Drugs Directorate
Tunney's Pasture
Postal Locator #0702A
OTTAWA, Ontario
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February 5, 1996

Sent to Associations

Dear :

As part of the Drugs Programme Advertising Action Plan, the Drugs Directorate has committed to review options for improving the linkages and flow of information between the Drugs Directorate and the Pharmaceutical Advertising Advisory Board (PAAB). As a first step, and in consultation with the PAAB, the attached policy has been developed to clarify the roles of both organisations with respect to the review of drug advertising directed to health professionals, and the processing of complaints. The policy also defines a framework for consultation and replaces the *Drugs Directorate Policy, Advertising of Prescription Drugs: Adjudication of Complaints,* dated April 23, 1993.

It is expected that dissemination of this policy will improve the understanding among stakeholders, and among PAAB and Drugs Directorate staff, of the complementary roles of the two organizations. In addition, compliance with the policy by all parties will avoid duplication of effort and contribute to more efficient mechanisms for regulating the content of advertising.

Any comments that you may have concerning editorial issues or the need for clarification should be directed to Dr. Valerie Robertson, Advertising Coordinator, telephone (613) 954-4889, fax (613) 954-6511.

Original signed by:

Dann M. Michols
Director General

Attachment

Policy Issues

January 11, 1996

Health Products and Food Branch

Administrative Update:August 2005

PAAB and Health Canada Roles and Consultation Related to Advertising Review

Issue:

This policy is intended to clarify the roles of the Pharmaceutical Advertising Advisory Board (PAAB) and Health Canada with respect to the review of drug advertising directed to healthcare professionals; to clarify their roles regarding the processing of complaints; and to define a procedure for consultation.

Scope:

This policy applies to the review of all advertisements directed to the health professional for drugs authorized for human use, as indicated in the PAAB Code of Advertising Acceptance (PAAB Code).

This policy does not apply to advertising for a drug for which market authorization has not been issued.

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., fewer side effects, longer acting, more effective than.....

.../2

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. 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.

Background:

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 comply with Section 9(1) information in a drug advertisement must be consistent with the conditions under which sale of the product has been authorized, as stipulated in the Notice of Compliance (NOC), the Product Monograph (PM) or other authorization to market a drug.

Additional requirements are set out in other applicable provisions of the *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*.

The PAAB is an autonomous, multidisciplinary body that provides a mechanism for the independent review and clearance of drug advertising and promotional materials, submitted by manufacturers on a voluntary basis prior to exposure to healthcare professionals. This system was set up in response to a call for improvement in the standard of health professional advertising, and as an alternative to government authorization of advertising prior to use. Standards for the PAAB review of advertising are set out in the PAAB Code which conforms with the relevant requirements of the *Act* and *Regulations*, and various applicable guidelines and policies.

1. It is recognized that during the preapproval review of an advertisement, or during the course of a review associated with processing an appeal or complaint, the PAAB may need to consult Health Canada regarding interpretation of the terms of market authorization. It is also recognized that Health Canada may sometimes wish to bring an advertising issue to the attention of the PAAB.

In the past, consultation between the PAAB and Health Canada regarding the content of an advertisement has led to the review of the advertising copy by both agencies. Inconsistency in review principles and criteria for decision-making has resulted from the dual review in some instances and not in others.

Operational Policy:

The roles of Health Canada and of the PAAB with respect to the review (as opposed to the regulation) of specific advertising material can be distinguished as follows:

I PAAB Role

The PAAB role is to review and clear advertising material prior to exposure to the health professional, and to administer a complaints and appeals procedure and related sanctions and remedial measures as outlined in the PAAB Code.

As well as review of advertising for consistency with the terms of market authorization, the PAAB role includes evaluation of marketing claims that make a direct (product X is more effective in relief of symptom Y than product Z) or implied comparison (e.g., 96% efficacy). The basis for comparative claims would not be found in the PM since information on comparative efficacy, or other comparison with another drug product, would not generally be reported therein.[1] In this case, the PAAB may clear information submitted by the advertising sponsor in support of such marketing claims provided that the claim or the supporting data **do not expand upon or go beyond the limits of the terms of product authorization outlined in the PM or labelling**.

The PAAB role also includes the review of Dear Health Professional letters issued by manufacturers, other than those that respond to a safety issue, when required by Health Canada. In case of doubt concerning the PAAB role in this respect, consultation between the PAAB and Health Canada will determine jurisdiction.

II Health Canada's Role

Health Canada's role is to set the minimum standards to be met in drug advertising by developing appropriate regulations, guidelines and policies and by bringing these standards to the attention of the PAAB so they may be incorporated in its Code. As indicated in Section I, Health Canada will review advertising directed to health professionals in the following circumstances:

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[1] Health Products and Food Branch Guideline, Product Monographs requires that the document is "devoid of promotional material"

a) when advertising that contravenes the *Act* and *Regulations* may present an imminent and/or significant health hazard, or

b) when contravening (the *Act* and *Regulations*) advertising arises from failure of the self-regulatory mechanism through willful nonparticipation with the self-regulatory system, or willful noncompliance with the PAAB Code.

Health Canada's role also includes the review of Dear Health Professional letters that have been required by Health Canada pursuant to a safety issue. PAAB will be simultaneously notified of the action taken.

III Consultation and Complaints

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

A PAAB with Health Canada:

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

   . the issue,

   . the PAAB interpretation of the PM and the contentious statement(s), and

   . the PAAB decision,

   and, where applicable:

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

   . the decision of the Complaints/ Appeals 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 claims/statements regarding the attributes of the advertised product that would require (or should have required) premarket, regulatory review and authorization, e.g., in a Supplementary New Drug Submission, Notifiable Change (Division 8, Part C of the Regulations).

   Health Canada should not be consulted if the issue relates to a claim for which the basis would not generally be reported in the PM (e.g., comparative

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efficacy of products) and which does not expand upon the terms of market authorization reported in the Product Monograph.

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

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

5. Complaints and appeals will be processed by the PAAB pursuant to provisions and timeframes expressed in the PAAB Code Complaints and Appeals mechanism except for:

   . those that relate to advertising which contravenes the *Act* and *Regulations* and may present an imminent and/or significant health hazard, or

   . those that relate to advertising which contravenes the *Act* and *Regulations* and which the PAAB have been unable to bring into compliance with the PAAB Code, e.g., through wilful nonparticipation or noncompliance with the PAAB Code.

6. The PAAB is expected to bring to the attention of Health Canada violative advertising that it believes may present an imminent or significant health hazard or advertising that it has failed to bring into compliance with the PAAB Code and which is believed to contravene the *Act* and *Regulations*.

B Health Canada with the PAAB

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

   . the issue, and

   . suggestions for addressing the issue

2. The first avenue for complaint resolution is the PAAB through the PAAB Code Complaints and Appeals mechanism. Complaints concerning advertising directed to the health professional for an authorized drug that are directed in error to Health Canada will be screened for content of an imminent and significant health hazard. Subsequent action will be as follows:

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a) where no significant/imminent hazard is found, the complaint will be forwarded to the PAAB for processing without comment, or

b) where screening reveals a health hazard that may be imminent and/or significant, the advertising material in question will be further evaluated in terms of Health Canada's health hazard evaluation procedure.

3. Further to item B (2b), where a health hazard is determined to be Class 1 in terms of the risk categories defined under Operational Policy Directive 86-0-1, Health Canada will deal directly and immediately with the sponsor and simultaneously inform the PAAB of the action taken.

4. Further to item B (2b), where a lesser hazard is found, Health Canada will forward the complaint for processing by the PAAB with a report that is limited to information contained in the health hazard evaluation. PAAB will process the complaint within the timeframe and according to the procedures expressed in the PAAB Code Complaints and Appeals mechanism.

5. Advertising material forwarded to Health Canada by the PAAB because it is believed to contravene the *Act* and *Regulations* and to pose an imminent or significant health hazard, as stated in item A(6), will be assessed according to Health Canada's health hazard evaluation procedure as in B(2b). Subsequent action taken by Health Canada will depend on the result of the health hazard evaluation described in items B (3) and (4).

6. Advertising material forwarded by PAAB because it has failed to bring it into compliance with the PAAB Code, and which is believed to be in violation of the *Act* and *Regulations*, as stated in item A(6), will be evaluated against the requirements of the *Act* and *Regulations*.

   Where noncompliance with the *Act* and *Regulations* is verified, Health Canada may elect to deal directly with the sponsor and simultaneously inform the PAAB of the action taken.