

# Guide to Advertising Compliance

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## CONTENTS

1	INTRODUCTION	3
2	LEGAL BASIS	3
3	DEFINITION OF MEDICINAL PRODUCT ADVERTISING	3
4	EXEMPTIONS	4
5	TYPES OF MEDICINES THAT MAY BE ADVERTISED	5
5.1	Advertising of over-the-counter codeine-containing medicinal products	6
6	ACCURACY OF ADVERTISEMENTS	6
7	GENERAL INFORMATION ON THE CONTENT OF ADVERTISEMENTS	7
7.1	General information on advertisements aimed at the public	7
7.2	General information on advertisements aimed at those qualified to prescribe or supply	8
8	GENERAL INFORMATION ON THE RESPONSIBILITIES OF A SCIENTIFIC SERVICE WITH RESPECT TO ADVERTISING	9
8.1	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	9
9	RECORD-KEEPING	9
10	INFORMATION ON HPRA ACTIVITIES WITH RESPECT TO ADVERTISING AND HOW TO CONTACT THE HPRA	9
1	INTRODUCTION	4
2	LEGAL BASIS	4
3	SCOPE OF THE REGULATIONS	4
4	EXEMPTIONS	5
5	GENERAL RULES	7
6	GENERAL INFORMATION ON THE CONTENT OF ADVERTISEMENTS	10
7	ADVERTISEMENTS DIRECTED AT THE GENERAL PUBLIC	11
8	ADVERTISEMENTS DIRECTED AT THOSE QUALIFIED TO PRESCRIBE OR SUPPLY	17
9	ADVERTISING TRADITIONAL HERBAL MEDICINAL PRODUCTS	22
10	ADVERTISING HOMEOPATHIC MEDICINES	23
11	GENERAL INFORMATION ON THE RESPONSIBILITIES OF A SCIENTIFIC SERVICE WITH RESPECT TO ADVERTISING	23

<u>12</u>	<u>DUTIES OF THE HOLDERS OF MARKETING AUTHORISATIONS, CERTIFICATES OF REGISTRATION AND CERTIFICATES OF TRADITIONAL-USE REGISTRATION</u>	<u>24</u>
<u>13</u>	<u>CLASSIFICATION OF PROMOTIONAL AND NON-PROMOTIONAL MATERIALS</u>	<u>24</u>
<u>14</u>	<u>RECORD-KEEPING</u>	<u>24</u>
<u>15</u>	<u>INFORMATION ON HPRA ACTIVITIES WITH RESPECT TO ADVERTISING AND HOW TO CONTACT THE HPRA</u>	<u>25</u>
	<u>APPENDIX 1: SUGGESTED CHECKS FOR COMPANIES TO CONSIDER WHEN REVIEWING AND APPROVING ADVERTISEMENTS FOR MEDICINES IN IRELAND</u>	<u>26</u>

## 1 INTRODUCTION

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

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

This guide does not apply to the advertising of veterinary ~~medicinal products~~medicines. The ~~Department of Agriculture, Food and the Marine is 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~~medicines in the European Union ~~are~~is set out in Directive 2001/83/EC of the *Community Code relating to medicinal products for human use*. The relevant provisions from the ~~directive~~Directive have been transposed into Irish law by the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007).

### ~~3~~ DEFINITION OF MEDICINAL PRODUCT ADVERTISING

~~S.I. No. 541 of 2007 outlines the requirements and restrictions that are in place for advertising human medicines in Ireland. It outlines the requirements for advertising medicines in general (Part 2 of S.I. No. 541 of 2007) and the specific requirements and restrictions for advertising medicines to the general public (Part 3 of S.I. No. 541 of 2007) or to persons qualified to prescribe or supply medicines in Ireland (Part 4 of S.I. No. 541 of 2007). Where an advertisement promotes more than one medicine, each medicine being advertised must comply with S.I. No. 541 of 2007.~~

### ~~3~~ SCOPE OF THE REGULATIONS

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;

~~Any~~This is a broad definition for the advertising of medicines, and it recognises that advertising can occur in many different ways and via many different activities. Any material or 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 subjectmedicine, is the advertising of a medicine and, as such, it **must** comply with the requirements of S.I. No. 541 of 2007. Advertising is not limited to the provisions of these a specific type of media or activity and it can include: posters, radio/ TV broadcasts, articles published in newspapers, magazines or scientific journals, material posted on the internet, social media or blog posts, emails, direct mail advertising, point-of-sale materials, promotional meetings, visits by sales representatives, etc.

It is important to note that S.I. No. 541 of 2007 refers to 'a person' advertising a medicine in Ireland. This means that the Regulations— apply to **any person** who promotes (i.e. advertises) a medicine in Ireland, and not just pharmaceutical companies. This includes marketing authorisation holder (MAH) companies, a private individual, or any third party such as broadcasters, pharmacies, other retailers, and medicinal treatment service providers.

#### **4 EXEMPTIONS**

As per Regulation 5 of S.I. No. 541 of 2007, the following is not considered advertising and 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~~The HPRAs considers that the advertising of wholesale discounts and prices available is ~~considered by the HPRAs 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, medicines~~. Direct reference to a medicine is considered to mean referring to the trade name or including an image of a specific medicine. Indirect reference to a medicine is considered to mean any other content that would lead to a viewer being able to identify a specific medicine, for example, naming the active pharmaceutical ingredient(s) when there is only one authorised medicine in Ireland containing it, or including the branded imagery associated with the medicine. 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~~medicine.

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~~the advertising of a medicine. For example, such booklets should not include promotional claims/statements about a medicine. Such patient information booklets should not be approved as promotional materials in a company's internal quality system.

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/medicine. Any accompanying items or literature that are promotional in nature should comply with S.I. No. 541 of 2007.

## **5 GENERAL RULES**

Part 2 of S.I. No. 541 of 2007 outlines the general requirements for advertising medicines in Ireland. These requirements apply to all advertising materials/activities, irrespective of the target audience of the advertisement.

Guidance on the specific requirements for advertisements directed at the general public and for advertisements directed at persons qualified to prescribe or supply medicines can be found in sections 7 and 8, respectively.

### **5.1 Prohibition on advertising unauthorised and unregistered human medicines**

#### **5 ALL CATEGORIES OF AUTHORISED HUMAN TYPES OF MEDICINES THAT MAY BE ADVERTISED**

All categories of authorised human medicines may be advertised in Ireland. However, there are restrictions in place regarding to whom the different classes of medicines may legally be advertised. See section 7 for more information on the classes of medicines that can legally be advertised to the general public in Ireland. See section 8 for more information on the classes of medicines that can legally be advertised to persons qualified to prescribe or supply in Ireland.

Regulation 6 of S.I. No. 541 of 2007 prohibits the advertising of unauthorised and unregistered medicines in Ireland. This means that it is illegal to advertise a human medicine in Ireland that does not have a:

- Marketing authorisation,
- Certificate of traditional-use registration (for traditional herbal medicinal products ~~may be advertised~~), or

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~~ Certificate of registration (for homeopathic medicines).

#### **5.1.1 Exempt medicinal products**

Medicines placed on the Irish market must be authorised by the HPRA or the European Medicines Agency. However, where an authorised medicine is not available; the exempt

medicinal products, it is product (EMP) route is available. These medicines are prescribed to meet the special needs of patients who are under the direct responsibility of the prescriber.

The advertising of the sale or supply of EMPs to the general public is not permitted. This is referred to in Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations of 2007 (S.I. No. 541 of 2007), as amended. This states that, "no advertisement or representation relating to the medicinal product is issued with a view to it being seen by the general public in the State and that no advertisement relating to the product, other than one that states only the trade name, pack size, price and dose, is issued at the request or with the consent of the person selling the product by retail or by way of wholesale dealing or the person who manufactures it and that the sale or supply is in response to a bona fide unsolicited order".

Wholesalers are not permitted to advertise or make any representations of those products EMPs with the exception of a statement containing only the following information: the product's medicine's trade name, pack size, price, and dose, as per. This is referred to in Schedule 2 of the Medicinal Products (Control of Wholesale Distribution) Regulations of 2007 (Amendment) 2009 (S.I. No. 2538 of 2009)-2007), as amended.

## **5.2 Accuracy of advertisements**

Regulation 7 of S.I. No. 541 of 2007 outlines the requirements for the accuracy of advertisements. Regulation 7 applies to all advertising materials/activities, irrespective of the target audience of the advertisement.

Careful consideration should be given when designing and updating advertisements to ensure that the advertisements fully comply with Regulation 7, as each subparagraph of it must be complied with. Appendix 1 provides some suggested checks for companies to consider when reviewing and approving advertisements for medicines in Ireland.

### **5.2.1 Compliance with the summary of product characteristics**

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

All parts of an advertisement must be in line with the information that is in the medicine's SmPC and amended, as required, in accordance with the marketing authorisation. This includes any taglines, imagery, product claims, and the abbreviated prescribing information presented within an advertisement.

An advertisement must not promote the off-label use of a medicine, i.e. using a medicine for anything other than what it is licensed and intended for. This means an advertisement cannot promote a medicine for use in treating or preventing conditions or illness for which it has not



been licensed. Nor can an advertisement promote a medicine for use by a patient group for which it has not been licensed.

An advertisement may include statements which are not included in the SmPC provided that these statements can be substantiated and are not inconsistent with the SmPC. Advertisements may include data from a clinical trial that is not one of the pivotal trials referenced in the SmPC, provided that it does not contradict the information in the SmPC.

Including information about planned or ongoing clinical trials in unlicensed indications in advertisements is likely to be seen as promoting the off-label use of the medicine and such information should not be included within advertisements.

While S.I. No. 541 of 2007 does not refer to timelines for updating advertisements following approvals to vary the marketing authorisation of a medicine, Regulation 7(a) requires advertisements to comply with the SmPC for a medicine. Advertising materials/activities should be reviewed promptly each time that the SmPC is updated to determine whether any advertisements need to be updated or withdrawn from use. This is particularly important for safety-related variations.

The HPRA's expectation is that no advertisements containing out-of-date SmPC information should be used after the implementation date of the approved variation. For existing advertisements, the company should start to switch over to the new advertisements with the updated SmPC information in a timely manner, and it can apply risk-based principles to determine a cut-off date by when the old advertisements may not be used any more. For example, if the SmPC variation was the outcome of a decision by the Pharmacovigilance Risk Assessment Committee (PRAC), this will be of a serious nature and the company should switch over as soon as possible and practicable. For advertisements directed at persons qualified to prescribe or supply, it is the HPRA's expectation that sales representatives or other staff communicate to those persons that the SmPC has changed and that there is new and important information that they should be aware of. With other SmPC changes, the company can define a later date to switch, but no later than the implementation date of the variation.

### 5.2.2 Encouraging the rational use of a medicine

As per Regulation 7(b) of S.I. No. 541 of 2007, a person shall not issue an advertisement in respect of a medicine unless the advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties.

The World Health Organisation has defined the rational use of medicines as, 'Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community.' (Promoting rational use of medicines: core components WHO, 2002).

To present a medicine in an objective manner in an advertisement, a balanced view of the medicine should be provided. A balanced view means that the information provided about the benefits and uses of the medicine are not exaggerated and that the risks and precautions associated with the medicine are not overlooked.

Advertisements that include efficacy and other claims about the benefits of the medicine, and which are directed at persons qualified to prescribe or supply, can achieve balance by ensuring that relevant risk and safety information is incorporated into the body of the advertisement. Safety information is considered to mean the information about adverse reactions, precautions, and relevant contraindications, as per the SmPC. If all the risk and safety information is included only at the end of an advertisement, within what is generally referred to as the abbreviated prescribing information, this may not render the advertisement to be balanced.

### 5.2.3 Misleading advertising

As per Regulation 7(c) of S.I. No. 541 of 2007, a person shall not issue an advertisement in respect of a medicine if the advertisement is misleading.

S.I. No. 541 of 2007 defines 'misleading advertising' as, '*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.*'

An advertisement that could lead to a mistaken belief about the qualities of the medicine could likely be considered 'misleading advertising.' This is because a patient may be prescribed, supplied, or use a medicine based on the misleading information in the advertisement.

## **6 GENERAL INFORMATION ON THE CONTENT OF ADVERTISEMENTS**

The information that must be included in an advertisement is dependent on whether an advertisement is directed at the public or at persons qualified to prescribe or supply medicines. 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.

The HPRA categorises advertisements as being full advertisements or reminder advertisements. Note that the term 'full advertisement' is not referred to in S.I. No. 541 of 2007, but the HPRA uses this term to help differentiate between them and advertisements intended to act only as a reminder in the context of Regulations 12(3) and 17.

### **6.1 Use of the word 'new' to describe a medicine**

While there is no restriction within S.I. No. 541 of 2007 on using the word 'new' in advertisements, the HPRA does not consider it good practice to describe a medicine as 'new' when it has been generally available in Ireland for more than 12 months. In cases where a 'new'

indication is being promoted, the HPRA considers it acceptable to describe the indication as 'new' for 12 months from the date of the indication's first authorisation.

## **6.2 Statements encouraging the reporting of adverse reactions**

While S.I. No. 541 of 2007 does not refer to including adverse event reporting statements in advertisements, the HPRA considers it good practice to include a statement expressly asking healthcare professionals and patients to report any suspected adverse reaction in accordance with the national spontaneous reporting system referred to in Article 107a(1) (Article 11 of Directive 2001/83/EC).

## **6.3 Medicines under additional monitoring**

While S.I. No. 541 of 2007 does not refer to including the black triangle symbol in advertisements for medicines under additional monitoring, Good Pharmacovigilance Practice (GVP) Module X on Additional Monitoring recommends that 'the MAH should include information on the status of additional monitoring in any material to be distributed to healthcare professionals and patients and should make all efforts to encourage reporting of adverse reactions, as agreed with national competent authorities'. The HPRA recommends that this guidance is followed for educational and promotional materials.

The black triangle symbol should appear once on promotional materials and be located adjacent to the most prominent display of the name of the product. The size of the symbol should be appropriate to the font size of the promotional materials. The MAH should also endeavour to include the explanation of the symbol in addition to wording to encourage reporting of adverse reactions on full advertisements for products subject to additional monitoring. On reminder advertisements, at least the inverted black triangle symbol should be included.

## **7 ADVERTISEMENTS DIRECTED AT THE GENERAL PUBLIC**

As 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. outlined previously, Part 3 of S.I. No. 541 of 2007 sets out the provisions for advertising medicines to the general public in Ireland.

### **Medicines which are legally permitted to**

#### **5.17.1 ~~All categories of authorised human medicinal products may be advertised to those qualified to prescribe or supply the general public~~**

Details of any restrictions placed on the advertising of a human medicinal product  
Only **certain authorised medicines that are** contained **available without prescription** in Ireland may legally be advertised to the general public. This is subject to compliance with S.I.

No. 541 of 2007 and with the conditions of the marketing authorisation for the product,medicine.

Information on the promotion status of the product (i.e.S.I. No. 541 of 2007 prohibits the advertising of prescription-only medicines to the general public in Ireland. The regulations are in place to safeguard the principle that a prescription-only medicine is recommended for use for a patient only where a doctor, or other health professional qualified to prescribe, recommends that medicine based on the patient's individual and personal medical history, and their needs.

While vaccines are prescription-only medicines, Regulation 13 provides a limited exemption in relation to vaccine advertisements which are part of a vaccination campaign, provided that the campaign has been approved by the Minister for Health. Please see Regulation 13 in S.I. No. 541 of 2007 for exact details.

S.I. No. 541 of 2007 prohibits the advertising of controlled drugs to the general public in Ireland, e.g. codeine-containing medicines.

It should be noted that the conditions of the marketing authorisation for a non-prescription medicine (i.e. its license) may restrict the advertising of it to healthcare professionals only. This means that these medicines cannot legally be advertised to the general public in Ireland. Information on whether a medicine is subject to prescription and on its advertising status (i.e. whether it may be promoted to the general public or to healthcare professionals only) is publicly available for each authorised medicinal product,medicine on the HPRA website.

## 7.2 AdvertisingCodeine-containing medicines

### 5.1.17.2.1 The advertising of over-the-counter codeine-containing medicinal products,medicines

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, regardless of the prescription status of the medicines. Regulation 10 of the Medicinal Products (Control of Advertising) Regulations, 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 defineS.I. No. 541 of 2007. Part 1 of S.I. No. 541 of 2007 defines a health professional as a person of any of the following classes:

- (i) \_\_\_\_\_ registered medical practitioners,
- (ii) \_\_\_\_\_ registered dentists,
- (iii) \_\_\_\_\_ registered pharmacists,

(iv) registered nurses-

#### 7.2.2 AccuracyThe training of non-healthcare professional staff on codeine-containing medicines

S.I. No. 541 of 2007 does not refer to MAHs or their sales representatives providing training/education on codeine-containing medicines to non-healthcare professional staff in pharmacies or other settings. 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.

### **5-27.3 Prohibition of certain material in advertisements directed at the general public**

As per Regulation 7(a), 11 of S.I. No. 541 of 2007 outlines the material that is prohibited in advertisements directed at the general public.

#### 7.3.1 Medical consultation and surgical operation

Advertisements directed at the general public should not give the impression that a person shall not issue medical consultation or surgical operation is unnecessary, for example by offering a diagnosis or suggesting treatment by post, telephone, email, or other electronic means of communication.

#### 7.3.2 Comparative statements

In relation to comparative statements in advertisements directed at the general public, Regulation 11 (1) (b) prohibits such advertisements from suggesting that the effects of the medicine are better than, or equivalent to, another named medicine or treatment, e.g. 'Works faster than Medicine'. Category claims such as, 'works faster than standard tablets' are acceptable provided that the medicine's SmPC fully supports the claim, for example, by having a similar comparative statement within it.

#### 7.3.3 Claims made in advertisements

Advertisements directed at the general public should not suggest that the effects of taking the medicine are guaranteed. Nor should they suggest that the medicine does not have any side-effects or that the safety or efficacy of the medicine is due to the fact that it is natural. Advertising should not include a description or detailed representation of a case history that may lead to an inaccurate self-diagnosis.

Advertisements should not suggest that the medicine is a foodstuff, cosmetic or other consumer product.

Advertising should not suggest that the health of a patient can be enhanced by taking a medicine or that their health could be affected by not taking the medicine.

Advertisements should not refer in improper, alarming or misleading terms to claims of recovery. For example, an advertisement in respect of a medicinal product unless all parts should not make a claim for the complete recovery of a chronic condition without evidence. Such claims may be considered to exaggerate the properties of a medicine and may have the potential to mislead the viewer of the advertisement-comply with the particulars set out in the summary of product characteristics for the product.

Advertisements should not use improper, alarming or misleading pictures (e.g. photos, diagrams, illustrations) of changes that occur in the human body because of disease or injury or of the action of a medicine on the human body.

Note that 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.

S.I. No. 541 of 2007 does

~~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.~~

**61 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.~~

require that

~~Careful consideration should be taken when designing and updating advertisements to ensure the directed at the general public include documented references to support product claims made in such advertisements fully comply with the above regulation.~~

## ~~7 — GENERAL INFORMATION ON THE CONTENT OF ADVERTISEMENTS~~

~~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.~~

~~Advertisements aimed at the public or at those qualified to supply medicinal products may be classified as full advertisements, reminder advertisements, or as promotional aids. Note that the term 'full advertisement' is not referred to in the legislation, but is used to help differentiate between normal advertisements and advertisements intended to act as a reminder.~~

### ~~7.1 — General information on advertisements aimed at the public~~

~~**7.21.1** 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.~~

~~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. It should consist solely of the product name/INN/trademark and 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.~~

~~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, Regulation 11(1)(b) prohibits any advertisement for a medicinal product that is aimed at the general public from suggesting that the product is better than, or equivalent to, another named medicinal product or 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.~~

#### 7.3.4 Children

Advertisements for medicines should not contain material that is directed exclusively or principally at children.

#### 7.3.5 Recommendations and endorsements

Advertisements directed at the general public should not contain material which refers to a recommendation or an endorsement of the medicine by scientists or health professionals (i.e. registered doctors, registered dentists, registered pharmacists, and registered nurses). Nor should they refer to a recommendation or endorsement by persons who, because of their celebrity status, could encourage consumption (i.e. use) of medicines.

### **7.4 Form and content of full advertisements directed at the general public**

Regulation 12 (1) of S.I. No. 541 of 2007 sets out the form and content **required** for full advertisements directed at the general public.

#### 7.4.1 Form of the advertisement

Advertisements directed at the general public should be presented in such a way that it is clear that it is an advertisement and that the product being advertised is a medicine.

#### 7.4.2 Minimum information required

Full advertisements directed at the general public must include the name of the medicine and, if the medicine has only one active ingredient, it must include the common name of the active ingredient.

Advertisements must include the information necessary for the correct use of the medicine. This is interpreted to mean that the advertisement includes one or more of the indications for the use of the medicine, as per the SmPC.

Advertisements directed at the general public must include a clear and legible invitation to read the instructions on the leaflet or label.

### **7.5 Pack images used in advertisements directed at the general public**

At present there is no restriction within S.I. No. 541 of 2007 on ~~the inclusion of~~including illustrations/pictures of the ~~product pack~~medicine in advertisements ~~aimed~~directed at the general public.



However, it is the HPRA's preference of the HPRA that images/illustrations of the smallest available pack size available on the market should be ~~illustrated~~used.

### **7.6 ~~General information on advertisements aimed~~Reminder advertisements directed at the general public**

Advertisements directed at the general public that are intended only as a reminder must contain only the information set out in Regulation 12 (3) of S.I. No. 541 of 2007, i.e. solely:

- the medicine's name or the international non-proprietary name (INN), or the trademark,  
and
- advice to read carefully the instructions on the leaflet contained within the package or on the label.

Reminder advertisements should not include any claims or information on the approved indication(s) of the medicine.

### **7.7 Sponsorship**

Sponsorship linked to a brand of medicine is considered to be an advertisement for the relevant medicine. The HPRA considers this acceptable in principle for medicines which are legally permitted to be advertised to the general public. All aspects of the sponsorship must comply with the requirements of S.I. No. 541 of 2007.

Statements such as, "Sponsored by 'medicine'" are considered advertisements for the medicine and each instance of such a statement being made must comply with S.I. No. 541 of 2007.

## **8 ~~ADVERTISEMENTS DIRECTED AT THOSE QUALIFIED TO PRESCRIBE OR SUPPLY~~**

As outlined previously, Part 4 of S.I. No. 541 of 2007 sets out the provisions for advertising medicines to ~~healthcare professionals~~persons qualified to prescribe or supply medicines.

~~Essential~~All categories of **authorised** human medicines may be advertised to those qualified to prescribe or supply.

### **8.1 Scope of the term 'persons qualified to prescribe or supply'**

The explanatory note in S.I. No. 541 of 2007 outlines that the Regulations 'cover advertising both to **health professionals** and to the **general public**'. As such, anyone who is not within the definition of 'health professional' as defined in S.I. No. 541 of 2007 is to be considered a member of the public in the context of these Regulations.

Part 1 of S.I. No. 541 of 2007 defines a health professional as a person of any of the following classes:

- (i) registered medical practitioners
- (ii) registered dentists
- (iii) registered pharmacists
- (iv) registered nurses

The term 'persons qualified to prescribe or supply' (PQPS) in the context of S.I. No. 541 of 2007 is considered to mean persons within these defined classes of health professional who are legally entitled to prescribe or supply a human medicine in Ireland.

## **8.2 Full advertisements directed at PQPS**

Full advertisements directed at PQPS must contain the information ~~to be included in an advertisement~~ outlined in Regulation 16.

Regulation 16(1) requires such advertisements to include 'essential information' compatible with the SmPC. The 'essential information' refers to the information listed in ~~parts~~ Parts (b) to (i) of Regulation 16(1) ~~(for full)~~. This is generally referred to as the abbreviated prescribing information in an advertisement; however, this is not an official or legal term.

Regulation 16(1) (b) requires that a list of the medicine's active ingredients is placed immediately adjacent to the most prominent display of the name of the product. 'Immediately adjacent to' is considered to mean immediately before, after, above, or below the most prominent display of the medicine's name in the advertisement.

Subparagraphs (e) and (f) of Regulation 16(1) requires that advertisements ~~aimed~~ include a clear statement of the entries in the SmPC relating to side-effects, precautions, relevant contraindications, dosing and method of use. If it is not obvious, the route of administration should be included too.

With regards to side-effects, the very common and common side-effects as per Section 4.8 of the SmPC should be included ~~at persons qualified to prescribe or supply) and to parts~~ a minimum. The HPRA considers it good practice to also include a statement that PQPS should consult the SmPC in relation to other possible adverse reactions associated with the medicine.

The HPRA considers it acceptable to include only those precautions or (very common and common) adverse reactions that are relevant to the indication being promoted in the advertisement, **only** when Sections 4.4 and 4.8 of the SmPC have stated that they are associated with a specific indication. If the SmPC does not indicate that a precaution or (very common and common) adverse reaction is associated with a specific indication, the HPRA expects that the information relating to these precautions and adverse reactions are referred to in a full advertisement for that medicine, irrespective of the indication that is being promoted.

Regulation 16(2) requires that the information in subparagraphs (e) and (f) of Regulation 16(1) is printed in a clear and legible manner and is placed in such a position in the advertisement that their relationship to the claims and indications for the medicine can readily be appreciated by the reader. The HPRA's expectation is that the text providing the information on side-effects, precautions, relevant contraindications, dosing and administration should be clear and legible, and this text should be included within the advertisement itself. This information does not need to be provided verbatim from the SmPC, but the key messages must be clearly conveyed.

The HPRA considers that including the safety information (i.e. adverse reactions, precautions, relevant contraindications) within the advertisement itself helps to present the medicine in an objective and balanced manner, and contributes towards encouraging the rational use of the medicine. See section 5.2 for guidance on Regulation 7.

#### 8.2.1 Medicines advertised on pull-up banner stands at promotional events/meetings

For medicines advertised on pull-up banner stands used at promotional events/meetings, the information required by Regulation 16(1) must either be included on the pull-up banner advertisement itself or copies of it must be available for PQPS at the company stand. If copies of the essential information are being made available at the company stand, a statement to this effect should be included on the pull-up banner advertisement.

### 8.3 Reminder advertisements directed at PQPS

Reminder advertisements directed at PQPS must contain the information outlined in Regulation 17. This Regulation requires such advertisements to include essential information compatible with the SmPC. The 'essential information' in this context refers to the information listed in Parts (b) to (f) of Regulation 17 ~~(for reminder advertisements aimed at persons qualified to prescribe or supply).~~

In relation to Regulation 17 describes reminder advertisements aimed at such persons, advertisements must contain the information set out in Regulation 17 of S.I. No. 541 of 2007. ~~The~~ directed at PQPS as being 'an abbreviated advertisement that is intended solely as a reminder'. The HPRA's expectation is that the advertisement's **only** purpose must be to remind the viewer of the existence or availability of the ~~product~~ medicine. The HPRA considers that any advertisement that does more than remind PQPS of the existence or availability of the medicine is a full advertisement, and full advertisements must include the information that is required by Regulation 16 (see section 8.2).

The approved indications, as per the SmPC, may be included ~~in reminder advertisements directed at PQPS. While the text of the indication does not need to be provided verbatim from the SmPC, the HPRA expects that it should fully reflect the information provided in Section 4.1 of the SmPC. For example, if Section 4.1 indicates that a medicine is authorised for use as a second-line treatment, the indication included in the reminder advertisement must also reflect this.~~

Promotional statements ~~may not be included.~~

~~or claims should not be included in reminder advertisements; this is inclusive of the imagery that is being used in such advertisements. For example, the imagery used in a reminder advertisement should not convey a claim for efficacy, as this goes beyond reminding the PQPS of the existence or availability of the medicine.~~ 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, as they~~ 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.~~

~~While there is no restriction within S.I. No. 541 of 2007 on issuing reminder advertisements directed at PQPS for a 'new' medicine, the HPRA does not consider it good practice that reminder advertisements are issued in the first 12 months of the medicine being generally available in Ireland. This is because the purpose of a reminder advertisement directed at PQPS should be to remind the viewer of the existence or availability of the medicine and it is possible that some (or many) PQPS may not be aware of the existence or availability of a medicine within this timeframe. The HPRA recommends that reminder advertisements directed at PQPS are not used for the first 12 months of a medicine being first marketed in Ireland.~~

#### **8.4 Promotional aids**

A promotional aid is defined ~~in S.I. No. 541/2007 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 outlines the requirements for promotional aids.~~ A promotional aid:

- ~~consists~~**Must consist solely** of the name of the product, ~~or its~~ INN, or ~~the~~ trademark (or in the case of a homeopathic ~~medicinal product~~**medicine** that is the subject of a certificate of registration, the scientific name of the stock or stocks or its invented name);
- ~~is~~**Must be** intended **solely** as a reminder; ~~advertisement,~~ and
- ~~is~~**Must be** intended for supply **only** to ~~persons qualified to prescribe or supply medicinal products~~**PQPS medicines.**

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

~~The Regulations do~~**S.I. No. 541/2007 does** not address supplying promotional aids to the general public. They are only addressed in the context of their supply to ~~persons qualified to prescribe or supply medicinal products. It is considered by~~**PQPS. The** HPRA ~~considers~~ that a promotional ~~aid~~**aids** **should not** be supplied to the general public.

#### **8.5 Digital advertisements**

##### **8.5.1 Digital banner advertisements**

The HPRa considers that a digital banner advertisement is a form of advertisement that is displayed in a banner style on a webpage of a host website, e.g. in a rectangular or square shape along the top, bottom or sides of the webpage.

If there is insufficient space in such banner advertisements for all of the information required by Regulation 16(1) (for full advertisements directed at PQPS) or subparagraphs (c) and (d) of Regulation 17 (for reminder advertisements directed at PQPS) to be included within it, the HPRa considers it acceptable for companies to use a hyperlink to a webpage to provide this information. This is on the provision that it is a direct, single-click link to the SmPC or an Abbreviated Prescribing Information (API). Indirect links to the SmPC or the API may not be acceptable.

If the linked webpage does not include an element of the information required by Regulation 16(1) or subparagraphs (c) and (d) of Regulation 17, then it is the HPRa's expectation that this information is included within the banner advertisement itself. For example, if a company uses a direct link to the SmPC, this document will not provide the classification for the sale or supply of the medicine and as such, this information should be included within the banner advertisement.

It is important to remember that full and reminder digital banner advertisements must also comply with the remaining, relevant Regulations of S.I. No. 541 of 2007. See section 5 for guidance on advertising medicines generally.

#### 8.5.1.1 Full, digital banner advertisements directed at PQPS

For full, digital banner advertisements, the HPRa expects at a minimum that the banner advertisement includes the name of the medicine and a list of the active ingredient(s) using the common name placed immediately adjacent to the most prominent display of the name of the medicine. The HPRa considers it acceptable to provide the remaining information required by Regulation 16(1) as a directly linked webpage to the SmPC or API.

Where there is more than one hyperlink included in a full, digital banner advertisement directed at PQPS (e.g. a link to the SmPC/API and a link to drive traffic to a different website), the HPRa expects that the hyperlink to the SmPC or API is given comparable prominence within the banner advertisement as those used to drive traffic to further promotional content about the medicine.

#### 8.5.1.2 Digital banner advertisements intended solely as a reminder to PQPS

As outlined in section 8.3, the **only** purpose of reminder advertisements directed at PQPS must be to remind the viewer of the existence or availability of the medicine.

For digital banner advertisements intended solely as a reminder, the HPRa expects at a minimum that the banner advertisement includes the name/INN/trademark of the medicine and

a statement which clearly indicates that further information is available on request to the holder of the authorisation or certificate, or in the SmPC. The HPRA considers it acceptable to provide the information required by subparagraphs (c) and (d) of Regulation 17 as a directly linked webpage to the SmPC or API.

#### 8.5.2 Promotional emails sent to PQPS

The HPRA considers that if the promotional content of the email does more than remind PQPS of the existence or availability of the medicine then the email is a full advertisement, and it must comply with Regulation 16.

If the information required by subparagraphs (e) and (f) of Regulation 16(1) is included within the content of the email, the HPRA considers it acceptable for companies to use a hyperlink to a webpage to provide the information required by subparagraphs (c), (d), (g), and (h) of Regulation 16(1). This is on the provision that it is a direct, single-click link to the SmPC or an Abbreviated Prescribing Information (API). Indirect links to the SmPC or the API may not be acceptable.

It is important to remember that promotional emails must comply with all relevant Regulations of S.I. No. 541 of 2007. See section 5 for guidance on advertising medicines generally. While not legally required by S.I. No. 541 of 2007, the HPRA considers it good practice that the subject line of a promotional email indicates the email's promotional intent and includes the name of the medicine that is being promoted within it.

#### 8.5.3 Promotional websites

The HPRA considers that if the promotional content of the website does more than remind PQPS of the existence or availability of the medicine then the website is a full advertisement, and it must comply with Regulation 16.

The information required by Regulation 16(1) for the medicine that is being promoted must be included within the content of the promotional website itself. The HPRA does not consider it acceptable for companies to use a hyperlink to a separate website to provide any of the elements required by Regulation 16(1), instead of including it on the promotional website itself.

## **9 ADVERTISING TRADITIONAL HERBAL MEDICINAL PRODUCTS**

Traditional herbal medicinal products (THMPs) that have been granted a certificate of traditional-use registration by the HPRA may be advertised in Ireland.

Advertisements for THMPs must comply with the requirements of S.I. No. 541 of 2007. Additionally, S.I. No. 541 of 2007 requires that all advertisements for THMPs granted a certificate of traditional-use registration include 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'.

THMPs that have **not** been granted a certificate of traditional-use registration by the HPRA **cannot** legally be advertised in Ireland, as this would be a breach of Regulation 6 of S.I. No. 541 of 2007.

## **10 ADVERTISING HOMEOPATHIC MEDICINES**

Homeopathic medicines that have been granted a product authorisation or a certificate of registration by the HPRA may be advertised in Ireland. Homeopathic medicines that have **not** been granted an authorisation or registration by the HPRA **cannot** legally be advertised in Ireland, as this would be a breach of Regulation 6 of S.I. No. 541 of 2007.

Advertisements for homeopathic medicines that have been authorised under the National Rules Scheme must comply with the requirements of S.I. No. 541 of 2007. These medicines will have a HPRA authorisation number with the prefix HOA.

S.I. No. 541 of 2007 restricts the information that is permitted in advertisements for homeopathic medicines registered through the Simplified Registration Scheme. These medicines will have a HPRA registration number with the prefix HOR (homeopathic registration). As outlined in Regulation 12(2), advertisements for registered homeopathic medicines directed at the general public must contain **only** the information that is set out in the Schedule of S.I. No. 541 of 2007. They are not legally permitted to contain any additional information. Please see the Schedule in S.I. No. 541 of 2007 for exact details on the permitted information.

### **911 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.

#### **9.1 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.~~

## **12 DUTIES OF THE HOLDERS OF MARKETING AUTHORISATIONS, CERTIFICATES OF REGISTRATION AND CERTIFICATES OF TRADITIONAL-USE REGISTRATION**

Regulation 24 of S.I. No. 541 of 2007 outlines the duties of those who hold a marketing authorisation, certificate of registration, or certificate of traditional-use registration for a medicine that they have placed on the Irish market. This includes that they must ensure that any advertising of a human medicine that is performed by or on their behalf is compliant with S.I. No. 541 of 2007.

When companies contract external parties to promote a medicine on the company's behalf, the company is responsible for ensuring that all promotional materials or activities are compliant with S.I. No. 541 of 2007.

## **13 CLASSIFICATION OF PROMOTIONAL AND NON-PROMOTIONAL MATERIALS**

The HPRA recognises that many promotional assets and activities include elements of education. However, their primary purpose is to promote a medicine, and this must be made clear to the audience by the appropriate classification of all items associated with the activity and by complying with S.I. No. 541 of 2007.

If there are non-product related presentations at a promotional meeting, the HPRA considers it acceptable to classify these presentations as non-promotional. If there are company product-related presentations at a promotional meeting, these should be classified as promotional items, and the slides should be clear that they are promotional in nature.

For medical education meetings (i.e. non-promotional), the intent of these must be truly non-promotional. References to a company product (e.g. by stating the brand name) may be considered promotional, and all named medicines in the material should be presented in a balanced manner.

## **1014 RECORD-KEEPING**

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



## **1115 INFORMATION ON HPRA ACTIVITIES WITH RESPECT TO ADVERTISING AND HOW TO CONTACT THE HPRA**

The HPRA ~~carries out~~ performs surveillance work to ensure that advertisements are compliant with the requirements of S.I. No. 541 of 2007 including that they are accurate, in line with the approved product information, and are not misleading. The HPRA does not routinely review advertising materials ~~before~~ prior to their ~~use;~~ issue (vetting), but reserves the right to review advertisements in certain cases.

In relation to the advertising of medicines by retail pharmacy businesses, the Pharmaceutical Society of Ireland (PSI) monitors advertising generated by pharmacies themselves. This may include a pharmacy's website (where applicable), pharmacy generated posters, etc. ~~The~~ With respect to in-pharmacy advertising, the HPRA monitors all other advertising of medicines that has not been generated by ~~companies who hold marketing authorisations for products~~ the pharmacy. This may include promotions in-pharmacy that have been supplied by the ~~marketing authorisation holder (MAH for display in the pharmacy, e.g.~~ 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.

Further clarification on any issue can be obtained by contacting the advertising compliance team at compliance@hpra.ie advertisingcompliance@hpra.ie, or by telephone at +353-1-676 4971. Complaints relating to an advertisement of a medicine or relating to a suspected non-compliant advertising activity may also be reported to the HPRA using the above contact details.

**APPENDIX 1 SUGGESTED CHECKS FOR COMPANIES TO CONSIDER WHEN REVIEWING AND APPROVING ADVERTISEMENTS FOR MEDICINES IN IRELAND**

The following suggested checks may be helpful for companies to consider when they are reviewing and approving advertisements for medicines in Ireland. Please note, they for the internal use of companies. They do **not** need to be submitted to the HPRA.

**1. ADVERTISEMENT DETAILS**

Date of review: _____	
Type of advertisement(s) under review and relevant details: <input type="checkbox"/> Print _____ <input type="checkbox"/> Digital _____ <input type="checkbox"/> Radio _____ <input type="checkbox"/> Television _____ <input type="checkbox"/> Free sample _____ <input type="checkbox"/> Promotional aid _____ <input type="checkbox"/> Public health awareness campaign _____ <input type="checkbox"/> Other (please specify): _____	
Target audience of advertisement(s)	<input type="checkbox"/> Public <input type="checkbox"/> Persons qualified to prescribe or supply
Advertisement title or advertisement reference number (if provided)	_____
Date of preparation or last revision of the advertisement(s)	_____
Date of preparation/last revision of the prescribing information (if different), where applicable <b>Note:</b> This relates to advertisements directed at persons qualified to prescribe or supply only.	_____
Product name(s), strength(s) and form(s) mentioned in advertisement	_____
Active substance(s)	_____
Name and address of the holder of the marketing authorisation / certificate of	_____

<u>registration / certificate of traditional-use registration, if known</u>	
<u>Marketing authorisation / certificate of registration / certificate of traditional-use registration number(s), if known</u>	_____
<u>Classification for the sale or supply of the medicine (e.g. POM, P, GSL):</u>	_____
<u>Version of the SmPC used during review of advertisement</u>	_____

## **2. ADVERTISING TO THE GENERAL PUBLIC**

### **2.1 PROHIBITED INFORMATION IN ADVERTISEMENTS DIRECTED AT THE GENERAL PUBLIC**

1.	<u>The advertisement gives the impression that medical consultation or surgery is unnecessary:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details: _____
2.	<u>Diagnosis or treatment offered by mail, e.g. post, telephone, email, and other electronic means of communication:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details: _____
3.	<u>Suggestion that the effects of the medicine are guaranteed:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details: _____
4.	<u>Suggestion that the medicine is unaccompanied by adverse reactions:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details: _____
5.	<u>Suggestion that the effects of taking the medicine are better than or equal to those of another treatment or medicine:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details: _____

6.	<p><u>Suggestion that the health of the patient can be enhanced by taking the medicine:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
7.	<p><u>Suggestion that the health of the patient will be affected by not taking the medicine:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
8.	<p><u>Advertisement is directed exclusively or principally at children:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
9.	<p><u>Advertisement refers to recommendations by scientists or health professionals (i.e. registered doctor, registered dentist, registered pharmacist, registered nurse):</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
10.	<p><u>Advertisement refers to recommendations from those who have celebrity status:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
11.	<p><u>Suggestion that the medicine is a foodstuff, cosmetic or other consumer product:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
12.	<p><u>Suggestion that the safety and efficacy of the medicine is due to the fact that it is natural:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>
13.	<p><u>Might lead to erroneous self-diagnosis (inclusion of case histories, etc.):</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If yes, provide details: _____</p>

14.	<p><u>Referral in improper, alarming or misleading terms to claims of recovery:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, provide details: _____</p>
15.	<p><u>Contains improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicine on the human body or parts thereof:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, provide details: _____</p>
<p><u>Comments:</u></p> <p>_____</p>	

**2.2 FULL ADVERTISEMENT DIRECTED AT THE GENERAL PUBLIC (REQUIRED INFORMATION)**

1.	<p><u>The advertisement is set out in such a way that it is clear that it is an advertisement, and that the product is clearly identified as a medicine:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
2.	<p><u>Name and, if it contains only one active ingredient, the international non-proprietary name (INN):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
3.	<p><u>Information necessary for the correct use of the medicine (i.e. approved indication as per the SmPC in Ireland):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
4.	<p><u>Clear invitation to read packaging/leaflet (as appropriate):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>

<p>5.</p>	<p><u>For traditional herbal medicinal products (THMPs), the following words are used 'Traditional herbal medicinal products for use in' followed by a statement of one or more of the therapeutic indications (compatible with the certificate of traditional-use registration for that product) followed by the words, 'exclusively based upon long standing use':</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p>6.</p>	<p><u>All parts of the advertisement comply with the particulars of the SmPC and marketing authorisation (e.g. taglines, claims, imagery, etc.):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p>7.</p>	<p><u>Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p>8.</p>	<p><u>Advertisement is not misleading:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p>9.</p>	<p><u>The medicine is not subject to medical prescription by virtue of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), as amended:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p>10.</p>	<p><u>The medicine is not a controlled drug under section 2 of the Misuse of Drugs Act 1977 (No. 12 of 1977), as amended:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p><u>Comments:</u></p> <p>_____</p>	

**2.3 REMINDER ADVERTISEMENT DIRECTED AT THE GENERAL PUBLIC (REQUIRED INFORMATION)**

1.	<p><u>Name, international non-proprietary name (INN) or trademark (or, in the case of a homeopathic medicine that is the subject of a certificate of registration, the scientific name of the stock or stocks or its invented name):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
2.	<p><u>Advice to read carefully the instructions on packaging/leaflet (as appropriate):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
3.	<p><u>No other information provided. Note: Imagery may be present as long as it does not convey a promotional message of any kind.</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
4.	<p><u>The information in item 1 above complies with the particulars in the SmPC:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
5.	<p><u>Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
6.	<p><u>Advertisement is not misleading:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
7.	<p><u>The medicine is not subject to medical prescription by virtue of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), as amended:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>

<u>8.</u>	<u>The medicine is not a controlled drug under section 2 of the Misuse of Drugs Act 1977 (No. 12 of 1977), as amended:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>If no, provide details:</u> _____
<u>Comments:</u> _____	

**2.4 PUBLIC HEALTH AWARENESS CAMPAIGN DIRECTED AT THE GENERAL PUBLIC**

<u>1.</u>	<u>Medicine mentioned, even indirectly:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>If yes, provide details:</u> _____
<u>2.</u>	<u>Website mentioned:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>If yes, does the website only refer to the disease in question and does it make no reference, direct or indirect, to a medicine?</u> <input type="checkbox"/> Yes <input type="checkbox"/> No
<u>Comments:</u> _____	

**2.5 FULL ADVERTISEMENTS DIRECTED AT THE GENERAL PUBLIC FOR HOMEOPATHIC MEDICINES GRANTED A CERTIFICATE REGISTRATION BY THE HPRA (INFORMATION THAT MAY BE INCLUDED)**

<u>1.</u>	<u>Clear mention of the words 'homeopathic medicinal product':</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
<u>2.</u>	<u>The scientific name of the stock or stocks followed by the degree of dilution or, an invented name where the homeopathic medicine is composed of two or more stocks:</u>



	<input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
3.	<u>The name and address of the certificate of registration holder and the name and address of the manufacturer, where different:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
4.	<u>The method of administration and, if necessary, the route:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
5.	<u>The expiry date of the product in clear terms, stating the month and year:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
6.	<u>The pharmaceutical form:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
7.	<u>The contents of the sales presentation:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____
8.	<u>Any special storage precautions:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Comment:</u> _____

9.	<p><u>Any special warning necessary for the product concerned:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>Comment:</u>          _____</p>
10.	<p><u>The manufacturer's batch number:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>Comment:</u>          _____</p>
11.	<p><u>The registration number allocated by the HPRA preceded by the letters 'HoR':</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>Comment:</u>          _____</p>
12.	<p><u>The words 'homeopathic medicinal product without approved therapeutic indications':</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>Comment:</u>          _____</p>
13.	<p><u>A warning advising the user to consult a doctor if the symptoms persist:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>Comment:</u>          _____</p>
14.	<p><u>No other information provided:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>If no, provide details:</u> _____</p>
15.	<p><u>Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <u>If no, provide details:</u> _____</p>

16.	<p><u>Advertisement is not misleading:</u></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
<p><u>Comments:</u></p> <p>_____</p>	

**3. ADVERTISING TO PERSONS QUALIFIED TO PRESCRIBE OR SUPPLY.**

**3.1 FULL ADVERTISEMENT DIRECTED AT THOSE QUALIFIED TO PRESCRIBE OR SUPPLY (REQUIRED INFORMATION)**

1.	<p><u>Name of the medicine and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the medicine:</u></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
2.	<p><u>Classification for the sale or supply of the medicine:</u></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
3.	<p><u>One or more of the indications for the use of the medicine compatible with the terms of the marketing authorisation, or certificate of traditional-use registration:</u></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
4.	<p><u>a) A clear statement of the entries in the SmPC relating to adverse reactions, precautions, and relevant contraindications:</u></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p> <p><u>If no provide details:</u> _____</p> <p><u>(b) The information is clear, legible, and placed in such a position in the advertisement that the relationship to the claims and indications for the medicine can readily be appreciated by the reader:</u></p> <p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>

	<p><u>If no, provide details:</u> _____</p>
5.	<p><u>a) A clear statement of the entries in the SmPC relating to dosage and method of use relevant to the indications shown:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p> <p><u>(b) The information is clear, legible, and placed in such a position in the advertisement that the relationship to the claims and indications for the medicine can readily be appreciated by the reader:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
6.	<p><u>The method of administration, where not obvious:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
7.	<p><u>Name and address of the holder of the marketing authorisation, certificate of registration or certificate of traditional-use registration, or the name and address of the part of the business responsible for placing the medicine on the market:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
8.	<p><u>The marketing authorisation number, certificate of registration number, or certificate of traditional-use registration number:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>
9.	<p><u>For Traditional Herbal Medicinal Products (THMPs), the following words are used, 'Traditional herbal medicinal product for use in' followed by a statement of one or more of the therapeutic indications (compatible with the certificate of traditional-use registration for that product) followed by the words, 'exclusively based upon long standing use':</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>If no, provide details:</u> _____</p>

10.	<p><u>Any information in written material which is part of a promotion of a medicine is accurate, up to date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine to which the material relates.</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
11.	<p><u>If any quotations, tables, or other illustrative matter is included which is taken from a medical journal or other scientific work, is the information accurately reproduced and are the precise sources of the information indicated?</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
12.	<p><u>Contains a statement showing the date on which the document was drawn up or last revised:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
13.	<p><u>All parts of the advertisement comply with the particulars of the SmPC and marketing authorisation (e.g. taglines, claims, imagery, prescribing information etc.):</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
14.	<p><u>Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
15.	<p><u>Advertisement is not misleading:</u></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, provide details: _____</p>
<p><u>Comments:</u></p> <p>_____</p>	

**3.2 REMINDER ADVERTISEMENT DIRECTED AT THOSE QUALIFIED TO PRESCRIBE OR SUPPLY  
(REQUIRED INFORMATION)**

1.	<p><u>Name or INN or trademark of the medicine:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If no, provide details: _____</p>
2.	<p><u>Classification for the sale or supply of the medicine:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If no, provide details: _____</p>
3.	<p><u>Name and address of the holder of the marketing authorisation, certificate of registration or certificate of traditional-use registration, or the name and address of the part of the business responsible for placing the medicine on the market:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If no, provide details: _____</p>
4.	<p><u>Includes a statement that clearly indicates that further information is available on request to the holder of the authorisation or certificate, or in the SmPC:</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If no, provide details: _____</p>
5.	<p><u>For Traditional Herbal Medicinal Products (THMPs), the following words are used, 'Traditional herbal medicinal product for use in' followed by a statement of one or more of the therapeutic indications (compatible with the certificate of traditional-use registration for that product) followed by the words, 'exclusively based upon long standing use':</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If no, provide details: _____</p>
6.	<p><u>All parts of the advertisement comply with the particulars of the SmPC and marketing authorisation.</u>  <input type="checkbox"/> Yes <input type="checkbox"/> No                  If no, provide details: _____</p>
7.	<p><u>Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties:</u></p>

	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
8.	Advertisement is not misleading: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
Comments: _____	

**3.3 PROMOTIONAL AID DIRECTED AT THOSE QUALIFIED TO PRESCRIBE OR SUPPLY**

Type of promotional aid (usually branded): <input type="checkbox"/> Pen <input type="checkbox"/> Notebook <input type="checkbox"/> Memory stick <input type="checkbox"/> Other (please specify): _____	
1.	The advertisement consists <b>solely</b> of the name of the product or its INN or the trademark (or in the case of a registered homeopathic medicine, the scientific name of the stock or stocks or its invented name): <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
2.	The advertisement is intended solely as a reminder: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
3.	The promotional aid is intended for supply only to those qualified to prescribe or supply medicines: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
4.	The promotional aid is inexpensive and relevant to the practice of medicine or pharmacy:

	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
Comments: _____	

### 3.4 FREE SAMPLES

1.	The sample is provided to a person qualified to prescribe the medicine <b>only</b> , and for the purpose of acquiring experience in dealing with the medicine: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
2.	The number of free samples of each medicine that is supplied to any one recipient in any one year is limited and does not exceed six samples: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
3.	The supply of a free sample is made only in response to a written request, signed and dated, by the recipient: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
4.	The supplier of the free sample maintains an adequate system of control and accountability: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
5.	The free sample is no larger than the smallest presentation of the medicine on the market: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide details: _____
6.	The sample is marked 'free medical sample – not for sale' or words to that effect: <input type="checkbox"/> Yes <input type="checkbox"/> No



	<u>If no, provide details:</u> _____
7.	<u>The sample is accompanied by a copy of the SmPC for each such medicine:</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>If no, provide details:</u> _____
8.	<u>The sample is not a controlled drug under section 2 of the Misuse of Drugs Act 1977 (No. 12 of 1977), as amended.</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>If no, provide details:</u> _____
9.	<u>The sample is not an antidepressant, hypnotic, sedative or tranquilliser.</u> <input type="checkbox"/> Yes <input type="checkbox"/> No <u>If no, provide details:</u> _____
<u>Comments:</u> _____	