SUBSIDIARY LEGISLATION 458.32

MEDICINAL PRODUCTS (ADVERTISING) REGULATIONS

30th October, 2005

LEGAL NOTICE 380 of 2005.

Title and scope.

1. (1) The title of these regulations is the Medicinal Products (Advertising) Regulations.

(2) The scope of these regulations is to transpose Directive 2004/27/EC.

Interpretation.

2. In these regulations, unless the context otherwise requires:

"the Act" means the Medicines Act; Cap. 458.

"the advertising committee" means the advertising committee for medicinal products working within the Authority;

"the Authority" means the Medicines Authority established under article 4 of the Act;

"medicine" means a medicinal product;

"starter packs" means small packs for which a marketing authorisation has been granted, designed to provide sufficient medicine for a prescriber to initiate treatment in such circumstances where there might be undesirable or unavoidable delay in having a prescription dispensed, where immediate commencement of treatment is necessary, or where the prescriber feels that the use of such presentation is indicated in the interests of the patient.

Advertising.

3. (1) Advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote through any means or media the prescription, supply, sale or consumption of medicinal products.

(2) Such advertising shall in particular include:

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

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

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

(*d*) the supply of samples;

(*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, except when their intrinsic value is minimal;

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

products; and

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

(3) The provisions of subregulation (1) shall not include:

(*a*) the labelling and the accompanying package leaflets, which are subject to the provisions of the Act or any regulations made thereunder;

(*b*) correspondence, possibly 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 to such matters as pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;

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

Scope of advertising.

4. The advertising of a medicinal product shall -

(*a*) encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties;

(*b*) comply with the particulars listed in the summary of product characteristics of the medicinal product; and

(*c*) not be misleading.

Advertising criteria.

5. (1) It shall not be lawful to advertise medicinal products for which no marketing authorisation has been granted.

(2) It shall not be lawful to advertise to the general public medicinal products which -

(*a*) are available on medical prescription only, in accordance with the classification of medicinal products as defined in the Act or any regulations made thereunder;

(*b*) contain substances defined as psychotropic or narcotic under the First Schedule to the Dangerous Drugs Ordinance and the Third Schedule to the Medical and Kindred Professions Ordinance.

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(3) No medicinal products may be distributed directly to the public by the industry for promotional purposes:

Provided that the provisions of subregulation (2) shall not apply to vaccination campaigns when these are carried out by industry after having obtained the approval of the Licensing Authority:

Provided further that the prohibition referred to in subregulation (2) shall apply without prejudice to Article 14 of

Directive 89/552/EEC.

(4) Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use with the advice of the pharmacist, if necessary, but without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment.

(5) The Licensing Authority shall be entitled to ban advertising to the general public of medicinal products the cost of which may be reimbursed.

Method of advertising.

6. (1) Without prejudice to regulation 5, all advertising to the general public of a medicinal product shall:

(*a*) be 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*) include the following minimum information:

(i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;

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

(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

(2) The advertising of a medicinal product to the general public may, notwithstanding subregulation (1), include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark if it is intended solely as a reminder and takes place by means of the use of promotional aids.

Excluded material in advertising.

7. The advertising of a medicinal product to the general public shall not contain 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 mail, internet or any other means;

(*b*) suggests that the effects of taking the medicine 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 medicine;

(*d*) suggests that the health of the subject could be affected by not taking the medicine provided that this shall not apply to the vaccination campaigns referred to in regulation 5;

(*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;

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

(*i*) could, 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.

Advertising material to persons qualified to prescribe.

8. Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

(*a*) essential information compatible with the summary of product characteristics which shall include:

(i) the trade name;

(ii) a list of active ingredients;

(iii) the pharmaceutical form;

(iv) major indications for use;

(v) the dosage and method of use;

(vi) side effects, warnings, precautions and contraindications;

(vii) the name and address of the marketing authorization holder;

(*b*) the supply classification of the medicinal product.

The advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraphs (*a*) and (*b*), include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark if it is intended solely as a reminder and takes place by means of the use of promotional aids.

Minimum information on documents.

9. (1) Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include, as a minimum, the particulars listed in regulation 8 and shall state the date on which it was drawn up or last revised.

(2) All the information contained in the documentation referred to in subregulation (1) shall be 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 concerned.

(3) Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in subregulation (1), shall be faithfully

reproduced and the precise sources indicated.

No gifts, or pecuniary advantages or benefits in kind.

10. (1) Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy:

Provided that this shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality shall always be strictly limited to the main scientific objective of the event; it must not be extended to persons other than health-care professionals.

(2) Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than health-care professionals.

(3) Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under subregulation (1) or contrary to subregulation (2):

Provided that existing measures or trade practices relating to prices, profit margins and discounts shall not be affected.

Free samples.

11. (1) Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(*a*) the number of samples for each medicinal product each year on prescription shall be limited;

(*b*) any supply of samples shall be in response to a written request, to be signed and dated, from the prescribing agent;

(*c*) persons supplying samples shall maintain an adequate system of control and accountability;

(*d*) each sample shall be no larger than the smallest presentation on the market;

(*e*) each sample shall be marked "free medical sample - not for sale" or shall show some other wording having the same meaning;

(*f*) each sample shall be accompanied by a copy of the summary of product characteristics;

(*g*) no samples of medicinal products containing psychotropic or narcotic substances as defined under the First Schedule to the Dangerous Drugs Ordinance and the Third Schedule to the Medical and Kindred Professions Ordinance, may be supplied.

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(2) Without prejudice to subregulation (1), samples of medicinal products classified in terms of article 29(2) of the Act as being medicinal products that can only be prescribed by a specific class of prescriber shall only be distributed to such class of prescribers.

(3) Starter packs shall not be regarded as samples and shall not

be labelled as such.

Sales representatives.

12. (1) Medical sales representatives shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicinal products which they promote.

(2) During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together with details of the price.

(3) Medical sales representatives shall transmit to the scientific service referred to in regulation 13 any information about the use of the medicinal products they advertise, with particular reference to any adverse reactions reported to them by the persons they visit.

Marketing authorisation holder.

13. (1) The marketing authorisation holder shall establish, within his undertaking, a scientific service in charge of information about the medicinal products which he places on the market.

(2) The marketing authorisation holder shall:

(*a*) keep available for, or communicate to, the advertising committee for medicinal products, a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;

(*b*) ensure that advertising of medicinal products by his undertaking conforms to the requirements of these regulations;

(*c*) verify that medical sales representatives employed by his undertaking have been adequately trained and that they fulfill the obligations imposed upon them by regulation 12(2) and (3);

(*d*) supply the advertising committee with the information and assistance it requires to carry out its responsibilities;

(*e*) ensure that the decisions taken and conditions imposed by the advertising committee are immediately and fully complied with.

(3) It shall be lawful for the market authorization holder and one or more companies nominated by him to co-promote a medicinal product.

Advertising of homeopathic medicinal products.
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14. Advertising of homeopathic medicinal products referred to in regulation 10(3) of the Medicines (Marketing Authorisation) Regulations shall be subject to the provisions of these regulations except regulation 5(1), provided that only the information specified in regulation 13(2) of the Medicinal Products (Labelling and Packaging) Regulations may be used in the advertising of such medicinal products.

Advertising Committee.

15. (1) There shall be established, within the Authority, an Advertising Committee made up of appropriately qualified staff as determined by the Chief Executive Officer of the Authority.

(2) The Advertising Committee shall be responsible for advertising issues which include:

(*a*) the offering of advice and information on advertising issues;

(*b*) the issuing of conditions and guidelines on advertising;

(*c*) the monitoring of advertisements of medicinal products;

(*d*) the investigation of cases suspected of breaching these regulations or any guidelines as may be issued by the Authority, including complaints made by the public.