

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

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—

[F33(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 and specify whether the incompatibility is insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland;**]**

(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

[F34(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

Textual Amendments

F33 Reg. 305(3)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 217A(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F34 Reg. 305(4)(a)-(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 217A(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

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 **[**F35and specify whether the incompatibility is insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

(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 **[**F36insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland**]**; and

(b) the original notice imposed a requirement under regulation 305(4),

the new notice must provide that the requirement no longer applies **[**F37 in Great Britain, Northern Ireland, or both Great Britain and Northern Ireland (as appropriate)**]**.

(5) The following provisions apply if the Ministers make a determination that the advertisement is incompatible with the prohibitions imposed by Chapter 2 **[**F38insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

(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 **[**F39,

and where that original notice related to both Great Britain and Northern Ireland, the new notice may be expressed to apply in relation to either of or both Great Britain and Northern Ireland**]**.

(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

[F40(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

Textual Amendments

F35 Reg. 306(2)(a)-(c) and words inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F36 Reg. 306(4)(a)(i)-(iii) and words inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(b)(i)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F37 Words in reg. 306(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(b)(ii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F38 Reg. 306(5)(a)-(c) and words inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(c)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F39 Words in reg. 306(7)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(d)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F40 Reg. 306(8)(a)-(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(e)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

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 **[**F41in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland**]**; or

(b) imposes a requirement to cease to publish that advertisement **[**F42in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland**]**.

(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 **[**F43in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

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.

Textual Amendments

F41 Reg. 307(1)(a)(i)-(iii) inserted (31.12.2020) by S.I. 2019/775, **reg. 217C(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F42 Reg. 307(1)(b)(i)-(iii) inserted (31.12.2020) by S.I. 2019/775, **reg. 217C(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F43 Reg. 307(2)(a)(i)-(iii) and words substituted for words (31.12.2020) by S.I. 2019/775, **reg. 217C(c)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

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 **[**F44Chapter 2 in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland; 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 **[**F45in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

as the case may be.**]**

(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.

Textual Amendments

F44 Reg. 311(1)(a)(i)-(iii) substituted for words in reg. 311(1)(a) (31.12.2020) by S.I. 2019/775, **reg. 217D(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F45 Reg. 311(3)(i)(iii) inserted (31.12.2020) by S.I. 2019/775, **reg. 217D(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

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 [M2] ("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

(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 [M3] or Part 1 or 2 of the Broadcasting Act 1996 [M4];

"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 [M5], Sianel Pedwar Cymru.

Marginal Citations

M2 2003 c.21.

M3 1990 c.42.

M4 1996 c.55.

M5 Section 56(1) was amended by section 406(7) of and Schedule 19(1) to the Communications Act 2003.

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.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
The Human Medicines Regulations 2012, PART 14 is up to date with all changes known to be in force on or before 20 August 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.