Therapeutic Products
Programme
Tunney's Pasture
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November 9, 1998

97-013115
9608-6-3/2

To Stakeholders:

Dear :

This is further to my letter dated June 5, 1997, in which I invited stakeholder input on an initial policy for comparative claims made on behalf of drug products with respect to the presentation and substantiation of comparisons relating to the **non-therapeutic** aspects of non-prescription drugs.

The attached policy: Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products is intended to define the conditions under which such comparisons will not be considered false, misleading or deceptive to the intended audience.

In response to the comments received on the initial policy proposal, the Therapeutic Products Programme (TPP) has finalized the broad principles related to substantiation and presentation of comparative non-therapeutic claims. The TPP is not responsible for reviewing non-therapeutic comparative claims, however, this policy is intended to guide the development by the independent review agencies endorsed by the TPP of more detailed standards for presentation of non-therapeutic comparative claims related to non-prescription drugs. This approach will also permit development of separate interpretative guidelines for health professional and consumer-directed advertising that will take into account the differences in these target audiences.

These broad principles are based on the fundamental

principles of scientific evidence and the basic tenets of interpretational guidance related to another federal statute that governs all marketing practices, the Competition Act. The principles developed by stakeholders at the June 1996, Comparative Advertising Consultation Workshop, and comments on the initial policy proposal, were also considered in the development of this policy.

The TPP received seven responses from stakeholders. Three of the respondents had no comments or agreed with the proposal. Specific comments from other stakeholders were incorporated in the policy, however a number of suggestions have been considered and addressed as follows:

1. What is the role of the TPP regarding the evaluation of non-therapeutic comparative claims?

   The TPP is not responsible for reviewing non-therapeutic claims for drug products, however the TPP wishes to ensure that any concern with misleading non-therapeutic claims does not adversely impact the therapeutic understanding of a drug product. TPP's responsibility lies in the interpretation of regulatory provisions and to set minimum standards that would help ensure that false, misleading or deceptive advertising for therapeutic products does not occur.

2. Two respondents were under the impression that this policy would address issues regarding the promotion or comparison of non-therapeutic aspects of other product categories (such as foods or cosmetics) with those of non-prescription drug products.

   The original intent of the policy was to set the parameters for comparative advertising of the non-therapeutic aspect of non-prescription drug products with other non-prescription drug products, or with other product categories (foods, cosmetics). Vice versa comparisons (eg. comparing foods to drugs) were not taken into consideration and future initiatives and consultation with parties in the food, cosmetic, natural health products and functional foods areas industries would be required. We are not in a position

   to develop the criteria for such comparisons until further analysis is conducted on how to best regulate these products.

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3. One respondent suggested that the onus should not be on the advertising sponsor to continually scan the worldwide literature to validate the data used in comparative claims and monitor any changes in formulation of the product that was compared and that might affect the comparison. It was felt to be cost prohibitive and inefficient.

   The TPP does not agree with the proposed amendment which indicates "... and amending the claim as necessary, in light of new contradictory evidence or information when it becomes known or made available to the advertising sponsor." The sponsors are responsible to monitor the marketplace and scientific information to ensure that claims are substantiated and up to date in order to prevent false, misleading or deceptive advertising of drug products. Thus, the original wording was kept.

The full impact of this policy on market behaviour and subsequent risks cannot be fully anticipated at this time. Because there is a lack of empirical evidence to support or refute the concern that comparisons of non-therapeutic aspects of non-prescription drugs with other product categories may put consumers at risk due to inappropriate product selection, we will monitor the impact of this policy. This will also permit the incorporation of changes to this policy in order to ensure its continuing relevance especially in the area of categorization of various products, such as herbal medicines and functional foods. The TPP encourages sponsors and associations to do research on consumer comprehension of the claims during the first few years of use of this policy. Independent review agencies will assist in the compilation of the nature and quantity of complaints that may result further to the implementation of this policy. These results, along with other information gathered may prompt amendments to the various sections of this policy. If significant health hazards are observed, major revisions or even withdrawal of this policy may be considered.

The attached policy is effective immediately, however we expect the provisions, as they relate to non-prescription drug advertising, to be put into effect by the independent pre-clearance agencies endorsed by the TPP upon finalization of the separate guidelines on data requirements.

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With regard to drug product labelling, the attached policy will be applied by the TPP to pre-market label review upon the date of publication.

We will be pleased to consider any comments that relate to interpretational issues or clarity. These comments should be forwarded to Ann Sztuke-Fournier, A/Head, Advertising and Promotions Unit, Bureau of Drug Surveillance, Finance Building, Tunney's Pasture, Address Locator 0201C1, Ottawa, Ontario, K1A 1B9.

Implementation of this policy and associated interpretative guidelines is expected to ensure that non-therapeutic comparative claims will not be misleading to the intended audience and will provide for consistency of advertising review.

Original signed by

Dann M. Michols
Director General

Attachment

POLICY **No. 1**

Issued:OCTOBER 1998 From the Health Products and Food Branch

Administrative Update: August 2005

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Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products

1. PURPOSE

To define the conditions under which comparison can be made of non-therapeutic aspects of non-prescription drug products with those of other non-prescription drug products, or with other product categories in labelling and advertising, such that these claims will not be false, misleading or deceptive as to the therapeutic character, value, quantity, composition, merit or safety of the drug product to the intended audience.

2. BACKGROUND

Section 9(1) of the Food and Drugs Act prohibits advertising and labelling for any drug that is "false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety". This legislative provision is intended to help minimize the risk associated with selection and use of drug products.

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The following broad principles of drug advertising are drawn from this statutory provision:

1. the primary representation of a drug product must be as a drug as defined in the Food and Drugs Act;

2. the primary focus of the advertising message must be on the therapeutic aspect;

3. advertising content must not be in conflict with the terms of market authorization as outlined in the Product Monograph and labelling cleared at the time of issuance of the drug identification number; and

4. claims made on behalf of a product that are not subject to pre-market authorization and that were not reviewed by the Health Products and Food Branch(HPFB) prior to issuance of a drug identification number, (eg., comparative claims) must be substantiated by conclusive evidence derived from adequate, unbiased and statistically valid data.

Although there is no published policy regarding inclusion in advertising of non-comparative statements that refer to non-therapeutic aspects of a drug product (eg., taste, cosmetic benefit), there has been no objection to this practice, since it is considered to pose little risk to consumer safety. Similarly, there has been no objection to a comparison of these aspects between drug products provided the comparisons are made between products in the same drug category, eg., fluoride toothpastes and they are adequately supported.

However, the Health Canada Guideline: Consumer Drug Advertising indicates that comparison of non-therapeutic aspects of "cosmetic-like" drugs, such as taste, appearance, cleansing ability, with those of other product categories (eg., cosmetics, foods), is not acceptable. This restriction has been based on a perception that such cross-category claims and counterclaims may lead to inappropriate product selection and expose consumers to unnecessary risk; for example, by encouraging selection of a drug product when a cosmetic product is indicated and vice versa.

There is no empirical evidence that would support or refute this concern.

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A preliminary round of stakeholder consultation on comparative advertising in June 1996, indicated that standards for comparative claims should ensure that the claim:

- is evidence-based and balanced,
- does not compromise health and safety,
- promotes informed choice,
- supports the selection of appropriate therapies that will lead to improved health outcomes,
- is subject to independent review prior to dissemination,
- is not unfairly disparaging of competing products or drugs, and that
- the standards consider the differing needs of the various target audiences.

It is Health Canada's responsibility to provide interpretation of regulatory provisions and to set minimum standards that would help ensure that false, misleading or deceptive advertising for therapeutic products does not occur. Health Canada wishes to ensure that any concern with misleading non-therapeutic claims does not adversely impact the <u>therapeutic</u> understanding of a drug product. Based on the above and an analysis of the risks involved, the development of this policy responds to the will to expand on previous restrictions on comparative advertising. The observation of the broad principles of drug advertising, as expressed in the provisions of this policy, would ensure that appropriate measures exist to minimize any potential risk associated with permitting such comparisons in consumer-directed advertising or labelling of non-prescription drugs. It is unlikely that a consumer would select a drug product instead of a cosmetic or food solely on the basis of non-therapeutic comparative claims where the <u>intended use</u> of the advertised drug product is stated both on the product label and in advertising. Furthermore, the risk associated with use of an antidandruff product (drug) instead of a regular shampoo (cosmetic), or an antiperspirant (drug) instead of a deodorant (cosmetic) etc. is negligible.

Since Health Canada is not responsible for reviewing non-therapeutic claims, this policy is intended to guide the development by the independent review agencies of more detailed standards for presentation of non-therapeutic comparative claims related to non-prescription drugs.

3. SCOPE

This policy applies to the comparison of the non-therapeutic aspects of a non-prescription drug product with that of other non-prescription drug products, or with that of other product categories for human use in consumer-directed labelling and advertising.

This policy does not apply to:

- the relative cost-effectiveness of drug products;
- comparative claims, relating to therapeutic attributes including quality of life claims, or relating to ingredients in a drug product that contribute to its intended therapeutic use (e.g., vitamins, minerals, fibre),[1] that are made in advertising for all drugs for human use;
- the promotion of other product categories compared to non-prescription drugs (e.g. foods to drugs) using non-therapeutic comparative claims;[2] and
- emerging issues that relate to the classification of a product such as natural health products or functional foods, unless a determination has been made that a product is classified as a drug.

Note that a separate directive exists with respect to the principles for comparative claims related to therapeutic aspects of drugs.

4. DEFINITIONS

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[1] The content of fibre, vitamin or mineral in a drug usually relates to the indications for use, eg, therapeutic benefit, and directives are included in the Principles for Comparative Claims Related to the Therapeutic Aspect of Drugs.

[2] The provision of interpretation of advertising claims for foods and cosmetics is not within the Marketed Health Products Directorate (MHPD) mandate. Additional initiatives would be required to address these types of comparisons.

For the purposes of this policy the following terms are defined:

Non-therapeutic attributes of a drug product relate to its physical, sensory[3] or market characteristics[4], to the impact on physical characteristics of the body organ[5] upon or in which it is used, to cosmetic-type characteristics and to other aspects such as presentation, but excluding any characteristics that relate to the classification of the product as a drug.

Other product categories refers to other product types such as cosmetics and foods.

Ingredient refers to the active ingredient(s) unless otherwise specified.

5. POLICY

I. Comparison between drug products

Comparison between drug products in terms of comparability or superiority with respect to non-therapeutic attributes can be made under the following conditions:

1. the advertised product is primarily represented as a drug as defined in the Food and Drugs Act;

2. the compared products have an authorized indication for use in common with the advertised product;

3. the information provided may be of some benefit to some or most consumers , e.g., relevant to product selection;

4. the claim is supported by adequate, up to date, unbiased and statistically valid data;

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[3] physical or sensory characteristics include colour, flavour, smell etc.

[4] e.g., market position, retail cost

[5] eg., cleansing/moisturizing effect; impact on texture, feel, softness, beauty, smoothness and any other cosmetic performance claims

5. the claim does not obscure information on the authorized indication(s) or intended medicinal use(s) of the advertised drug product;

6. any comparison of non-therapeutic characteristics should also include a reference to therapeutic characteristics; and

7. messages with comparison of non-therapeutic characteristics should carry a statement to the effect that superiority in these areas does not mean better compliance and/or better therapeutic characteristics, unless such a claim can be substantiated by scientific data.

II. Comparison between a drug product and products in other product categories

Comparison between a drug product and products in other product categories in terms of comparability or superiority with respect to non-therapeutic attributes can be made under the following conditions:

1. the advertised product is primarily represented as a drug, and the other product's identity/function/purpose is clearly identified (e.g. food, cosmetic...);

2. there is no implication of therapeutic activity attributed to the non-drug product(s);

3. the compared products are intended for use on or in the same body organ, e.g., hair, skin, mouth, teeth;

4. the information provided may be of some benefit to some or most consumers , e.g., relevant to product selection;

5. the claim is supported by adequate, up to date, unbiased and statistically valid data;

6. the claim does not obscure information on the authorized indication or intended medicinal use of the advertised drug product; and

7. the overall impression of the advertisement does not mislead the consumer as to the overall

character, merit, composition, identity, function etc of the drug or non-drug product.

6. RESPONSIBILITIES & PROCEDURES

Advertising sponsors are responsible for ensuring that applicable comparative claims meet the requirements of this policy. It is also the advertising sponsor's responsibility to ensure the continuing validity of comparative claims made in drug advertising by reassessing the supporting evidence, and amending the claim as necessary, in the light of new evidence or information.

The independent pre-clearance agencies endorsed by Health Canada are responsible for the evaluation of non-therapeutic comparative claims in accordance with the principles outlined in this policy. Health Canada does not accept complaints concerning the overall impression of non-therapeutic comparative claims. Complainants may refer this type of complaint:

- to the sponsor of the allegedly non-compliant advertising;
- for complaints concerning advertising that allegedly violates this policy, to pre-clearance agencies endorsed by Health Canada for consideration under their formal complaints procedure;
- to Advertising Standards Canada (ASC) for consideration under ASC's Trade Dispute Procedure (for complaints brought under the Canadian Code of Advertising Standards);
- to the courts (for complaints brought under the Competition Act).

7. EFFECTIVE DATE

With respect to the review of product labelling, this policy is effective upon the date of publication.

With respect to product advertising, this policy is effective upon the date of publication and will be put into operation upon finalization of implementation guidelines by the independent pre-clearance agencies endorsed by Health Canada.