Statutory Document No. 2005/0294

Medicines Act 2003

MEDICINES (ADVERTISING) REGULATIONS 2005[1]

Approved by Tynwald: *17 January 2006*
Coming into Operation: *1 February 2006*

In exercise of the powers conferred on the Department of Health and Social Security by sections 15 and 52 of the Medicines Act 2003[1] and of all other enabling powers, the following Regulations are hereby made: -.

PART 1

GENERAL

1 Citation and Commencement

These Regulations may be cited as the Medicines (Advertising) Regulations 2005 and shall come into force on 1st February 2006.

2 Interpretation

(1) In these Regulations —

"the Act" means the Medicines Act 2003;

"abbreviated advertisement" means an advertisement, other than a loose insert, which does not exceed in size an area of 420 square centimetres, in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply relevant medicinal products;

"common name" in relation to a relevant medicinal product means the international non-proprietary name, or, if one does not exist, the usual common name;

"essential information compatible with the summary of product characteristics" means essential information compatible —

(a) with the summary of product characteristics, if there is one, or

(b) if there is no summary of product characteristics, with the data sheet;[2]

[1] 2003 c.4

"medicinal product for supply by prescription only" means a medicinal product of a description or falling within a class specified in any regulations made under section 2 of the Act;

"medicinal product on a general sale list" means a medicinal product of a description or falling within a class specified in any regulations made under section 2 of the Act;

"name" in relation to a medicinal product means the name given to the product which may be either an invented name or a common or scientific name, together with a trade mark or the name of the person responsible for marketing the product;

"pharmacy medicinal product" means a medicinal product which is neither a medicinal product for supply by prescription only nor a medicinal product on a general sale list;

"promotional aid" means a non-monetary gift made for a promotional purpose by a commercially interested party;

"reference material" includes entries which are in the form of, and limited to, a brief description of a medicinal product, its uses and any relevant contra-indications and warnings, appearing without charge in a publication consisting wholly or mainly of such entries where the publication is sent or delivered to persons qualified to prescribe or supply medicinal products by a person who is not a commercially interested party;

"registered homoeopathic medicinal product" [Revoked][3]

"registrable homoeopathic medicinal product" has the meaning given in the Human Medicines Regulations 2012 (of Parliament)[2];[4]

"summary of product characteristics" means the information required to accompany any application for a UK authorisation;

"temporary authorisation" means an authorisation granted by the UK licensing authority on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc.) of the Human Medicines Regulations 2012 (of Parliament)[3];[5]

"UK licensing authority" means either or both of the United Kingdom Secretary of State and the Minister for Health, Social Services and Public Safety responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under the Human Medicines Regulations 2012[4].[6]

(2) For the purposes of these Regulations, "advertisement" has the meaning assigned to it by section 17 of the Act, except that, in relation to a medicinal product —

[2] SI 2012/1916
[3] SI 2012/1916
[4] SI 2012/1916

(a) provided that it makes no product claim, reference material, a factual, informative statement or announcement, a trade catalogue or a price list shall not be taken to be an advertisement; and

(b) an advertisement includes a representation, and for the purposes of this paragraph, "representation" has the meaning assigned to it by section 17 of the Act, except that it does not include the making of a factual, informative statement or announcement which includes no product claim.

(3) In these Regulations, unless the context requires otherwise, a reference to a regulation, Part or Schedule is to that regulation in, Part of or Schedule to, these Regulations and any reference in a regulation or Schedule to a numbered paragraph is to the paragraph of that regulation or Schedule bearing that number.

PART 2

ADVERTISING- GENERAL

3 Prohibition of advertisements for unlicensed products

(1) Subject to paragraph (2), no person shall issue an advertisement relating to a medicinal product in respect of which no UK authorisation or temporary authorisation is in force.[7]

(2) This regulation shall not apply to any advertisement relating to a registrable homoeopathic medicinal product.[8]

4 Duties of UK authorisation holders

Any person who holds a UK authorisation or a temporary authorisation relating to a medicinal product which is to be promoted in the Island must —

(a) ensure that in relation to any such product which a medical sales representative promotes, that the representative is given adequate training and has sufficient scientific knowledge to enable him or her to provide as precise and complete information as possible about that product;

(b) whenever the Department requires, furnish it with the particulars of any advertisement or proposed advertisement for which the authorisation holder is responsible relating to that product, including particulars as to—

(i) the content and form, and

(ii) the method and first date of dissemination,

of the advertisement;

(c) ensure that, in relation to an advertisement for a medicinal product, any decision taken by the UK licensing authority or the Department is immediately and fully complied with.[9]

PART 3

ADVERTISING TO THE PUBLIC

5 Scope of Part 3

This Part, with the exception of regulation 12 (prohibition of supply of medicinal products to the public), applies only to advertisements wholly or mainly directed at members of the general public, and accordingly references in this Part to advertisements are to advertisements to which this Part applies.

6 Prohibition of advertisements referring to specified diseases

(1) Subject to paragraph (2) and to regulation 11, no person shall issue an advertisement which is likely to lead to the use of a medicinal product for the purpose of the treatment, prevention or diagnosis of any disease specified in, or any disease falling within a class of disease specified in Schedule 1.

(2) Paragraph (1) shall not be taken to prohibit a person from issuing an advertisement which is likely to lead to the use of a medicinal product

(a) for the purpose of the prevention of neural tube defects; and,

(b) for the purpose of the treatment of

(i) the symptoms of sprains and strains; or

(ii) the pain or stiffness of rheumatic or non-serious arthritic conditions.

(3) No person shall issue an advertisement which is likely to lead to the use of a medicinal product or any other medicinal product, substance or article for the purpose of inducing an abortion in women.

7 Prohibition of advertisements for medicinal products on prescription only

Subject to regulation 11 and regulation 11A, no person shall issue an advertisement which is likely to lead to the use of a medicinal product for supply by prescription only and which is subject to any of the restrictions imposed by section 2 of the Act.[10]

7A Prohibition of advertisements for medicinal products licensed on a

temporary basis

A person must not publish an advertisement for a medical product in relation to which there is in force a temporary authorisation (but not a UK authorisation) unless it is published as part of a campaign that has been approved by the Department.[11]

8 Prohibition of advertisements relating to certain medicinal products

Subject to regulation 11 and regulation 11A, no person shall issue an advertisement relating to any medicinal product which —

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention[5] (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 of 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).[12]

9 Prohibition of certain material in advertisements

(1) Subject to regulation 11 and regulation 11A, no person shall issue an advertisement relating to any medicinal product which contains any material which —

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by post, fax or telephone;

(b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product;

(c) suggests that health can be enhanced by taking the medicinal product;

(d) suggests that health could be affected by not taking the medicinal product;

(e) is directed exclusively or principally at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

[5] SI 1992/3271

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery;

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof; or

(l) mentions that the medicinal product has been granted a UK authorisation.[13]

(2) In this regulation, "fax" means the making of a facsimile copy of a document by the transmission of electronic signals.

10 Form and content of advertisements

(1) Subject to paragraph (2), no person shall issue an advertisement relating to a medicinal product unless that advertisement —

(a) is set out in such a way that it is clear that the message is an advertisement and so that the product is clearly identified as a medicinal product; and

(b) subject to regulation 22(2), includes the following —

(i) the name of the medicinal product;

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

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

(iv) an express and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be.

(1A) Paragraph (1)(b)(iv) is subject to regulation 11A.[14]

(2) This regulation shall not apply to an advertisement relating to a medicinal product which is on a promotional aid if. —

(a) the advertisement consists solely of the name of the product (or, in the case of a registrable homoeopathic medicinal product, the scientific name of the stock or stocks); and[15]

(b) the advertisement is intended solely as a reminder.

11 Exception for approved vaccination campaigns

The provisions of regulations 6(1), 7, 8 and 9(1)(d) shall not apply to any advertisement as part of a vaccination campaign relating to a medicinal product which is a vaccine or serum, provided that such campaign has been approved by the Department.

11A Campaigns relating to the suspected or confirmed spread of pathogenic agents etc.

Regulations 7 (prohibition of advertisements for medicinal products on prescription only), 8 (prohibition of advertisements relating to certain medicinal products), 9(1)(d) (prohibition of certain materials in advertisements) and 10(1)(b)(iv) (form and content of advertisements) 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 Department.[16]

12 Prohibition of supply of medicinal products to the public

No person —

(a) being the holder of a UK authorisation; or

(b) in the course of a business carried on by them and consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing;

shall sell or supply for a promotional purpose any unsolicited medicinal product to any member of the general public.

PART4

ADVERTISING ETC. TO HEALTH PROFESSIONALS

13 Scope of Part 4

(1) Subject to paragraph (2), this Part, with the exception of regulations 19, 20 and 21, applies only to advertisements wholly or mainly directed at persons qualified to prescribe or supply medicinal products, and accordingly references in this Part to advertisements are to advertisements to which this Part applies.

(2) Nothing in this Part has any effect in relation to veterinary surgeons or veterinary practitioners.

14 Advertisements to health professionals

(1) Subject to paragraphs (1A) and (2) and to regulations 17 and 22(2), no person shall issue an advertisement relating to a medicinal product unless such advertisement

(a) contains essential information compatible with the summary of product characteristics;

(b) contains the particulars set out in paragraphs 1 to 9 of Schedule 2; and

(c) is in accordance with paragraph 10 of Schedule 2.[17]

(1A) Despite paragraph (1)(b), paragraph 1 of Schedule 2 does not apply in the case of a medicinal product in relation to which there is a temporary authorisation in force.[18]

(2) This regulation shall not apply to an advertisement to which regulation 15 or 16 applies.

15 Audio-visual advertisements

(1) Subject to regulations 17 and 22(2), no person shall issue in a programme service or video recording any advertisement relating to a medicinal product which includes or shows any words, unless that advertisement —

(a) contains essential information compatible with the summary of product characteristics; and

(b) refers to the particulars contained in paragraphs 1 to 8 of Schedule 2.

(2) For the purposes of this regulation the particulars contained in Schedule 2 may (where appropriate) be supplied by way of written material made available to all persons to whom the advertisement is shown or sent as an alternative to being referred to in the advertisement.

(3) In this regulation, "programme service" has the meaning assigned to it in section 13(2) of the Broadcasting Act 1993[6].

16 Abbreviated advertisements

Subject to regulations 17 and 22(2), no person shall issue an abbreviated advertisement relating to a medicinal product unless such advertisement —

(a) contains essential information compatible with the summary of product characteristics;

[6] 1993c.12

(b) contains the particulars set out in Schedule 3, and any warning which the licensing authority has required in exercise of powers under Part 3 of the Act to be included in any advertisement relating to that medicinal product has been included.

17 Exception for promotional aids

The prohibitions and requirements imposed by regulations 14, 15 and 16 shall not apply to an advertisement relating to a medicinal product which is on a promotional aid it —

(a) the advertisement consists solely of the name of the product (or, in the case of a registrable homoeopathic medicinal product, the scientific name of the stock or stocks); and[19]

(b) the advertisement is intended solely as a reminder.

18 Written material accompanying promotions

(1) No person shall send or deliver to persons qualified to prescribe or supply medicinal products as part of the promotion of a medicinal product any written material relating to that product unless it —

(a) includes essential information compatible with the summary of product characteristics;

(b) contains the particulars specified in paragraph 3 of Schedule 2; and

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

(2) No person shall include any information in written material to which paragraph (1) applies which is not accurate, up-to-date, verifiable or sufficiently complete to enable the recipient to form his own opinion of the therapeutic value of the product to which the documentation relates.

(3) No person shall include in written material to which paragraph (1) applies any quotation, table or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and the precise sources of the information indicated.

19 Free samples

(1) This regulation applies only to the supply of a free sample of a medicinal product to a person who receives it for the purpose of acquiring experience in dealing with such a product.

(2) A person may supply a sample to which this regulation applies only —

(a) to a person qualified to prescribe medicinal products;

(b) if the sample is of a medicinal product which does not contain —

(i) 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

(ii) a substance which is listed in any of Schedules I to IV of 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); and

(c) in accordance with Schedule 4.

20 Medical sales representatives

(1) This regulation applies only to the activities of medical sales representatives who promote medicinal products to persons qualified to prescribe such products.

(2) In relation to any medicinal product which they promote, all medical sales representatives shall, during each visit, give to all persons whom they visit or have available for them a copy of the summary of product characteristics (or, if there is no summary of product characteristics, a copy of the data sheet) for each such product.

(3) In relation to the use of any medicinal product which they promote, all medical sales representatives shall forthwith report all information which they receive from persons whom they visit, including reports of any adverse reactions, to the UK authorisation holder.[20]

21 Inducements and hospitality

(1) Subject to paragraphs (2) and (4), where medicinal products are being promoted to persons qualified to prescribe or supply medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

(2) The provisions of paragraph (1) shall not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply medicinal products, provided that —

(a) such hospitality is reasonable in level;

(b) it is subordinate to the main scientific objective of the meeting; and

(c) it is offered only to health professionals.

(3) Subject to paragraph (4), no person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of medicinal products unless —

(a) such hospitality is reasonable in level;

(b) it is subordinate to the main purpose of the meeting or event; and

(c) the person to whom it is offered is a health professional.

(4) Nothing in this regulation shall affect measures or trade practices relating to prices, margins or discounts which were in existence before the coming into effect of these regulations.

(5) No person qualified to prescribe or supply medicinal products shall solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.

PART 5

REGISTRABLE HOMOEOPATHIC MEDICINAL PRODUCTS[21]

22 Advertisements for registrable homoeopathic medicinal product[22]

(1) No person shall issue an advertisement relating to a registrable homoeopathic medicinal product which —

(a) contains any details which are not specified in Schedule 5; or

(b) mentions any specific therapeutic indications.[23]

(2) Nothing in regulations 10(1)(b), 14(1), 15(1) or 16 shall be construed as requiring in an advertisement relating to a registrable homoeopathic medicinal product the inclusion of any detail which is not specified in Schedule 5.[24]

PART 6

OFFENCES

23 Offences

(1) Any person who contravenes regulations 3(1), 4, 6(1) or (3), 7, 8, 10(1), 14(1), 15(1), 16, 18(1), (2) or (3), 20(2) or (3), 21(1) or (3), or 22(l)(a) shall be guilty of an offence and shall be liable —

(a) on summary conviction, to a fine not exceeding £5,000;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(2) Any person who contravenes regulation 19 or 21(5) shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £5,000.

MADE 9 DECEMBER 2005

SCHEDULE 1

DISEASES IN RESPECT OF WHICH ADVERTISEMENTS TO THE PUBLIC ARE PROHIBITED

[Regulation 6]

Bone diseases

Cardiovascular diseases

Chronic insomnia

Diabetes and other metabolic diseases

Diseases of the liver, biliary system and pancreas

Endocrine diseases

Genetic disorders

Joint, rheumatic and collagen diseases

Malignant diseases

Psychiatric diseases

Serious disorders of the eye and ear

Serious gastrointestinal diseases

Serious infectious diseases including HIV-related diseases and tuberculosis

Serious neurological and muscular diseases

Serious renal diseases

Serious respiratory diseases

Serious skin disorders

Sexually transmitted diseases.

SCHEDULE 2

PARTICULARS TO BE CONTAINED IN ADVERTISEMENTS TO HEALTH PROFESSIONALS

[Regulations 14 and 15]

1. The UK authorisation number of the medicinal product.

2. The name and address of the holder of the UK authorisation or temporary authorisation which relates to the medicinal product or the business name and address of the part of his business that is responsible for its sale or supply.[25]

3. The supply classification of the medicinal product, specifying whether the product is a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.

4. The name of the product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.

5. One or more of the indications for the product consistent with the terms of the UK authorisation or, in the case of a product in relation to which there is a temporary authorisation in force, the indications for the medicinal product consistent with the recommendation or requirement of the UK licensing authority as to the use of that product.[26]

6. The entries or a succinct statement of the entries (if any) in the summary of the product characteristics, or in any equivalent summary published by the holder of a temporary authorisation, relating to —

   (a) adverse reactions, precautions and relevant contra-indications;

   (b) dosage and method of use so far as relevant to the indications shown in the advertisement; and

   (c) where this is not obvious, method of administration so far as relevant to those indications.[27]

7. [Revoked][28]

8. A warning issued by the licensing authority under Part II of the Act which is required to be included in advertisements.

9. The cost (excluding value added tax) of either a specified package of the medicinal product to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except that such cost may be omitted in the case of an advertisement inserted in a publication which is printed in the United Kingdom but with a circulation outside the United Kingdom of more than 15 per cent. of its total circulation.

10. The particulars contained in paragraphs 6, 7 and 8 shall be printed in a clear and legible manner and be placed in such a position in the advertisement that their relationship to the claims and indications for the product can readily be appreciated by the reader.

SCHEDULE 3

PARTICULARS TO BE CONTAINED IN ABBREVIATED ADVERTISEMENTS

[Regulation 16]

1. The name and address of the holder of the UK authorisation or temporary authorisation which relates to the medicinal product or the business name and address of the part of his business that is responsible for its sale or supply.[29]

2. The supply classification of the medicinal product, specifying whether the product is a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.

3. The name of the product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.

4. A form of words which clearly indicates that further information is available on request to the authorisation holder or in the summary of product characteristics, or, if there is no summary of product characteristics, the data sheet, relating to the product.

SCHEDULE 4

CONDITIONS FOR THE SUPPLY OF FREE SAMPLES

[Regulation 19]

1. Samples shall be supplied on an exceptional basis only.
2. A limited number only of samples of each product may be supplied in any one year and to any one recipient.
3. Samples shall be supplied only in response to a written request, signed and dated, from the recipient.
4. Suppliers of samples shall maintain an adequate system of control and accountability.
5. Every sample shall be no larger than the smallest presentation available for sale in the United Kingdom.
6. Every sample shall be marked "free medical sample-not for resale" or shall bear a similar description.
7. Every sample shall be accompanied by a copy of the summary of product characteristics (or, if there is no summary of product characteristics, a copy of the data sheet) for each such product.

SCHEDULE 5

PARTICULARS WHICH MAY BE CONTAINED IN ADVERTISEMENTS FOR REGISTRABLE HOMOEOPATHIC MEDICINAL PRODUCTS[30]

[Regulation 22]

1. The scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homoeopathic manufacturing procedure described therein for that stock or stocks.
2. The name and address of the holder of the certificate of registration and, where different, the name and address of the manufacturer.
3. The method of administration and, if necessary, route.
4. The expiry date of the product in clear terms (stating the month and year).
5. The pharmaceutical form.
6. The contents of the sales presentation.
7. Any special storage precautions.
8. Any special warning necessary for the product concerned.
9. The manufacturers batch number.
10. The registration number allocated by the licensing authority proceeded by the letters "HR" in capital letters.
11. The words "Homoeopathic medicinal product without approved therapeutic indications".
12. A warning advising the user to consult a doctor if the symptoms persist during the use of the product.

ENDNOTES

Table of Endnote References

[1] The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.
[2] Definition of "essential information compatible with the summary of product characteristics" amended by SD2019/0102.
[3] Definition of "registered homoeopathic medicinal product" revoked by SD2019/0102.
[4] Definition of "registerable homoeopathic medicinal product" inserted by SD2019/0102.
[5] Definition of "temporary authorisation" inserted by SD2020/0468.
[6] Definition of "UK licensing authority" inserted by SD2020/0468.
[7] Para (1) amended by SD2020/0468.
[8] Para (2) amended by SD2019/0102.
[9] Reg 4 substituted by SD2020/0468.
[10] Reg 7 amended by SD2020/0468.
[11] Reg 7A inserted by SD2020/0468.
[12] Reg 8 amended by SD2020/0468.
[13] Para (1) amended by SD2020/0468.
[14] Para (1A) inserted by SD2020/0468.
[15] Subpara (a) amended by SD2019/0102.
[16] Reg 11A inserted by SD2020/0468.
[17] Para (1) amended by SD2020/0468.
[18] Para (1A) inserted by SD2020/0468.
[19] Subpara (a) amended by SD2019/0102.
[20] Para (3) amended by SD2020/0468.
[21] Part 5 heading substituted by SD2019/0102.
[22] Reg 22 heading substituted by SD2019/0102.
[23] Para (1) amended by SD2019/0102.
[24] Para (2) amended by SD2019/0102.
[25] Para 2 amended by SD2020/0468.
[26] Para 5 amended by SD2020/0468.
[27] Para 6 substituted by SD2020/0468.
[28] Para 7 revoked by SD2020/0468.
[29] Para 1 amended by SD2020/0468.
[30] Sch 5 heading substituted by SD2019/0102.