

Guide to Advertising Compliance

SUR-G0025-4
12 AUGUST 2017

This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.



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1 INTRODUCTION

The advertising of human medicinal products

1 INTRODUCTION

in Ireland is regulated by the Health Products Regulatory Authority (HPRA).

This document ~~gives~~provides guidance on the regulation of the advertising ~~compliance of~~human medicinal products.

This guide does not apply to the advertising of veterinary medicinal products. The competent authority for the advertising of veterinary medicines in Ireland is the Department of Agriculture, Food and the Marine.

This guide does not apply to the advertising of medical devices. Any medical device being advertised must have a CE mark and such advertisements must comply with the Advertising Standards Authority for Ireland's Code of Standards for Advertising and Marketing Communications in Ireland.

2 LEGAL BASIS

The legal basis for the requirements for the advertising of human medicinal products in the European Union are set out in Directive 2001/83/EC of the *Community Code relating to medicinal products for human use*. The relevant provisions from the directive have been transposed into Irish law by the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007).

~~Further clarification on any issue can be obtained by contacting the Compliance department at compliance@hpra.ie.~~

2 LEGISLATION AND REGULATION OF ADVERTISING COMPLIANCE

3 DEFINITION OF MEDICINAL PRODUCT ADVERTISING

As per the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007):

“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;¹¹

Any activity which is designed, in full or in part, to promote the prescription, supply, sale or consumption of a medicinal product, constitutes advertising and is therefore subject to the provisions of these Regulations.

4 EXEMPTIONS

As per Regulation 5 of S.I. No. 541 of 2007, the Regulations do 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 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.

Trade catalogues and price lists are exempt from S.I. No. 541 of 2007 provided that they do not include any medicinal claims about the product. Advertising of wholesale discounts and prices available is considered by the HPRA to be part of business practice and does not constitute advertising.

Health/disease awareness campaigns are exempt from S.I. No. 541 of 2007 provided there is no reference, even indirectly, to medicinal products. Active pharmaceutical ingredients should not normally be named in disease awareness campaigns unless the mention of an active would be unlikely to lead to the identification of a specific medicinal product.

Patient information booklets are normally considered to be factual, informative literature relating to the diagnosed disease or the medicine. When the booklet is intended to be non-promotional, the party responsible for generating it should ensure that the booklet design and content does not constitute advertising of a medicinal product.

Sending a copy of the product information leaflet to pharmacists does not constitute advertising. It is acceptable to furnish those qualified to prescribe or supply with information about a product as long as the information is factual and up-to-date and in compliance with the marketing authorisation of the product. Any accompanying items or literature that are promotional in nature should comply with S.I. No. 541 of 2007.

45 TYPES OF MEDICINES THAT MAY BE ADVERTISED

All categories of authorised human medicinal products may be advertised. ~~There are restrictions in place regarding those at whom advertising is aimed.~~

It is prohibited to advertise medicinal products that are not the subject of a marketing authorisation or certificate of traditional-use registration in Ireland. As unauthorised (unlicensed) medicinal products do not have a marketing authorisation, they cannot legally be advertised.

In the case of exempt medicinal products, it is not permitted to advertise or make any representations of those products with the exception of a statement containing only the following information: the product's trade name, pack size, price and dose, as per the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) 2009 (S.I. No. 2 of 2009).

There are restrictions in place regarding those at whom advertising is aimed:

- Prescription-only medicines, controlled drugs and certain pack sizes of non-prescription medicines may not be advertised to the public.
- All categories of authorised human medicinal products may be advertised to those qualified to prescribe or supply.

- ~~Details of~~ any restrictions ~~that may be~~ placed on the advertising of ~~a~~ human medicinal ~~products~~~~product~~ are ~~detailed~~~~contained~~ in the marketing authorisation for the product.

4.1 — Irish legislation

~~The advertising of human~~Information on the promotion status of the product (i.e. whether it may be promoted to the general public or to healthcare professionals only) is publicly available for each authorised medicinal product on the HPRA website.

5.1 Advertising of over-the-counter codeine-containing medicinal products

~~As codeine is a controlled substance, codeine-containing medicines may only be advertised to healthcare professionals. This is reflected in the conditions attached to the marketing authorisations for the relevant products-is governed by, regardless of the prescription status of the medicines. Regulation 10 of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No., S.I. No. 541 of 2007, also prohibits the advertising of controlled drugs to members of the public. Note that codeine-containing medicines may not be advertised to sales assistants/counter staff or other persons working in pharmacies who are not health professionals as per the definition of health professionals in the regulations. Those regulations define a health professional as a person of any of the following classes: 541 of 2007).~~

~~Medical devices do not fall under S.I. No. 541 of 2007. Any medical device being advertised must have a CE mark and such advertisements must comply with the Advertising Standards Authority for Ireland's Code of Standards for Advertising, Promotional and Direct Marketing in Ireland. For more details please see the Advertising Standards Authority for Ireland website.~~

~~The advertising of human medicinal products is regulated by the Health Products Regulatory Authority (HPRA).~~

4.2 — Pharmacy-generated advertising

~~The HPRA monitors advertising generated by companies who hold marketing authorisations for products. This may include promotions in pharmacy that have been supplied by the marketing authorisation holder (promotional stands, shelf wobblers etc.)~~

~~The Pharmaceutical Society of Ireland monitors advertising generated by the pharmacy itself. This may include the pharmacy's website (where applicable), pharmacy generated posters etc.~~

4.3 — Unlicensed medicines

~~Unlicensed medicinal products do not have a marketing authorisation and therefore cannot be legally advertised.~~

~~It is not permitted to advertise or make any representations in respect of exempt (unauthorised) medicinal products in Ireland with the exception of a statement of trade name, pack size, price and dose (ref: Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) 2009 (S.I. No. 2 of 2009)).~~

~~(a) Wholesaler/supplier mailings~~

~~Trade catalogues and price lists are exempt from S.I. No. 541 of 2007 provided that they do not include any medicinal claims about the product. Advertising of wholesale discounts and prices available is considered by the HPRA to be part of business practice and does not constitute advertising.~~

4.4 Pre-review of advertising materials

The HPRA does not routinely pre-review advertising materials before their use, but reserves the right to pre-review advertisements in certain cases.

(i) registered medical practitioners.

(ii) registered dentists.

(iii) registered pharmacists.

(iv) registered nurses.

6 ACCURACY OF ADVERTISEMENTS

As per Regulation 7(a), a person shall not issue an advertisement in respect of a medicinal product unless all parts of the advertisement comply with the particulars set out in the summary of product characteristics for the product.

All parts of an advertisement (for example, any taglines, imagery, claims, abbreviated prescribing information presented within it) must be in line with the information set out in the product's SmPC, and amended as required in accordance with the marketing authorisation.

As per Regulation 7(b), a person shall not issue an advertisement in respect of a medicinal product unless the advertisement encourages the rational use of the medicinal product by presenting it objectively and without exaggerating its properties.

It is important that an advertisement presents a balanced view of the benefits and risks of a medicine.

As per Regulation 7(c), a person shall not issue an advertisement in respect of a medicinal product unless the advertisement is not misleading.

Careful consideration should be taken when designing and updating advertisements to ensure the advertisements fully comply with the above regulation.

5 — GENERAL INFORMATION ON THE CONTENT OF ADVERTISEMENTS

67 3.1 — GENERAL

The information that must be included in an advertisement is dependent on whether an advertisement is aimed at the public or at those qualified to prescribe or supply medicinal products. Part 3 of the Regulations sets out the provisions for advertising to the public and Part 4 sets out the provisions for advertising to persons qualified to prescribe or supply medicinal products.

3.2 — Types of advertisements

Advertisements aimed at the public or at those qualified to supply medicinal products may be classified as full advertisements, ~~as~~ reminder advertisements, or as promotional aids. Note that the term 'full advertisement' is not referred to in the legislation, but ~~it is a convenient term used to use as it helps to help~~ differentiate between normal advertisements and advertisements intended to act as a reminder. ~~Note also that promotional aids are a type of advertisement intended for supply to persons entitled to prescribe or supply medicinal products. They are not intended to be supplied to the general public.~~

7.1 General information on advertisements aimed at the public

As outlined above, Part 3 of the Regulations sets out the provisions for advertising medicines to the public.

Regulation 12(1)(b) in Part 3 of S.I. No. 541 of 2007 requires that information necessary for the correct use of the medicinal product is included in all full advertisements to the public. This requirement is interpreted to mean that one or more indications for use of the product should be presented in the advertisement.

Note that there is no requirement in S.I. No. 541 of 2007 for product claims in advertisements aimed at the general public to be supported by documented references within the advertisement. However, all medicinal claims should be capable of substantiation and details must be provided to the HPRA if requested.

3.3 — Reminder advertisement requirements

A reminder advertisement aimed at the public must contain only the information set out in Regulation 12(3) of S.I. No. 541 of 2007. ~~This means that a reminder advertisement~~ ~~it~~ should consist solely of the product name/INN/trademark and ~~the~~ advice to read carefully the instructions on the leaflet contained within the package, or on the label. Medicinal claims or information on the approved indications should not be present in such reminder advertisements.

~~A reminder advertisement aimed at those qualified to prescribe or supply medicinal products must contain the information set out in Regulation 17 of S.I. No. 541 of 2007. The inclusion of medicinal claims or information on the approved indications of the medicinal product may render an advertisement to be a full advertisement. A full advertisement must contain the information set out in Regulation 16 of the Regulations. Any additional information, other than the information set out in Regulation 16, must be referenced within the advertisement and should be capable of substantiation.~~

~~3.4 — Product claims~~ In relation to non-medicinal claims (e.g. that the product is the number one selling brand in Ireland), the HPRA considers that all such claims should be adequately substantiated. Non-medicinal claims are regulated by the Advertising Standards Authority of Ireland (ASAI).

In relation to comparative statements made in full advertisements aimed at the general public

~~There is no requirement in S.I. No. 541 of 2007 for product claims in full advertisements aimed at the general public to be supported by documented references within the advertisement. However, all medicinal claims should be capable of substantiation and details must be provided to the HPRA if requested.~~

3.5 — Comparative statements in full advertisements aimed at the general public

~~Regulation 11(1)(b) relates to the use of comparative statements in full advertisements aimed at the general public. It (b) prohibits any advertisement for a medicinal product that is aimed at the general public from making suggestions suggesting that the product is better than, or equivalent to, another named medicinal product or another treatment. Category claims such as 'works faster than standard tablets' are not prohibited in such advertisements if the product's SmPC fully supports the claim, for example, by having a similar comparative statement within it.~~

3.6 — Non-medicinal claims

~~Non-medicinal claims (e.g. that the product is the number one selling brand in Ireland) are regulated by the Advertising Standards Authority of Ireland (ASAI). The HPRA considers that all such claims should be adequately substantiated. For further details please see the Advertising Standards Authority for Ireland website.~~

71 — 3.7 — APPROVAL BY A MEDICAL DOCTOR

~~There is no requirement in S.I. No. 541 of 2007 for advertising materials to be approved by a medical doctor. However, adequate medical oversight should be applied to all advertisements making medicinal claims.~~

3.8 — ‘Information necessary for the correct use of the medicinal product’

~~Regulation 12 (1)(b) in Part 3 S.I. No. 541 of 2007 requires that information necessary for the correct use of the medicinal product is included in all full advertisements to the public. This requirement is interpreted to mean that one or more indications for use of the product should be presented in the advertisement and that there is an express and legible invitation to always read the label/leaflet.~~

3.9 — ‘Essential information’

~~Essential information to be included in an advertisement refers to the information listed in parts (b) to (i) of Regulation 16 (1) (for full advertisements aimed at persons qualified to prescribe or supply) and to parts (b) to (f) of Regulation 17 (for reminder advertisements aimed at persons qualified to prescribe or supply).~~

3.10 — Product pack pictures

At present there is no restriction within S.I. No. 541 of 2007 on the inclusion of illustrations/pictures of the product pack in advertisements aimed at the general public. However, it is the preference of the HPRA that the smallest available pack size should be illustrated.

7.2 General information on advertisements aimed at those qualified to prescribe or supply

Part 4 sets out the provisions for advertising medicines to healthcare professionals.

Essential information to be included in an advertisement refers to the information listed in parts (b) to (i) of Regulation 16

3.11 — Promotional aids

S.I. No. 541 of 2007 defines (1) (for full advertisements aimed at persons qualified to prescribe or supply) and to parts (b) to (f) of Regulation 17 (for reminder advertisements aimed at persons qualified to prescribe or supply).

In relation to reminder advertisements aimed at such persons, advertisements must contain the information set out in Regulation 17 of S.I. No. 541 of 2007. The advertisement’s **only** purpose must be to remind the viewer of the existence of the product. The approved indications, as per the SmPC, may be included. Promotional statements may not be included.

Statements that are auxiliary to what is stated in the SmPC and auxiliary to the other approved product information (e.g. the package leaflet, the outer carton, etc.) **should not** be included in reminder advertisements. They may render the advertisement to be a *full* advertisement. Examples of such auxiliary statements include 'powerful pain relief' or 'gets to work fast'. A full advertisement must contain the information set out in Regulation 16.

A promotional aid is defined as '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'. Regulation 18 indicates that a promotional aid:

- consists solely of the name of the product, INN, or 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);
- is intended solely as a reminder; and
- is intended for supply only to persons qualified to prescribe or supply medicinal products.

Promotional aids are normally ~~such~~ items such as pens, notebooks, sticky-notes, etc.

~~Although~~ The Regulations do not address supplying promotional aids to the general public ~~with promotional aids, the legal definition of a promotional aid indicates that promotional aids. They are only to be given~~ addressed in the context of their supply to persons qualified to prescribe or supply ~~Therefore medicinal products. It is considered by HPRA that~~ a promotional aid **should not** be supplied to the general public.

8 GENERAL INFORMATION ON THE RESPONSIBILITIES OF A SCIENTIFIC SERVICE WITH RESPECT TO ADVERTISING

There is no requirement in S.I. No. 541 of 2007 for advertising materials to be approved by a medical doctor. However, adequate medical oversight should be applied to all advertisements making medicinal claims.

8 PATIENT INFORMATION

8.1 Patient information booklets

~~Patient information booklets are normally considered to be factual and informative literature relating to the diagnosed disease or information relating to the medicine. When the booklet is designed to be non-promotional, the party responsible for generating it should ensure that the booklet does not constitute advertising of a medicinal product.~~

8.2 Sending pharmacists the product information leaflet

~~Sending a copy of the product information leaflet to pharmacists constitutes advertising. It is acceptable to furnish those qualified to prescribe or supply with information about a product as~~

~~long as the information is factual and up to date and in compliance with the marketing authorisation of the product. Any accompanying items or literature that are promotional in nature should comply with S.I. No. 541 of 2007.~~

8.3 — Health/disease awareness campaigns

8.1 ~~Health/disease awareness campaigns are exempt from S.I. No. 541 of 2007 provided there is no reference, even indirect, to medicinal products. Active pharmaceutical ingredients should not normally be named in disease awareness campaigns unless the mention of an active would not lead to the identification of a specific medicinal product.~~ Training of non-healthcare professional staff on codeine-containing medicines in pharmacies (or other settings) given by Marketing Authorisation Holders (MAH) or their sales representatives

Such training/educational activities are not addressed in the Medicinal Products (Control of Advertising) Regulations, S.I. No. 541 of 2007; however, the HPRA considers that it is inappropriate for sales representatives and other sales-related staff from MAHs to be involved in the provision of such training/education to non-health professional staff, given that their role is predominantly promotional in nature, with a focus on sales.

9 RECORD-KEEPING

9.1 — Records on the distribution of free medicinal samples

~~The~~The HPRA recommends that records of superseded/out of date/unused advertising materials should be kept for a **minimum of three years after they have ceased to be used.** These records can be stored either electronically or in hard copy.

In relation to documentation relating to free medicinal product samples distributed to those qualified to prescribe ~~or supply,~~ the HPRA recommends records should be kept for a **minimum of one year after the expiration of the batch of product provided.**

10 INFORMATION ON HPRA ACTIVITIES WITH RESPECT TO ADVERTISING AND HOW TO CONTACT THE HPRA

The HPRA carries out surveillance work to ensure that advertisements are accurate, in line with the approved product information and are not misleading. The HPRA does not routinely review advertising materials before their use, but reserves the right to review advertisements in certain cases.

9.2 — In relation to the advertising of medicines by retail pharmacy businesses, the Pharmaceutical Society of Ireland monitors advertising generated by pharmacies

themselves. This may include a pharmacy's website (where applicable), pharmacy generated posters, etc. The HPRA monitors advertising generated by companies who hold marketing authorisations for products. Records of unused/out of date/superseded advertising materials

~~The HPRA recommends that copies should be kept for a minimum of three years after they have ceased to be used. These copies can be stored either electronically or in hard copy.~~

10 — REPORTING AND COMPLAINTS

10.1 — Non-compliant advertising

~~To report suspected non-compliant advertising please contact the HPRA by e-mail at This may include promotions in-pharmacy that have been supplied by the marketing authorisation holder (promotional stands, shelf-wobblers, etc.).~~

~~The HPRA responds to advertising-related queries and complaints from patients, healthcare professionals, marketing authorisation holders and others. The HPRA also performs inspections at MAH premises to check that the marketing and advertising activities for medicines are compliant with the provisions of S.I. No. 541 of 2007.~~

10.2 — Further clarification on any issue can be obtained by contacting the advertising compliance team at compliance@hpra.ie, or by telephone at +353-1-676 4971. **Complaints**

~~To submit a complaint relating to an advertisement of a medicine, please or relating to a suspected non-compliant advertising activity may also be reported to the HPRA using the above contact the HPRA by e-mail at compliance@hpra.ie or by telephone at +353-1-676 4971.details.~~