HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Advertising Compliance

SUR-G0025-7
28 MARCH 2025
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 INTRODUCTION

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

Coimisiún na Meán is Ireland's media regulator. For radio and television broadcasting, audiovisual on-demand media services, and video-sharing platform services, it is important to also refer to the statutory regulations applied by An Coimisiún, which are referred to as Codes and Rules. The HPRA liaises with Coimisiún na Meán in relation to advertising compliance issues which may also come within the regulatory framework of Coimisiún na Meán.

This document provides guidance on the regulation of the advertising of human medicines and does not apply to the advertising of veterinary medicines. The Department of Agriculture, Food and the Marine is the competent authority for the advertising of veterinary medicines in Ireland.

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

2 LEGAL BASIS

The legal basis for the advertising of human medicines in the European Union 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 have been transposed into Irish law by the Medicinal Products (Control of Advertising) Regulations of 2007 (S.I. no. 541 of 2007).

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 should comply with S.I. no. 541 of 2007.

3 SCOPE OF THE REGULATIONS

As per the Medicinal Products (Control of Advertising) Regulations of 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;'

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 medicine, is the advertising of a medicine and, as such, it should comply with the requirements of S.I. no. 541 of 2007. Advertising is not limited to 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. The HPRA considers that the advertising of wholesale discounts and prices available is 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 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 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 the advertising of a medicine. For example, such booklets should not include promotional claims/statements about a medicine and they should not be approved as promotional materials in a company's internal quality system. If patient information booklets

are approved as promotional materials, they are considered to be part of a company's promotional offering. This renders them to be legally regarded as advertisements and, as such, they should comply with the requirements of S.I. no. 541 of 2007. This would not be appropriate for patient information booklets about prescription-only medicines, as such medicines cannot legally be advertised to the general public (Regulation 9 of S.I. no. 541 of 2007 prohibits the advertising of prescription-only medicines to the general public).

Exemptions 5(b) and (c) indicate that sending a copy of the summary of product characteristics (SmPC) or package leaflet (PL) does not constitute advertising. The HPRA considers it acceptable to furnish those qualified to prescribe or supply with non-promotional information about a medicine, as long as the information is factual, up to date, in compliance with the marketing authorisation of the medicine, and is sent by those working in a non-promotional role, e.g. Scientific Services, Medical Affairs, etc. However, any items or literature that is promotional in nature and sent to those qualified to prescribe or supply would legally be regarded as advertisements to those persons and should, therefore, fall outside the exemptions and should comply with the requirements for advertisements as per 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

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 of this guide for more information on the classes of medicines that can legally be advertised to the general public in Ireland, and 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), or
- 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 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 EMPs with the exception of a statement containing only the medicine's trade name, pack size, price, and dose.

This is referred to in Schedule 2 of the Medicinal Products (Control of Wholesale Distribution) Regulations of 2007 (S.I. no. 538 of 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 and each of its subparagraphs. Appendix 1 provides some suggested checks for companies to consider when reviewing and approving advertisements for medicines in Ireland in the context of the requirements of S.I no. 541 of 2007.

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 SmPC for the product.

All parts of an advertisement should 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 should 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 information that is not included in the SmPC provided that this information can be substantiated and is not inconsistent with the SmPC. For example, advertisements may include data from a clinical trial in a licensed indication for that medicine which is not one of the pivotal trials referenced in the SmPC, provided that it does not contradict the information in the SmPC or promote the off-label use of the medicine. When in doubt regarding including information of this nature, advice can be sought from the HPRA via its Swift scientific advice process.

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 advertisements containing information that is not in line with the SmPC should not be used after the implementation date of the approved variation. In general, 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 Rational use of medicines

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.

Larger promotional materials that include efficacy and other claims about the benefits of the medicine and are directed at persons qualified to prescribe or supply (e.g. detail aids, promotional presentations, multi-page leave pieces, etc.) 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. In these types of advertisements, if all of the risk and safety information is included only at the end, within what is generally referred to as the abbreviated prescribing information, this may not render the advertisement to be balanced.

For shorter advertisements directed at persons qualified to prescribe or supply which are required to include the information listed in Regulation 16(1) (e.g. one-page journal advertisements, etc.), including the abbreviated prescribing information as an integral part of the advertisement (i.e. within the advertisement itself) helps to present the medicine in an objective and balanced manner.

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 it could lead to the prescription, supply, or use of a medicine based on the misleading information in the advertisement.

6 GENERAL INFORMATION ON THE CONTENT OF ADVERTISEMENTS

The information that should 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 first marketed 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 that the extension to the indication is approved.

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 HPRA considers it good practice 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 outlined previously, Part 3 of S.I. no. 541 of 2007 sets out the provisions for advertising medicines to the general public in Ireland.

7.1 Medicines which are legally permitted to be advertised to the general public

Only certain authorised medicines that are 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 medicine.

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 medicine on the HPRA website.

7.2 Codeine-containing medicines

7.2.1 The advertising of over-the-counter codeine-containing 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 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 S.I. no. 541 of 2007. In this regard, 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 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.

7.3 Prohibition of certain material in advertisements directed at the general public

Regulation 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 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 X'. 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 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.

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 S.I. no. 541 of 2007 does not require that advertisements directed at the general public include documented references to support product claims made in such advertisements. However, all medicinal claims should be capable of substantiation and details should be provided to the HPRA if requested.

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 (ASA).

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 should include the name of the medicine and, if the medicine has only one active ingredient, it should include the common name of the active ingredient.

Advertisements should 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 should 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 including illustrations/pictures of the medicine in advertisements directed at the general public. However, it is the HPRA's preference that images/illustrations of the smallest available pack size available on the market should be used.

7.6 Reminder advertisements directed at the general public

Advertisements directed at the general public that are intended only as a reminder should 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 should comply with the requirements of S.I no. 541 of 2007.

Statements such as, 'Sponsored by 'Medicine X' are considered advertisements for the medicine and each instance of such a statement being made should 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 persons qualified to prescribe or supply medicines.

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**'.

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) used in the context of S.I. no. 541 of 2007 is considered to mean persons within the above defined classes of health professional who are legally entitled to prescribe or supply a human medicine in Ireland (i.e. registered medical practitioners, registered dentists, registered pharmacists, and registered nurses).

As S.I. no. 541 of 2007 does not refer to other classes of health professionals, e.g. allied healthcare professionals, anyone who is not one of the listed health professionals in S.I. no. 541 of 2007 should be considered a member of the public in the context of these Regulations.

8.2 Full advertisements directed at PQPS

Full advertisements directed at PQPS should contain the information 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 arts (b) to (i) of Regulation 16(1). 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 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 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 a succinct summary with the key messages should be clearly conveyed. See section 8.5 for guidance on advertisements published via specific types of electronic media.

While it is acceptable to include QR codes that directly link to the SmPC or abbreviated prescribing information in full advertisements directed at PQPS, in general, such QR codes should not be used as a substitute for including the information required by Regulation 16(1) and 16(2) within the advertisement itself. See section 8.2.1 for guidance on pull-up banner advertisements.

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 it contributes towards encouraging the rational use of the medicine. See section 5.2 for more guidance on Regulation 7.

8.2.1 Medicines advertised on banner stands at promotional events/meetings

For medicines advertised on banner stands used at promotional events/meetings (e.g. pull-up banner stands), the information required by Regulation 16(1) should either be included:

- On the banner advertisement itself,
- Through provision of a QR code that links directly to the information required, or
- Copies of the required information should be available for PQPS at the company stand.

The company stand should be adjacent to the banner advertisement and the advertisement should include a statement indicating that copies of the required information are available at the company stand.

8.3 Reminder advertisements directed at PQPS

Reminder advertisements directed at PQPS should 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.

Regulation 17 describes reminder advertisements 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 should be to remind the viewer of the existence or availability of the medicine. The HPRA considers that an advertisement that does more than remind PQPS of the existence or availability of the medicine is a full advertisement, and full advertisements should 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 should also reflect this. Promotional statements or claims should not be included in reminder advertisements; this is inclusive of the imagery that is being used in such advertisements. The imagery used in a reminder advertisement should only remind the viewer of the existence or availability of the medicine, e.g. pack images. Statements and imagery 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, as they render the advertisement to be a full advertisement. Examples of such auxiliary statements and imagery include those that indicate 'powerful pain relief', 'gets to work fast', etc.

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 first marketed 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 of 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 outlines the requirements for promotional aids. A promotional aid should:

- Consist **solely** of the name of the product, or its INN, or the 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),
- Be intended **solely** as a reminder advertisement, and
- Be intended for supply **only** to PQPS medicines.

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

S.I. no. 541 of 2007 does not address supplying promotional aids to the general public. They are only addressed in the context of their supply to PQPS. The HPRA considers that promotional aids **should not** be supplied to the general public.

8.5 Digital advertisements for medicines (i.e. via electronic media)

8.5.1 Digital banner advertisements

The HPRA considers that a digital banner advertisement is a form of electronic 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. The HPRA considers that such banner-style advertisements should take up no more than 30% of the webpage (Note: this 30% limit is not specified in S.I. no. 541 of 2007, but the HPRA considers that it would appear to be reasonable).

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 should 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 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 (reference Regulation 16(1)(b)). The HPRA considers it acceptable to provide the remaining information required by Regulation 16(1) via a directly linked webpage to the SmPC or API. Indirect links to the SmPC or the API may not be acceptable.

Where there is more than one hyperlink included in these types of advertisement (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 advertisement to that 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 HPRA's expectation is that the **only** purpose of reminder advertisements directed at PQPS should 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 advertisement includes the name and/or INN and/or 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 (reference subparagraphs (b) and (e) of Regulation 17). 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. Indirect links to the SmPC or the API may not be acceptable.

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 should 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 API. Indirect links to the SmPC or the API may not be acceptable.

It is important to remember that promotional emails should 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 for medicines

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 should comply with Regulation 16.

The information required by Regulation 16(1) and 16(2) for the medicine that is being promoted should be included within the content of the promotional website itself. It is acceptable to use a hyperlink to take a user/viewer from one webpage of the promotional website to another webpage of the **same** website to access the required information (e.g. a webpage on the same website which provides safety-related information or dosing-related information, or the API, etc.). However, hyperlinks to **separate** websites should not be used as a substitute for including the information required by these Regulations within the content of the promotional website itself.

It is important to remember that promotional websites should also comply with the remaining, relevant Regulations of S.I. no. 541 of 2007. See section 5 for guidance on advertising medicines generally, including on encouraging the rational use of a medicine.

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 should 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 should 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 should 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.

11 GENERAL INFORMATION ON THE RESPONSIBILITIES OF A SCIENTIFIC SERVICE

There is no requirement in S.I. no. 541 of 2007 for advertising materials to be approved by a medical doctor.

Adequate oversight should be applied to all outputs of the Scientific Service, such as responses to medical information queries, etc.

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 should 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. Non-promotional presentations can be delivered by a member of the Scientific Service team working in a non-promotional capacity. Such presentations should be delivered in line with the principles of medical education in a fair and balanced manner and, as such, these presentations may be classified as non-promotional. Presentations of this nature, and classified as such, are possible in the context of a promotional meeting.

Where reference to an INN (i.e. active substance) is made in a presentation that is intended to be non-promotional, and where only the company concerned has authorised products on the Irish market that contain that substance, this should be regarded as an indirect reference to the company's product, and care should be taken not to include any promotional content about that active substance in the presentation. Such presentations should be balanced, and in this regard, it can be helpful if they refer to other active substances in the same therapeutic class. If the active substance in the company's product is presented favourably in such presentations relative to the active substances that are in products from other MAHs, then this will likely render the presentation to be a promotional one, and it cannot be considered non-promotional. For medical education meetings (i.e. non-promotional), the intent of these should 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.

14 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.

For documentation relating to free samples 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**.

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

The HPRA 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 prior to their 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. With respect to in-pharmacy advertising, the HPRA monitors all other advertising of medicines that has not been generated by the pharmacy. This may include promotions in-pharmacy that have been supplied by the MAH for display in the pharmacy, e.g. promotional stands, shelf-wobblers, etc. (Note: the HPRA liaises with the PSI with respect to advertising compliance issues, where necessary).

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 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 in the context of the requirements of S.I. no. 541 of 2007. Please note, they are for the internal use of companies. They do **not** need to be submitted to the HPRA. (Note: It is the responsibility of the advertiser to ensure that its advertisements comply with any other applicable legal/regulatory requirements, e.g. those relating to advertisements transmitted by broadcast media, which also fall within the regulatory remit of Coimisiún na Meán.)

1. ADVERTISEMENT DETAILS

Date of review:	
Type of advertisement(s) under review and relevant details: ☐ Print ☐ Digital ☐ Radio ☐ Television ☐ Free sample ☐ Promotional aid ☐ Public health awareness campaign ☐ Other (please specify):	
Target audience of advertisement(s)	☐ Public ☐ 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 **Note**: 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 registration / certificate of traditional-use registration, if known	
Marketing authorisation / certificate of registration / certificate of traditional-use registration number(s), if known	
Classification for the sale or supply of the medicine (e.g. POM, P, GSL)	
Version of the SmPC used during review of advertisement	

2. ADVERTISING TO THE GENERAL PUBLIC

2.1 PROHIBITED INFORMATION IN ADVERTISEMENTS DIRECTED AT THE GENERAL PUBLIC

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

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

	☐ Yes ☐ No If yes, provide details:
14.	Referral in improper, alarming or misleading terms to claims of recovery: ☐ Yes ☐ No If yes, provide details:
15.	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: ☐ Yes ☐ No If yes, provide details:
Comments:	

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

1.	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: ☐ Yes ☐ No If no, provide details:
2.	Name and, if it contains only one active ingredient, the international non-proprietary name (INN): ☐ Yes ☐ No If no, provide details:
3.	Information necessary for the correct use of the medicine (i.e. approved indication as per the SmPC in Ireland): ☐ Yes ☐ No If no, provide details:
4.	Clear invitation to read packaging/leaflet (as appropriate): ☐ Yes ☐ No

	If no, provide details:
5.	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': ☐ Yes ☐ No If no, provide details:
6.	All parts of the advertisement comply with the particulars of the SmPC and marketing authorisation (e.g. taglines, claims, imagery, etc.): ☐ Yes ☐ No If no, provide details:
7.	Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties: ☐ Yes ☐ No If no, provide details:
8.	Advertisement is not misleading: ☐ Yes ☐ No If no, provide details:
9.	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: ☐ Yes ☐ No If no, provide details:
10.	The medicine is not a controlled drug under section 2 of the Misuse of Drugs Act 1977 (S.I. no. 12 of 1977), as amended: ☐ Yes ☐ No If no, provide details:
Comments:	

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

1.	Name and/or international non-proprietary name (INN), and/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): ☐ Yes ☐ No If no, provide details:
2.	Advice to read carefully the instructions on packaging/leaflet (as appropriate): ☐ Yes ☐ No If no, provide details:
3.	No other information provided. Note: Imagery may be present as long as it does not convey a promotional message of any kind. ☐ Yes ☐ No If no, provide details:
4.	The information in item 1 above complies with the particulars in the SmPC: ☐ Yes ☐ No If no, provide details:
5.	Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties: ☐ Yes ☐ No If no, provide details:
6.	Advertisement is not misleading: ☐ Yes ☐ No If no, provide details:
7.	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: ☐ Yes ☐ No

	If no, provide details:
8.	The medicine is not a controlled drug under section 2 of the Misuse of Drugs Act 1977 (S.I. no. 12 of 1977), as amended: ☐ Yes ☐ No If no, provide details:
Comments:	

2.4 PUBLIC HEALTH AWARENESS CAMPAIGN DIRECTED AT THE GENERAL PUBLIC

1.	Medicine mentioned, even indirectly: ☐ Yes ☐ No If yes, provide details:
2.	Website mentioned: ☐ Yes ☐ No If yes, does the website only refer to the disease in question and does it make no reference, direct or indirect, to a medicine? ☐ Yes ☐ No
Comments:	

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

1.	Clear mention of the words 'homeopathic medicinal product': ☐ Yes ☐ No Comment:

2.	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: ☐ Yes ☐ No Comment:
3.	The name and address of the certificate of registration holder and the name and address of the manufacturer, where different: ☐ Yes ☐ No Comment:
4.	The method of administration and, if necessary, the route: ☐ Yes ☐ No Comment:
5.	The expiry date of the product in clear terms, stating the month and year: ☐ Yes ☐ No Comment:
6.	The pharmaceutical form: ☐ Yes ☐ No Comment:
7.	The contents of the sales presentation: ☐ Yes ☐ No Comment:
8.	Any special storage precautions: ☐ Yes ☐ No

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

	☐ Yes ☐ No If no, provide details:
16.	Advertisement is not misleading: ☐ Yes ☐ No If no, provide details:
Comments:	

3. ADVERTISING TO PERSONS QUALIFIED TO PRESCRIBE OR SUPPLY

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

1.	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: ☐ Yes ☐ No If no, provide details:
2.	Classification for the sale or supply of the medicine: ☐ Yes ☐ No If no, provide details:
3.	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: ☐ Yes ☐ No If no, provide details:
4.	a) A clear statement of the entries in the SmPC relating to adverse reactions, precautions, and relevant contraindications: ☐ Yes ☐ No If no provide details:

	(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: ☐ Yes ☐ No If no, provide details:
5.	a) A clear statement of the entries in the SmPC relating to dosage and method of use relevant to the indications shown: ☐ Yes ☐ No If no, provide details: (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: ☐ Yes ☐ No If no, provide details:
6.	The method of administration, where not obvious: ☐ Yes ☐ No If no, provide details:
7.	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 business responsible for placing the medicine on the market: ☐ Yes ☐ No If no, provide details:
8.	The marketing authorisation number, certificate of registration number, or certificate of traditional-use registration number: ☐ Yes ☐ No If no, provide details:
9.	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':

	☐ Yes ☐ No If no, provide details:
10.	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. ☐ Yes ☐ No If no, provide details:
11.	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? ☐ Yes ☐ No If no, provide details:
12.	Contains a statement showing the date on which the document was drawn up or last revised: ☐ Yes ☐ No If no, provide details:
13.	All parts of the advertisement comply with the particulars of the SmPC and marketing authorisation (e.g. taglines, claims, imagery, prescribing information etc.): ☐ Yes ☐ No If no, provide details:
14.	Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties: ☐ Yes ☐ No If no, provide details:
15.	Advertisement is not misleading: ☐ Yes ☐ No If no, provide details:
Comments:	

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

1.	Name and/or INN and/or trademark of the medicine: ☐ Yes ☐ No If no, provide details:
2.	Classification for the sale or supply of the medicine: ☐ Yes ☐ No If no, provide details:
3.	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 business responsible for placing the medicine on the market: ☐ Yes ☐ No If no, provide details:
4.	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: ☐ Yes ☐ No If no, provide details:
5.	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': ☐ Yes ☐ No If no, provide details:
6.	All parts of the advertisement comply with the particulars of the SmPC and marketing authorisation. ☐ Yes ☐ No If no, provide details:

7.	Advertisement encourages the rational use of the medicine by presenting it objectively and without exaggerating its properties: ☐ Yes ☐ No If no, provide details:
8.	Advertisement is not misleading: ☐ Yes ☐ No If no, provide details:
Comments:	

3.3 PROMOTIONAL AID DIRECTED AT THOSE QUALIFIED TO PRESCRIBE OR SUPPLY (REQUIREMENTS)

Type of promotional aid (usually branded): ☐ Pen ☐ Notebook ☐ Memory stick ☐ Other (please specify):	
1.	The advertisement consists **solely** 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): ☐ Yes ☐ No If no, provide details:
2.	The advertisement is intended solely as a reminder: ☐ Yes ☐ No If no, provide details:
3.	The promotional aid is intended for supply only to those qualified to prescribe or supply: ☐ Yes ☐ No If no, provide details:

4.	The promotional aid is inexpensive and relevant to the practice of medicine or pharmacy: ☐ Yes ☐ No If no, provide details:
Comments:	

3.4 FREE SAMPLES (REQUIREMENTS)

1.	The sample is provided to a person qualified to prescribe the medicine **only**, and for the purpose of acquiring experience in dealing with the medicine: ☐ Yes ☐ 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: ☐ Yes ☐ 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: ☐ Yes ☐ No If no, provide details:
4.	The supplier of the free sample maintains an adequate system of control and accountability: ☐ Yes ☐ No If no, provide details:
5.	The free sample is no larger than the smallest presentation of the medicine on the market: ☐ Yes ☐ No If no, provide details:

6.	The sample is marked 'free medical sample – not for sale' or words to that effect: ☐ Yes ☐ No If no, provide details:
7.	The sample is accompanied by a copy of the SmPC for each such medicine: ☐ Yes ☐ No If no, provide details:
8.	The sample is not a controlled drug under section 2 of the Misuse of Drugs Act 1977 (S.I. no. 12 of 1977), as amended. ☐ Yes ☐ No If no, provide details:
9.	The sample is not an antidepressant, hypnotic, sedative or tranquilliser. ☐ Yes ☐ No If no, provide details:
Comments:	