

Guide to **Advertising Compliance**



1 INTRODUCTION

This document gives guidance on the regulation of advertising compliance.

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

2 LEGISLATION AND REGULATION OF ADVERTISING COMPLIANCE

2.1 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;”

2.2 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.
- 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.
- Any restrictions that may be placed on the advertising of human medicinal products are detailed in the marketing authorisation for the product.

2.3 Irish legislation

The advertising of human medicinal products is governed by Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 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).

2.4 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.

2.5 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)).

2.6 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.

2.7 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.

3 CONTENT OF ADVERTISEMENTS

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 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 to use as it helps to 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.

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 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 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 prohibits any advertisement for a medicinal product that is aimed at the general public from making suggestions 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](#).

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.

3.11 Promotional aids

S.I. No. 541 of 2007 defines a promotional aid 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'. Promotional aids are normally such items as pens, notebooks, sticky-notes etc. Although the Regulations do not address supplying the general public with promotional aids, the legal definition of a promotional aid indicates that promotional aids are only to be given to persons qualified to prescribe or supply. Therefore a promotional aid should not be supplied to the general public.

4 PATIENT INFORMATION

4.1 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.

4.2 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.

4.3 Health/disease awareness campaigns

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.

5 RECORD-KEEPING

5.1 Records on the distribution of free medicinal samples

The documentation relating to free medicinal samples distributed to those qualified to prescribe or supply should be kept for a minimum of one year after the expiration of the batch of product provided.

5.2 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.

6 REPORTING AND COMPLAINTS

6.1 Non-compliant advertising

To report suspected non-compliant advertising please contact the HPRA by e-mail at compliance@hpra.ie or by telephone at +353-1-676 4971.

6.2 Complaints

To submit a complaint relating to an advertisement of a medicine, please contact the HPRA by e-mail at compliance@hpra.ie or by telephone at +353-1-676 4971.