POLICY
Health Products and Food Branch

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# The Distinction Between Advertising and Other Activities

## Issue

Health Canada recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access non-promotional information regarding drugs for human use. The purpose of this policy is to clarify the distinction between advertising to promote the sale of a drug and activities that are not primarily intended to promote the sale of a drug (e.g., education, scientific exchange, labelling, shareholder's report, etc.).

This policy is NOT intended for use in determining whether or not the drug advertising provisions of the *Food and Drugs Act* and *Regulations* are observed.

## Scope

This policy applies to all types of information disseminated in relation to drugs for use in humans.

## Background

There are numerous provisions within the *Food and Drugs Act* and *Regulations* that apply to drug advertising. In order to determine the applicability of those provisions it is first necessary to determine whether or not a particular message can be considered to be advertising. For the purposes of the *Act*, advertising is defined as including "*any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device*". If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the *Food and Drugs Act* and *Regulations*.

There is a particular need to distinguish between advertising and non-promotional information in the following situations:

i) **Prior to market authorization**:

- promotion of a drug prior to market authorization is not permitted (Section 9(1) of the *Act*, Section C.08.002 of the *Regulations*) because the terms of such authorization have not been established and the proposed indication(s) for use have not been verified.

ii) **After market authorization when information on a drug is disseminated to the general public:**

- promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the *Regulations*).

- a drug (prescription or nonprescription) may not be advertised to the general public for the treatment, preventative or cure for any Schedule A disease (Section 3 of the *Act)*.

**Considerations**

In determining whether a message falls within the definition of advertising, the purpose of the message is very significant. It must be determined whether the primary purpose of the message is to promote the sale of a drug or to provide information. Where the primary purpose is not clear, the following factors should be considered in determining whether the message is primarily intended to promote the sale of a drug:

- **What is the context in which the message is disseminated?**

  e.g., when and how is the message delivered; what is the milieu or medium of dissemination? Is it a science-based message delivered to scientists/healthcare professionals by an expert, e.g., researcher at a conference with a varied agenda, or is it a product-related message delivered to a group of practicing physicians by the pharmaceutical manufacturers sales representative at a meeting with a limited agenda?

- **Who are the primary and secondary audiences?**

  e.g., are the target audiences limited or unlimited in scope; are the primary and the secondary audiences the same? Where they are different, the message to the secondary audience is more likely to be advertising**.**

- **Who delivers the message (the provider)?**

  e.g., the drug manufacturer/its agent or an independent third party (e.g., patient support group). Where delivered by an independent party, the message is less likely to be considered as advertising.

- **Who sponsors the message and how?**

  e.g., the drug manufacturer/its agent or an independent third party; is the sponsorship funding targeted to a specific message, or is it added to the general operating budget for an organization, conference etc.? If the message is sponsored by an independent third party and the funding is added to the general operations budget, the message is less likely to be advertising. Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.

- **What influence does a drug manufacturer have on the message content?**

  e.g., what are the linkages between the information, the provider and the manufacturer, the provider and the writer, etc.? Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.

- **What is the content of the message**?

  eg., are the facts described objectively in a balanced manner, or is emphasis placed on a particular drug or its merits; is the message balanced with respect to description of risks as well as benefits of a treatment option? Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?

- **With what frequency is the message delivered?**

  e.g., is it delivered once or repeatedly? Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.

No one factor in itself will determine whether or not a particular message is advertising. Each message must be evaluated on its own merit and other factors may apply.

Examples of messages delivered in different contexts are discussed in Appendix I. The list of examples is intended as a guide only and is not all inclusive. The same factors for consideration will be applied to other types of messages not listed here.

This clarification should assist in distinguishing between advertising and non-promotional information. **It is only after having determined that the primary purpose of a message is advertising that an assessment can be made regarding compliance with the regulations pertaining to drug advertising.**

## APPENDIX I

## Examples of Message Types in the Context of Advertising and Non-promotional Information

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## Examples of Message Types in the Context of Advertising and Nonpromotional Information

### Press Releases/Press Conferences:

It is common practice for a pharmaceutical manufacturer to release information on new developments in research and at the time of launch of a new drug or a new indication for use of a previously authorized product.

A press release or information disseminated at a press conference concerning a drug may be a nonpromotional activity in the following circumstances:

- the announcement is directed to shareholders or potential shareholders,
- the announcement is limited to the name of the drug and its authorized or proposed therapeutic use,
- no statement is made regarding the degree of safety or efficacy expected,
- no comparison is drawn with other treatments,
- in the case of unauthorized drugs, or unauthorized indications, the message cautions that the safety and efficacy are still under investigation and that market authorization has not yet been obtained, and
- there is no attempt to influence the pick-up, placement or emphasis given in subsequent publication or broadcast, e.g., no payment is made by the manufacturer to influence the visibility (e.g., section) in the press.

In contrast, a press release or information disseminated at a press conference may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the message is to promote the sale of a drug, for example:

- undue emphasis is placed on the drug being a "breakthrough",
- the press release is subsequently sent or provided to another audience, e.g., mailed to physicians,
- a fee is paid by the sponsor to have the message published, or broadcast, or
- in the case of an unauthorized drug, it is indicated that the drug is available through the Special Access Programme,

**Patient Support Group Literature**

Patient support groups often publish information in the form of brochures/leaflets that are intended to promote a better understanding of a disease and its treatment among members and potential members. It can be difficult to distinguish between advertising and nonpromotional information in this context.

Declaration of sponsorship of the brochure by a drug manufacturer does not in itself render the brochure promotional. Patient support group publications that include information on drugs may be a nonpromotional activity in the following circumstances:

- the content is disease related rather than product related,
- the various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a " breakthrough", and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Patient support group publications may be advertising where any of the aforementioned conditions are not met, and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

**Patient Information Booklets**

Information in the form of a leaflet, brochure, or booklet published by the manufacturer about a drug product is not advertising if it pertains only to the drug which it accompanies, and is given to a patient for whom the drug is being, or already has been, prescribed. In these circumstances, the information is considered to be part of the labelling and is, therefore, subject to the relevant regulatory and policy requirements relating to labelling rather than advertising.

By contrast, such information packages about a specific product that are distributed independently of the product to consumers for whom the drug has not been prescribed, fall within the definition of advertising.

**Consumer Brochures:**

i) Consumer brochures include leaflets/brochures that may make reference to but do not accompany a drug product, and are made available directly or indirectly to the consumer by a drug manufacturer, or other organization, by various means, e.g., by mail, in retail outlets, in health professionals waiting rooms, etc.

Declaration of sponsorship of such a brochure by a drug manufacturer does not in itself render the information promotional. Consumer brochures may be nonpromotional information in the following circumstances:

- the content is disease related rather than product related,
- the various treatment options (drug and non-drug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description of a product as a "breakthrough", and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Consumer brochures may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

ii) Consumer brochures also include leaflets/brochures that are not product-specific but expound on the pharmacological properties/actions of an ingredient, e.g., herb, vitamin, mineral, etc., and are made available in retail outlets selling products containing the same ingredients.

Such information packages may be considered to be advertising for a drug product when displayed in close proximity to or distributed with products containing the same ingredient, in the same retail outlet.

**Videos and Interactive Electronic Databases**

Videos are defined as messages recorded on videotape that make reference to drug products and that may be played, with or without a request, e.g., in healthcare professional waiting rooms, pharmacies etc.

Interactive electronic databases are defined as electronic information systems that provide menus through which the consumer can control the level of information detail accessed upon request, e.g., drug store kiosks, Internet.

The circumstances under which information about drugs disseminated by videos and interactive electronic databases may or may not be advertising are similar to those specified for consumer brochures and Patient Support Group literature.

**Continuing Medical Education (CME)/Scientific Symposia/Exhibits**

CME events and scientific symposia related to drugs are sometimes sponsored by pharmaceutical manufacturers. Such activities may not be advertising when they provide a forum for exchange of information on related clinical and scientific issues. The key factor in determining the status of such an activity is the degree to which the programme is independent of the drug manufacturer. The information may be nonpromotional in the following circumstances:

- sponsorship by a drug manufacturer is not targeted to specific aspects of the agenda,
- the sponsor's role is adequately disclosed,
- the programme is directed to scientists and/or health professionals,
- the programme allows for exchange of information/debate,
- the content of the agenda is not influenced by the sponsor,
- the content of an individual presentation is not influenced by the sponsor where it concerns a drug manufactured by that sponsor,
- there is no inducement provided to participants,
- there are no ancillary commercial or promotional activities relating to drug products,
- the limitations of the data and of the drug are adequately discussed,
- discussion of an unauthorized drug or indication for use includes a statement indicating that the drug/indication has not been authorized for marketing in Canada, and
- no reference is made to the availability of unauthorized drugs through the Special Access

Programme.

Such an activity may be advertising where any of the aforementioned conditions are not met or where other factors indicate that the primary purpose of the activity is to promote the sale of a specific drug.

Moreover, reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a specific drug may be advertising if they are disseminated by the sponsor, or the sponsor's agent, to a wider audience after the meeting.

**International Conferences**

The considerations described above for scientific symposia also apply to international medical/scientific conferences held in Canada. However, in the context of an international conference, display of a drug product prior to market authorization in Canada, or a product that is labelled for a use that has not been authorized in Canada, may be a nonpromotional activity in the following circumstances:

- the conference must clearly be an international event, e.g., a significant proportion of the conference delegates are from other jurisdictions,
- the material must emanate from the parent company of the manufacturer,
- the material must only be for use within the confines of the conference, and
- the material is prominently identified as **not being authorized for sale in Canada**.

**Help Seeking Announcements**

Help seeking announcements are defined as announcements that ask patients among the general public having a particular medical disorder, or that experience a given set of symptoms, to consult a physician for discussion of treatment, or to call a 1-800 telephone number for further information.

Such an announcement may be a nonpromotional activity in the following circumstances:

- no specific drug is identified,
- there is no implication that a drug is the sole treatment available for the disease or condition, and
- no drug manufacturer's name is included.
- Such an activity may be advertising where any of the aforementioned conditions are not

met, or where other factors indicate that the primary purpose is to promote the sale or disposal of a drug.

**1-800 Telephone Numbers**

Information provided by the sponsor to a member of the general public in response to a call placed on a 1-800 line set out in a help-seeking announcement may be a nonpromotional activity, in the following circumstances:

- the content is disease related rather than product related,
- the various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a " breakthrough", and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Information supplied pursuant to a call placed on the 1-800 telephone line may be advertising where any of the aforementioned conditions are not met or where other factors indicate that the primary purpose is to promote the sale of a drug.

**Unsolicited Requests for Information**

Information provided to an individual about a drug treatment(s) by a pharmaceutical manufacturer in response to a request for information that has not been solicited in any way (by the manufacturer of the drug) is not considered to be advertising for the sale of a drug.

**Journal Supplements/Inserts**

Journal supplements are usually comprised of a collection of articles that deal with related issues or topics, are published as a separate issue of the journal, or as a second part of a regular issue, and are funded by sources other than the journal publisher, e.g., by the pharmaceutical manufacturer.

Where publication is sponsored, in whole or in part, by a drug manufacturer, it may be a nonpromotional activity in the following circumstances:

- the content of the insert comprises unedited symposium proceedings that address a variety of issues relating to different disease entities or drug treatments,

- the content of the insert reports on a variety of treatment approaches for the same medical condition,

- the publication is targeted to its customary readership,

- no link is established between conventional advertising and the articles, e.g., by proximity,

- sponsorship by the pharmaceutical manufacturer is declared in such a way that there is no obvious link to a drug discussed, and

- the supplement is identified in such a way that it is distinct from the regular journal edition.

In contrast, a journal supplement may be advertising where the aforementioned conditions are not met and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug, for example:

- the supplement, in whole or part, is disseminated by the sponsor rather than by the publisher of the journal itself,

- the publication or an article contained in it is edited by the sponsor, or

- a conventional advertisement is placed in close proximity to an article discussing an unauthorized use for the same chemical entity/drug product.

**Clinical Trial Recruitment**

An announcement that is intended to assist in the recruitment of patients or clinical investigators for a clinical trial, including an Open-label or Treatment IND, may be a nonpromotional activity in the following circumstances:

- the intent of the announcement is clearly identified as being for recruitment of clinical trial participants,

- the announcement indicates the patient profile required (the disease/symptoms to be treated, age, etc.),

- the announcement includes a telephone number for obtaining further information that is related only to the clinical trial, and

- in the case of patient recruitment, no reference is made to the drug manufacturer's name, or to the name of the drug under investigation.

In contrast, an announcement used in the recruitment of clinical trial participants (patient and investigator) may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary intent of the announcement is to promote the sale of a drug, for example:

- the announcement makes claims respecting the safety and efficacy of the drug, or

- the announcement draws a comparison with other treatments.

**Formulary Kits**

Formulary kits are defined as material prepared for review by pharmaceutics and therapeutics and formulary committees, on which a decision to include a drug product in a formulary may be based. Such information may not be advertising provided the information is limited to that which would normally be required to support such an application.

Where such an information package is disseminated, in whole or part, to a wider audience simultaneously, or at a later date, it may be advertising to promote the sale of the drug concerned.

**Institutional Messages**

An institutional message is defined as a communication (e.g., brochure, published article, prospectus, annual report, etc.), which provides information about a pharmaceutical manufacturer, or other institution, concerning its philosophy, activities, product range (by name), financial details, area of future development or research, etc. Such a message may be a nonpromotional activity in the following circumstances:

- the purpose of the communication is clearly to provide information about the institution rather than about the drugs being marketed, developed or researched,

- information about the drugs being marketed, developed or researched is limited to the name and therapeutic use of the drug, and

- no emphasis is given to any one or more products, or their benefits.

**Reference texts, Peer-reviewed Journal Articles**

Dissemination of full, unedited reference texts (textbooks, chapters of textbooks), government publications or reprints of published, peer-reviewed articles from medical or

scientific journals, that are identified as being provided courtesy of a pharmaceutical manufacturer, may be a nonpromotional activity provided that:

- no link between the text and promotion of a drug is established by the manufacturer.

Such material may be considered to be advertising where the aforementioned condition is not met or where other factors indicate that the primary purpose is to promote the sale of a drug, for example:

- the material is accompanied by any form of additional information (e.g., printed, word of mouth) designed by or on behalf of the manufacturer for the purpose of promoting a drug (e.g., detail aid),

- the material was written or edited by an employee or agent of the pharmaceutical manufacturer,

- a summary or interpretation of the text prepared by the pharmaceutical manufacturer or his agent accompanies the material,

- reference is made to the availability of an unauthorized drug through the Special Access Programme.