POLICY
From the Health Products and Food Branch

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Advertising Standards Canada and Health Canada's Roles and Consultation Related to Advertising Review and Complaint Adjudication

Issue:

Health Canada and Advertising Standards Canada (ASC) share the common goal of maintaining integrity in drug advertising. It is therefore necessary to ensure that the respective roles of these organizations in meeting this goal are clear to all stakeholders and to Health Canada and ASC staff.

Scope:

This policy is intended to clarify the roles of the ASC and Health Canada with respect to the review of advertising directed to the consumers for **nonprescription drugs authorized** for human use; to clarify their roles regarding the processing of complaints; and to define procedures for inter-agency consultation.

Definitions:

For the purpose of this policy, the following terms are defined:

Claim:
Any representation made on behalf of the drug including the indication for use and marketing claims.

Indication for Use:
A statement that describes the limitations for use of a drug product that include the disease state, condition(s) or symptom(s) and the target population, if specified, for which the drug is intended to be used. The indication for use is part of the terms of product authorization, as identified in the Product Monograph (PM) accompanying the Notice of Compliance (NOC) or in the document that assigns a Drug Identification Number (DIN) and related labelling.

Marketing Claim:
A statement that is designed to promote the sale or disposal of a drug product and which highlights a specific product attribute, such as a direct or implied comparative claim, eg., more effective than....., non-drowsy

Terms of Market/Product Authorization:

The terms of market authorization are comprised of all information in the PM that accompanies the NOC and in the document that assigns a DIN and related product labelling for drugs that are subject to the requirements of Division 8, Part C of the **Regulations** (new drugs). For drugs that are not subject to Division 8, Part C of the Regulations, the terms of market authorization are identified in the document that assigns a DIN and related product labelling. This information is derived from the review of information on the drug product that is required to be submitted for regulatory review and authorization, as outlined in the **Food and Drugs Act** and **Regulations** and interpretative guidelines and policies.

Unauthorized Product:

This refers to a drug product for which no NOC and/or DIN has been issued by Health Canada.

Complaint:

Complaint refers to a written submission by any party alleging that a consumer-directed nonprescription drug advertisement does not conform, in whole or in part, to ASC's standards for review referenced in this document.

Appeal:

Appeal refers to a written request submitted to ASC, under an appeal process and procedure stipulated by the ASC, for review of an ASC decision to deny approval of advertising material submitted for clearance.

Background:

In accordance with the requirements of the **Food and Drugs Act** and **Regulations**, pharmaceutical manufacturers are required to file a submission containing information and material to establish the safety and efficacy of a drug product for the intended use prior to marketing, and to be in receipt of marketing authorization in the form of a Notice of Compliance (NOC) and/or a Drug Identification Number (DIN).

Section 9 (1) of the Food and Drugs Act establishes, inter alia, general prohibitions regarding the content of drug advertising as follows:

> **"No person shall label, package, treat, process, sell or advertise any drug ..... in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its composition, merit or safety."**

To meet this condition, information in an advertisement must not be in conflict with the terms of market authorization and with the Health Canada Guidelines and Policies related to advertising provisions of the **Food and Drugs Act** and **Regulations**.

It is the responsibility of all advertisers to ensure that drug advertisements comply with the requirements of the **Act** and **Regulations**. It is the responsibility of Health Canada to administer the **Act** and **Regulations**.

Advertising Standards Canada (ASC) is a national association committed to assuring the integrity and viability of advertising through voluntary compliance with standards agreed upon by the relevant industry sectors.

On March 3, 1997, ASC was delegated the responsibility for preclearing consumer-directed broadcast and mass media print advertising for nonprescription drugs, for administering an alternative mechanism for monitoring non-mass media print advertising and for adjudication of related trade disputes, complaints and appeals. The standards for review of such advertising will be the product-specific terms of market authorization and the ASC Consumer Drug Advertising Standards and Procedures ("ASC Standards and Procedures") which are consistent with the principles outlined in the advertising provisions of the **Food and Drugs Act** and **Regulations** and related Health Canada Guidelines and Policies.

It is recognized that during the preclearance review of a drug advertisement, or during the processing of an appeal or complaint, ASC may need to consult Health Canada regarding policy related issues. It is also recognized that Health Canada may sometimes wish to bring an advertising issue to the attention of ASC.

Operational Policy:

The roles of Health Canada and of ASC with respect to the **review** (as opposed to the **regulation**) of specific advertising material, and to processing of disputes, complaints and appeals, can be distinguished as follows:

I ASC Role

A. ASC role is to review and clear advertising material prior to being disseminated to consumers via the broadcast media and mass-media print publications; to monitor other print media by an alternative mechanism; and to administer complaints and appeals procedures, related sanctions and remedial measures referenced in the ASC Standards and Procedures and Canadian Code of Advertising Standards.

B. As well as review of advertising for consistency with the terms of market authorization, the ASC role includes evaluation of advertising claims for which substantiation is not necessarily found in the terms of market authorization. Examples of such marketing claims include comparative claims (product X is more effective than product Z), absence of side effect claims (eg., non-drowsy). In

this case, ASC may evaluate information and data submitted by the advertising sponsor in support of such marketing claims **provided** that the claim or the supporting data **do not expand upon or conflict with the terms of product authorization outlined in the PM or labelling.**

II Health Canada's Role

A. Health Canada's role is to set the minimum standards to be met in drug advertising by establishing the terms of product authorization, by developing appropriate regulations, guidelines and policies and by bringing these standards to the attention of ASC.

B. Health Canada will review and process complaints concerning consumer-directed advertising for nonprescription drugs which are brought to the attention of Health Canada pursuant to item III.A.6 below when:

a) Health Canada determines that advertising contravenes the **Act** and **Regulations** and presents an imminent and/or significant health hazard defined as:

> a situation in which there is a reasonable probability that the inappropriate use of, or exposure to, a product as prompted by violative advertising, will cause serious adverse health consequences or death.

b) advertising contravenes the **Act** and **Regulations** through nonparticipation or willful noncompliance with ASC Standards and Procedures.

C. Health Canada will not otherwise become involved in the ASC complaint and appeal procedures.

III Consultation and Complaints

The procedures for consultation between ASC and Health Canada, and the handling of complaints, shall be as follows:

A ASC with Health Canada:

Consultation

1. Any ASC concern/question should be posed in writing, as **an issue** which sets out:

. the issue,

. the ASC interpretation of the PM or labelling relative to the contentious statement(s),

. the ASC analysis and preliminary decision,

and, where applicable:

. the sponsor's interpretation of the PM/labelling and contentious statements, and/or

. the decision of ASC's applicable panel

The advertisement from which the issue in question arises should be forwarded to Health Canada for review only in circumstances described in item A(6).

2. Issues raised for consultation with Health Canada should be limited to those relating to advertising claims/statements that require (or should have required) regulatory review and authorization, e.g., in a Supplementary New Drug Submission, Notifiable Change (Division 8, Part C of the Regulations), DIN submission[1].

Health Canada should not be consulted if the issue relates to a claim for which substantiation would not generally be reported in the PM (e.g., comparative efficacy), and which does not conflict with the terms of market authorization reported in the PM/labelling.

3. The dialogue will be between ASC and Health Canada. The advertising sponsor will be apprised of the decision by ASC.

4. Health Canada will make every effort to review an advertising issue and provide a written response to ASC within 10 calendar days.

Complaints

5. Except for the circumstances outlined in Section II.B, complaints related to consumer-directed nonprescription drug advertising, disseminated by any means, will be processed by ASC pursuant to provisions and timeframes expressed in ASC's dispute/complaints resolution procedures (ASC's Complaints Procedures). This includes complaints concerning advertising for **authorized** products that were **not** (or were not required to be) submitted for preclearance review.

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[1] For drugs subject to the requirements of Division 8, Part C of the Regulations, (new drugs) Health Canada's Policy: Changes to Marketed Drugs provides guidance on product information changes that require the submission of a Supplemental New Drug Submission, Notifiable Change etc. For drugs which bear a DIN but are **not** subject to Division 8, Part C of the Regulations, Section C.01.014.4. of the Regulations identifies the product information changes that require a new DIN application (where an added indication does not render the product subject to Division 8, Part C of the Regulations).

6. ASC is expected to bring to the attention of Health Canada:

   . complaints that relate to advertising which, in ASC's judgement, contravenes the **Act** and **Regulations and** presents an imminent and/or significant health hazard, or

   . complaints that relate to advertising which, in ASC's judgement, contravenes the **Act** and **Regulations and** which ASC has been unable to bring into compliance with ASC's Standards and Procedures, e.g., through willful nonparticipation in, or noncompliance with, ASC's Standards and Procedures.

7. In the event that a complaint concerning advertising for an **unauthorized** product is submitted to ASC in error, ASC is expected to return the complaint to the complainant and request that it be directed to the Health Products and Food Branch Regional Office nearest to the complainant.

B Health Canada with ASC

Consultation

1. A Health Canada concern about ASC's advertising review will be brought to the attention of ASC in terms of an issue (rather than the actual advertisement) which sets out:

   . the issue, and

   . suggestions for addressing the issue

Complaints

2. Since complaint resolution is through ASC'S Complaint Procedures, complaints concerning consumer-directed advertising for authorized products that are directed in error to Health Canada will be forwarded to ASC for processing **without comment** within 10 calendar days **except in the circumstance outlined in B3**. ASC will process the complaint redirected from Health Canada within the timeframe and according to the procedures expressed in ASC's Complaints Procedures.

3. In the event that an advertisement submitted in error to Health Canada presents an imminent and/or significant health hazard defined in item II.B(a), Health Canada will take direct action with the sponsor and will simultaneously inform ASC of that action.

4. Advertising material forwarded to Health Canada by ASC because it is believed to contravene the **Act** and **Regulation*s* and** to pose an imminent or significant health hazard, as stated in item A(6), will be assessed according to Health Canada health hazard evaluation procedure as in

B(2). Where a Class I health hazard is confirmed, Health Canada will take direct action with the sponsor and simultaneously inform ASC of that action. Where a Class 1 health hazard is **not** confirmed, the complaint will be returned to ASC for further processing.

5. Advertising material that, in ASC's judgement, contravenes the **Act** and **Regulations** and that is forwarded to Health Canada by ASC because of failure to bring it into compliance with ASC Standards (item A(6)) will be evaluated against the requirements of the **Act** and **Regulations**.

   Where noncompliance with the **Act** and **Regulations** is confirmed, Health Canada will take action in a manner that is consistent with the principles of risk management, and simultaneously inform ASC of that action.