STATUTORY INSTRUMENTS.

S.I. No. 541 of 2007

MEDICINAL PRODUCTS (CONTROL OF ADVERTISING) REGULATIONS 2007

(Prn. A7/1462)

S.I. No. 541 of 2007

MEDICINAL PRODUCTS (CONTROL OF ADVERTISING) REGULATIONS 2007

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S.I. No. 541 of 2007

MEDICINAL PRODUCTS (CONTROL OF ADVERTISING) REGULATIONS 2007

The Minister for Health and Children, in exercise of the powers conferred on her by section 32 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and as adapted by the Health (Alteration of Name of Department and Title of Minister) Order 1997 (S.I. No. 308 of 1997) and for the purpose of giving full effect to Titles VIII and VIIIa of Directive 2001/83/EC (as amended by Directive 2004/27/EC), hereby make the following regulations—

PART 1

GENERAL

Citation.

1. These Regulations may be cited as the Medicinal Products (Control of Advertising) Regulations 2007.

Commencement.

2. These Regulations shall come into operation on 23rd July 2007.

Revocations.

3. The Medical Preparations (Advertisement and Sale) Regulations 1958 (S.I. No. 135 of 1958), the Medical Preparations (Advertising) Regulations 1993 (S.I. No. 76 of 1993) and the Medical Preparations (Advertising) (Amendment) Regulations 1996 (S.I. No. 308 of 1996) are hereby revoked.

Interpretation.

4. (1) In these Regulations—

'2001 Directive' means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use[1] as amended by—

(*a*) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[2],

(*b*) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[3],

[1]OJ No. L. 311, 28.11.2001, p.67.
[2]OJ No. L. 33, 8.02.2003, p.30.
[3]OJ No. L. 159, 27.06.2003, p.46.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 31*st July*, 2007.

(*c*) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use[4], and

(*d*) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[5];

'advertising', in relation to a medicinal product, includes any form of door to door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and including in particular—

(*a*) the advertising of medicinal products to the general public;

(*b*) the advertising of medicinal products to persons qualified to prescribe or supply them;

(*c*) visits by medical sales representatives to persons qualified to prescribe medicinal products;

(*d*) the supply of samples of medicinal products;

(*e*) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;

(*f*) the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and

(*g*) the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith;

and cognate words shall be construed accordingly;

'Board' means the Irish Medicines Board established by section 3 of the Irish Medicines Board Act 1995;

'certificate of registration' means a certificate of registration which is for the time being in force and which has been granted by the Board under the Medicinal Product (Control of Placing on the Market) Regulations 2007 in respect of a homeopathic medicinal product;

'certificate of traditional-use registration' means a certificate of traditional-use registration which is for the time being in force and which has been granted by

[4]OJ No. L. 136, 30.4.2004, p.85.
[5]OJ No. L. 136, 30.4.2004, p.34.

the Board under the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a traditional herbal medicinal product;

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

'EEA Agreement' means the Agreement on the European Economic Area signed in Oporto on 2 May 1992 as adjusted by the Protocol to that Agreement done at Brussels on17 March 1993[6];

'EEA State' means a State which is a contracting party to the EEA Agreement;

'health professional' means a person of any of the following classes—

(i) registered medical practitioners,

(ii) registered dentists,

(iii) registered pharmacists,

(iv) registered nurses;

'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

'homeopathic medicinal product' means any medicinal product, which may contain a number of principles, prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in an EEA State. The term also includes anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method;

'international non-proprietary name' in relation to a medicinal product means the international non-proprietary name recommended by the World Health Organisation;

'marketing authorisation' means an authorisation which is for the time being in force and which has been granted by the Board in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) and includes a product authorisation, a parallel import licence, an authorisation granted by the Commission under Regulation (EEC) No. 2309/93[7] or Regulation (EC) No 726/2004[8] and an authorisation granted by the Board in accordance with Article 126a of the 2001 Directive;

'Minister' means the Minister for Health and Children;

[6]OJ No. L 1, 3.01.1994, p.572.
[7]OJ No. L.214, 24.8.1993, p.1
[8]OJ L 136, 30.4.2004, p. 1.

'misleading advertising' means any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor;

'name' in relation to a medicinal product, means the name given to the product which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder;

'parallel import licence' means a marketing authorisation, or a certificate of traditional-use registration, which is for the time being in force and which has been granted by the Board under the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a medicinal product which is imported into the State from another EEA state in accordance with the rules of Community law relating to parallel imports;

'product authorisation' means an authorisation which is for the time being in force and which has been granted in pursuance of the Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998);

'promotional aid' means a non-monetary gift, that is inexpensive, relevant to the practice of medicine or pharmacy, and is made for a promotional purpose by a commercially interested party;

'registered dentist' means a person registered in the register established under the Dentists Act 1985 (No. 9 of 1985);

'registered homeopathic medicinal product' means a homeopathic medicinal product which is the subject of a certificate of registration;

'registered medical practitioner' means a person registered in the register established under the Medical Practitioners Act 1978 (No. 4 of 1978);

'registered nurse' means a person registered in the register of nurses maintained by An Bord Altranais under section 27 of the Nurses Act 1985 (No. 18 of 1985);

'registered pharmacist' means a registered pharmaceutical chemist or a registered dispensing chemist and druggist, under the Pharmacy Acts 1875 to 1977;

'sale by wholesale' means sale or supply for the purposes of sale in the course of a business or for administration to patients in the course of a professional practice and cognate words shall be construed accordingly;

'summary of product characteristics' means the information required to accompany any application for a marketing authorisation or certificate of traditional-use registration by virtue of article 11 of the 2001 Directive.

(2) In these Regulations, unless the context otherwise requires—

(*a*) any reference to a Regulation or Schedule shall be construed as a reference to a Regulation contained in these Regulations or, as the case may be, to a Schedule thereto, and

(*b*) any reference in a Regulation, or a Schedule, to a paragraph shall be construed as a reference to a paragraph in that Regulation or Schedule and in a paragraph, any reference to a subparagraph shall be construed as a reference to a subparagraph in that paragraph.

(3) A word or expression which is used in these Regulations and which is also used in the 2001 Directive has, unless the context otherwise requires, the same meaning in these Regulations, as it has in that Directive.

Exemptions.

5. The provisions of these Regulations shall not apply to—

(*a*) the labelling of medicinal products and the accompanying package leaflets, where such labelling and package leaflets are in compliance with Regulation 16 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

(*b*) correspondence, which may be accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

(*c*) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;

(*d*) books, journals, periodicals and other publications that are imported into the State and which contain advertising which is not intended for or directed at persons resident in the State;

(*e*) information relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

PART 2

ADVERTISING GENERALLY

Prohibition on the advertisement of medicinal products that are not the subject of a marketing authorisation or certificate of traditional-use registration.

6. (1) A person shall not issue an advertisement in respect of a medicinal product unless such product is the subject of a marketing authorisation or certificate of traditional use registration.

(2) This Regulation shall not apply to any advertisement relating to a registered homeopathic medicinal product.

(3) This Regulation shall not apply until 30 April 2011 in the case of herbal medicinal products and homeopathic medicinal products on the market in the State on the date of coming into force of these Regulations.

Requirements as to the accuracy of advertisements.

7. A person shall not issue an advertisement in respect of a medicinal product unless—

(*a*) all parts of the advertisement comply with the particulars set out in the summary of product characteristics for the product;

(*b*) the advertisement encourages the rational use of the medicinal product by presenting it objectively and without exaggerating its properties; and

(*c*) the advertisement is not misleading.

PART 3

ADVERTISING TO THE PUBLIC

Scope of Part 3 of Regulations.

8. The provisions of this Part of the Regulations apply only to advertisements that are directed wholly or mainly at members of the general public and accordingly any references in this Part to advertisements are references to advertisements to which this Part applies.

Prohibition on the advertisement of prescription-only medicinal products.

9. A person shall not issue an advertisement in respect of any medicinal product which, by virtue of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) may not be sold except in accordance with a prescription.

Prohibition on the advertisement of certain other medicinal products.

10. A person shall not issue an advertisement in respect of any medicinal product which is a controlled drug under section 2 of the Misuse of Drugs Act 1977 (No. 12 of 1977).

Prohibition of certain material in advertisements.

11. (1) A person shall not issue an advertisement in respect of any medicinal product that contains 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 mail;

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

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

(*d*) suggests that the health of the subject 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 status, could encourage the consumption of medicinal products;

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

(*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.

(2) In this Regulation the term 'mail' includes post, telephone, e-mail and other electronic means of communication.

Form and content of advertisements.

12. (1) Without prejudice to the other provisions of this Part, and subject to paragraph (2), a person shall not issue an advertisement in respect of a medicinal product unless the advertisement—

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

(*b*) includes the following minimum information—

(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 the correct use of the medicinal product,

(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, and

(v) if it is a traditional herbal medicinal product, the following words "Traditional herbal medicinal product for use in" followed by a statement of one or more therapeutic indications for the product compatible with the terms of the certificate of traditional-use registration for that product, followed by the words "exclusively based upon long-standing use.".

(2) Notwithstanding paragraph (1)(*b*), only the information set out in the Schedule may be used in the advertising of a registered homeopathic medicinal product.

(3) This Regulation shall not apply to an advertisement, relating to a medicinal product, that is intended only as a reminder, if the advertisement consists solely of—

(*a*) the name of the product, or its international non-proprietary name, where such exists, or the trademark (or, in the case of a homeopathic medicinal product that is the subject of a certificate of registration, the scientific name of the stock or stocks or its invented name), and

(*b*) advice to read carefully the instructions on the leaflet contained within the package, or on the label, as the case may be.

Exception for approved vaccination campaign.

13. The provisions of Regulations 9 and 11(*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 Minister.

Prohibition of supply of medicinal products to the public for promotional purposes.

14. (1) A person to which this Regulation applies shall not sell or supply for promotional purposes any medicinal product to any member of the general public.

(2) The persons to which this Regulation applies are—

(*a*) a person being the holder of a marketing authorisation, a certificate of registration or a certificate of traditional-use registration, or a person acting on behalf of any such person; and

(*b*) a person who in the course of his or her business manufactures medicinal products, or who sells medicinal products by wholesale, whether or not any such activities form a significant part of his or her business, or a person acting on behalf of any such person.

PART 4

ADVERTISING TO PERSONS QUALIFIED TO PRESCRIBE OR SUPPLY

Scope of Part 4 of Regulations.

15. The provisions of this Part of the Regulations apply only to advertisements that are directed wholly or mainly at persons qualified to prescribe or supply medicinal products and accordingly any references in this Part to advertisements are references to advertisements to which this Part applies.

Restrictions on advertisements to persons qualified to prescribe or supply.

16. (1) Subject to Regulations 17 and 18, a person shall not issue an advertisement relating to a medicinal product unless such advertisement contains—

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

(*b*) 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;

(*c*) the classification for the sale or supply of the product;

(*d*) one or more of the indications for the use of the product compatible with the terms of the marketing authorisation, or certificate of traditional-use registration;

(*e*) a clear statement of the entries in the summary of product characteristics relating to adverse reactions, precautions and relevant contra-indications;

(*f*) a clear statement of the entries in the summary of product characteristics relating to the dosage and method of use relevant to the indications shown. The method of administration should be shown where this is not obvious;

(*g*) the name and address of the holder of the marketing authorisation, certificate of registration or certificate of traditional-use registration or the business name and address of the part of the business responsible for placing the medicinal product on the market;

(*h*) the marketing authorisation, certificate of registration or certificate of traditional-use registration number of the medicinal product; and

(*i*) if it is a traditional herbal medicinal product, the following words "Traditional herbal medicinal product for use in" followed by a statement of one or more therapeutic indications for the product compatible with the terms of the certificate of traditional-use registration for that product, followed by the words "exclusively based upon long-standing use.".

(2) The information contained in subparagraphs (*e*) and (*f*) of paragraph (1) 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.

Advertisements intended only as a reminder.

17. Subject to Regulation 18, a person shall not in respect of a medicinal product issue an abbreviated advertisement that is intended solely as a reminder, unless such advertisement contains—

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

(*b*) the name of the product, or its international non-proprietary name, where such exists, or the trademark;

(*c*) the classification for the sale or supply of the medicinal product;

(*d*) the name and address of the holder of the marketing authorisation, certificate of registration or certificate of traditional-use registration or the business name and address of the part of the business responsible for placing the medicinal product on the market;

(*e*) a statement which clearly indicates that further information is available on request to the holder of the authorisation or certificate, or in the summary of product characteristics relating to the product; and

(*f*) if it is a traditional herbal medicinal product, the following words "Traditional herbal medicinal product for use in" followed by a statement of one or more therapeutic indications for the product compatible with the terms of the certificate of traditional-use registration for that product, followed by the words "exclusively based upon long-standing use.".

Exemption for promotional aids.

18. The provisions of Regulations 16, and 17 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 its international non-proprietary name, where such exists, or the trademark (or in the case of a homeopathic medicinal product that is the subject of a certificate of registration, the scientific name of the stock or stocks or its invented name);

(*b*) the advertisement is intended solely as a reminder; and

(*c*) the promotional aid is intended for supply only to persons qualified to prescribe or supply medicinal products.

Written material accompanying promotions.

19. (1) A person shall not send or deliver to persons qualified to prescribe or supply medicinal products as part of a promotion of a medicinal product any written material relating to that product unless it includes as a minimum—

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

(*b*) the classification for the sale or supply of the medicinal product; and

(*c*) a statement showing the date on which the document was drawn up or last revised.

(2) A person shall not include any information in written material to which paragraph (1) applies which is not accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product to which the material relates.

(3) A person shall not include in written material to which paragraph (1) applies any quotation, tables 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 are indicated.

Medical sales representatives.

20. (1) Subject to Regulation 23, a medical sales representative who promotes medicinal products to persons qualified to prescribe or supply such products shall, during each visit, give to all such persons that he or she visits, or have available for them, a copy of the summary of product characteristics for each such product that he or she promotes.

(2) A medical sales representative shall, in relation to any medicinal product that he or she promotes, forthwith report, to the scientific service established in accordance with Regulation 24, any information about the use of such products, with particular reference to any adverse reactions reported by such persons in the course of such visits.

Inducements and hospitality.

21. (1) A person shall not, in the course of promoting medicinal products to persons qualified to prescribe or supply such products, 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) Notwithstanding the provisions of paragraph (1), a person may offer hospitality at sales promotion events or at other events for purely professional and scientific purposes, provided such hospitality—

(*a*) is reasonable in level,

(*b*) is strictly limited to the main purpose or scientific objective of the event, and

(*c*) is not extended to persons other than health professionals.

(3) A person qualified to prescribe or supply medicinal products shall not solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality, sponsorship, or any other inducement, where the provision of such is prohibited by paragraphs (1) and (2) of this Regulation.

(4) The provisions of this Regulation shall not prejudice the negotiation of prices, margins and discounts in the ordinary course of business provided such prices, margins and discounts are incorporated in the sales invoice as a consequence of such negotiation.

Free samples.

22. (1) A person shall not supply a free sample of a medicinal product to any person unless that person is qualified to prescribe such product, and in such case only where the following conditions are satisfied—

(*a*) such sample is provided on an exceptional basis only and for the purpose of acquiring experience in dealing with such a product;

(*b*) the number of such samples of each product that may be supplied to any one recipient in any one year shall be limited and in any case shall not exceed six in number;

(*c*) the supply of any such sample is made only in response to a written request, signed and dated, by the recipient;

(*d*) the supplier of such samples maintains an adequate system of control and accountability;

(*e*) each such sample is no larger than the smallest presentation of the product on the market;

(*f*) each such sample is marked "free medical sample — not for sale" or words to the like effect; and

(*g*) each such sample is accompanied by a copy of the summary of product characteristics for each such product.

(2) A person shall not supply a sample of a medicinal product which is a controlled drug under section 2 of the Misuse of Drugs Act 1977 or which is an antidepressant, hypnotic, sedative or tranquilliser.

Compendium of summaries of product characteristics.

23. (1) Subject to paragraphs (2) and (3), the provisions of Regulations 20(1) and 24(1)(*c*) shall not apply in respect of a medicinal product if—

(*a*) the summary of product characteristics in respect of such product has been included in a compendium or other such reference publication which has been delivered within the previous twelve months to the

class of health professional visited by the medical sales representatives in the advertising or promotion of such product; and

(*b*) the summary of product characteristics for such product has not been amended from that included in the aforementioned compendium or other such reference publication.

(2) This Regulation shall not apply to a medicinal product that has been placed on the market in the State for the first time during the period of twelve months after the date of the most recent publication of the compendium or other such publication referred to in paragraph (1).

(3) In this Regulation the expression "compendium or other such publication" shall include any electronic version of any such publication that is freely accessible by health professionals.

PART 5

DUTIES OF HOLDERS OF MARKETING AUTHORISATIONS, CERTIFICATES OF REGISTRATION AND CERTIFICATES OF TRADITIONAL-USE REGISTRATION

Duties.

24. (1) The holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration, in respect of a medicinal product he or she has placed on the market, shall—

(*a*) establish, within his undertaking, a scientific service to compile and collate all information, whether received from medical sales representatives employed by him or her or from any other source, relating to that product;

(*b*) ensure that, in relation to any such medicinal product which medical sales representatives promote, those medical sales representatives are given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about that product;

(*c*) subject to Regulation 23, ensure that any medical sales representative employed by him or her has available summaries of product characteristics for each medicinal product that he or she presents to health professionals and which may be supplied to such persons during visits;

(*d*) ensure that any such medical sales representative transmits to the scientific service such information about the use of the medicinal products that he or she advertises, with particular reference to any adverse reactions reported to such representative by the persons he or she visits;

(*e*) keep available a sample of all advertising emanating from his or her undertaking together with information indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;

(*f*) whenever requested by an officer of the Board, furnish particulars of any advertisement or proposed advertisement for which he or she is responsible relating to that product, including the samples, information and particulars referred to in sub-paragraph (*d*);

(*g*) ensure that, in relation to an advertisement relating to that medicinal product, any decision taken by the Board is immediately and fully complied with; and

(*h*) ensure that any advertising of medicinal products carried out by or on behalf of his or her undertaking conforms with the requirements of these Regulations.

(2) Where in the opinion of the Board the requirements in relation to the training and scientific knowledge referred to in paragraph (1)(*b*) are not being observed, the Board may specify the training and scientific knowledge so required.

PART 6

MONITORING AND SELF-REGULATION

Requirement for corrective advertising.

25. (1) A person who—

(*a*) has issued or displayed or caused to be issued or displayed, or

(*b*) proposes to issue or display or causes to be issued or displayed,

any advertisement which in the opinion of the Board is misleading shall, if so directed by the Board, ensure that such advertisement or proposed advertisement is withdrawn and he or she shall in the case of an advertisement which has been issued or displayed, if further directed by the Board, publish a corrective statement in a form and by a means acceptable to the Board.

(2) A person who has been convicted of an offence under section 32 of the Irish Medicines Board Act 1995 in relation to these Regulations, where the Court was satisfied that an advertisement was misleading, shall if so directed by the Court withdraw the advertisement and, if required by the Court, publish a corrective statement in a form and by a means acceptable to the Court.

(3) Any direction given under paragraph (1) shall state in detail the reasons on which it is based.

Approval of voluntary codes of advertising practice.

26. (1) The Minister may, for the purpose of facilitating the voluntary control of the advertising of medicinal products by self regulatory bodies, approve of any code of practice or any part of any code of practice for the purpose of providing practical guidance with respect to the requirements or prohibitions of any of the provisions of these Regulations, and he or she may withdraw any such approval.

(2) Where the Minister approves or withdraws approval as provided for in paragraph (1), he or she shall publish a notice to that effect in Iris Oifigiúil.

(3) The operation of any code of practice that may be approved under this Regulation shall be without prejudice to the provisions of sections 32A to 32F of the Act relating to enforcement of the provisions of these regulations by authorised officers.

SCHEDULE

(Regulation 12(2)).

PARTICULARS THAT MAY BE CONTAINED IN ADVERTISEMENTS FOR REGISTERED HOMEOPATHIC MEDICINAL PRODUCTS

1. The clear mention of the words "*homeopathic medicinal product*".

2. 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 homeopathic manufacturing procedure described for that stock or stocks and, where the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks may be supplemented by an invented name.

3. The name and address of the holder of the certificate of registration and, where different, the name and address of the manufacturer.

4. The method of administration and, if necessary, the route.

5. The expiry date of the product in clear terms, stating the month and year.

6. The pharmaceutical form.

7. The contents of the sales presentation.

8. Any special storage precautions.

9. Any special warning necessary for the product concerned.

10. The manufacturer's batch number.

11. The registration number allocated by the Board preceded by the letters "HoR".

12. The words "homeopathic medicinal product without approved therapeutic indications".

13. A warning advising the user to consult a doctor if the symptoms persist.

L.S.

GIVEN under the Official Seal,
20 July 2007

MARY HARNEY.
Minister for Health and Children.

EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation).

The main purpose of these Regulations is to implement TITLES VIII and VIIIa of Directive 2001/83/EC (as amended by Directive 2004/27/EC) relating to the advertising of medicinal products for human use. They cover advertising both to health professionals and to the general public.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
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