Roundtable Stakeholder Consultation on Section 2.21 (Risk/Safety Information Communication) of the Consumer Advertising Guidelines for Marketed Health Products (for nonprescription drugs including natural health products)

Ottawa, June 28, 2006

Roundtable Report

1. Purpose

Health Canada held a Roundtable Discussion on June 28, 2006 with various stakeholder groups affected by the proposed Section 2.21 of the Consumer Advertising Guidelines for Marketed Health Products (for nonprescription drugs including natural health products) (the Guidelines) in order to:

i. Review and provide feedback on Section 2.21;
ii. Establish a better mutual understanding of each others' concerns and perspectives; and,
iii. Propose viable options for moving forward in finalizing the Guidelines.

The report is intended to document the results of the roundtable by highlighting areas of agreement between participants as well as potential solutions that were proposed for areas of non-agreement so that the pathway forward towards finalizing the Consumer Advertising Guidelines can be achieved.

2. Approach

The roundtable was planned and designed to include a diverse and balanced range of stakeholders representing the full spectrum of interests. Participants were invited to submit a position paper, prior to the roundtable, outlining the potential impacts of the proposed text in Section 2.21 from their respective viewpoints and to propose alternatives approaches. Submissions were then consolidated, by the third-party neutral facilitators, into a discussion paper summarizing the perspectives [Attachment A] and distributed to participants in preparation for the roundtable. (For background information on consultations on this topic see (http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/reports-rapports/index_e.html).

The one-day roundtable proceeded through a series of presentations, whole group discussions and small group discussions. To help bring participants to a common level of understanding, two presentations were delivered. Health Canada's presentation [Attachment B] outlined the background, rationale and progress to date on revisions to Section 2.21 of the Guidelines. This was followed by a presentation by Advertising Standards Canada [Attachment C] which summarized the results of the April-May 2006 electronic consultation on the draft text for Section 2.21. After each presentation, there was opportunity for questions and discussion. A full session was then devoted to roundtable discussions, where each participant was afforded an opportunity to outline the benefits and drawbacks of the currently proposed text, from the perspective of the people and organizations they represent.

During the first session in the afternoon, the participants were divided into three small groups, each having balanced representation from the various interests present, to discuss the wording in section 2.21. During the last session, participants reconvened into plenary to discuss the results of small group deliberations, and to begin to identify where potential areas of consensus might

have been achieved as a mechanism to moving forward with the completion of these Guidelines. Any additional options that were identified during the small group discussions were also recorded. Results of the small group deliberations and those of the whole group during the closing plenary are documented as roundtable outputs, below.

This report was developed by the third-party neutral facilitators (Delaney and Associates Inc. - rmdelaney.com) and will assist Health Canada in developing the final text for Section 2.21 of the Guidelines.

3. Small Group Discussions

Small groups were structured to be diverse in perspectives and equal in number. There was a facilitator and recorder in each group. Each group approached their discussions slightly differently; group #1 reviewed each section of the proposed section 2.21, group #2 discussed an overall approach and then reviewed each section and group #3 dealt almost exclusively with the "When applicable or where appropriate" clause and options for implementation. The results of discussions are listed below by group.

Group #1

This group started discussion by working through the wording of Section 2.21 as proposed by Health Canada.

All participants in the group felt that the wording under the heading of "Guideline" was appropriate, and there was agreement on the language and intent of this part of Section 2.21. This reflects the discussion that occurred earlier in the Roundtable, where all participants agreed that consumers and the public should be provided with fair and balanced information about the benefits and risks associated with a product in order to make informed decisions.

The group then reviewed the next section of 2.21 – "Application". There was group agreement that consumers should always be advised to read the label, and be provided with an easily accessible source of additional, appropriate information. It was noted that label information should be complete and that the label itself should also include a reference to an additional source of information. It was also noted that a review of the labeling requirements would be useful to address some concerns raised during the discussion.

The group discussed a number of potential options for applicability.

The majority of group members agreed that some products should be exempt (cosmetic and personal care products). There was further agreement that advertising should both link to the label as a source of additional information and also that a standard message (i.e. refer to insert and/or refer to a health professional) could be developed for use in advertising. There was very little agreement by members of the group that all potential risks should be outlined, and discussion revolved around liability, advertising effectiveness and consumer fear.

The next part of section 2.21 discussed was the "When applicable or where appropriate" section. Building on discussion from the previous section, some participants expressed concern that not mentioning risk may lead someone to believe that there are no risks and that the risk of lawsuits or liability would not be minimized by not saying anything about risk. The group discussed the

lack of knowledge related to risks of Natural Health Products (NHPs.), and speculated on how much information was enough information? A few stakeholders also expressed concern about "spill-over" from US ads, and noted that TV advertising is brand placement and this requirement should not be isolated to other mediums.

The group discussed several options ranging from taking out the "when applicable or where appropriate" section to identifying all risks in advertising.

The majority of group participants were in support of considering risk information as a signal in an ad and that it should be linked to another source of information. As well, the inclusion of the words "may not be appropriate for everyone" or other type of standard wording was an option that the majority agreed upon. It was also suggested that Health Canada further defines "when applicable", develops a requirement for the inclusion of major risks and establishes criteria to determine when or if risk information needs to be included in advertising.

The group was in complete agreement on the next section relating to "safety advisories" and also suggested that where the safety advisory results in a label change, advertisers need only to provide this information where the label has not yet been updated. Once a label change has been made, the safety advisory in advertising could be discontinued. The group suggested that Health Canada takes measures to ensure that all safety advisories reach health professionals, reporting instances where this was not the case.

The last section discussed was "technical requirements", where the group was in unanimous agreement with the intent of this part where there should be sufficient clarity in relaying information that the public could be certain to comprehend the risks and benefits. The group agreed that the specifics of the requirements could be part of the advertising preclearance agency review process, and requirements may be different depending on technology and medium used.

The participants ended the small group discussion by making a number of suggestions outside the scope of Section 2.21. These included:

- Would like to see labels carry a Health Canada phone number for contact and reporting when a consumer experiences an Adverse Drug Reaction
- Health Canada needs to undertake a comprehensive review of labels, what is listed on them, effectiveness, etc.

Group #2

This group reviewed the proposed text of the guideline section-by-section and line-by-line. It was agreed that the "Guideline" section should be kept as proposed.

The first subsection of the "Application" section, particularly the first bullet, should be modified in order to include a requirement to provide consumers with a general risk/cautionary statement followed with the invitation to read the label. In addition, the second bullet should specify that the reference to an additional source of information should only be required when the label is not up to date. Referring consumers to the label would be considered an appropriate source of additional information only if it is fully up-to-date. However, should a source of any additional

relevant information already exist, sponsors would be encouraged to provide that information in the advertisement.

With respect to the second subsection of the "Application" section ("when applicable or where appropriate"), there was consensus towards the removal of this part in its entirety. It was felt that providing information on specific risks or in relation to specific at-risk populations is problematic and is operationally difficult and that a general risk/cautionary statement such as "Product X may not be suitable to everyone" or "Product X may not be suitable for you" followed by the statement to read the label would do a better job in raising awareness without creating doubt among the population. The specific risks and the specific at-risk populations would be depicted on the label of the product or in the package insert.

With respect to the third part of the "Application" section (safety advisories), there was a consensus in keeping that part as proposed. It was suggested that this requirement could be fulfilled through the dissemination of an additional advertisement by sponsors of products which have been the subject of a safety advisory (without necessarily stopping the dissemination of ads already in circulation). Such an additional ad would serve as a communication tool to outline the safety advisory that was issued and would be in circulation for a certain amount of time (e.g. until the label is updated to reflect the new safety information). No consensus was reached on that suggestion, but it appears to have been well accepted.

With respect to the "Technical Requirements" section, those proposed have been deemed appropriate. An additional requirement should be added in order to require that the general risk/cautionary statement ("Product X may not be suitable for you") be also verbally communicated in an appropriate manner in television and radio advertisements.

With respect to other potential options which could be used to achieve the goal of informing consumers appropriately in terms of adequate use of nonprescription products, it was suggested to develop national campaigns to raise awareness. Such campaigns could be related to the responsible use of these products and/or to the importance of reading the label.

Group #3

This group had a more wide-ranging discussion than the first two groups. The discussion started with roundtable statements from each participant on their specific concerns and then progressed to a discussion about principles that should be embedded in Section 2.21 and potential options.

There was consensus that consumers need to be provided with fair and balanced information, including information about risks prior to the point of purchase.

There was consensus that advertising is a powerful vehicle to motivate action by consumers and that information about the risks of certain products by certain populations in advertising would be effective to raise awareness. There was also agreement that information about risk in advertising should best take a systematic approach. Under this approach consumers would be provided with some risk information through advertising and linked to a source of more detailed information, where they can make a determination if the product they are considering is right for them.

There was agreement that health care service/product providers, including the distributors and retailers should be part of the systematic approach to providing information to consumers. An option that was strongly endorsed by the group was the development of a simple three or four line checklist, prominently displayed at point of purchase (pharmacies), that consumers would use to determine if the product was appropriate and safe for their use. This checklist could be one element of a national campaign for "responsible use". The last line of the checklist would be "If you are not sure, check with your health care professional." Under this arrangement all the ingredients necessary to reduce risk to the consumer would be present: messaging about risk, the product, information about the product (label), the health care professional (pharmacist) and the consumer would be together prior to the point of purchase.

There was also consensus that a national campaign would be very helpful to raise awareness about "responsible use" and that the campaign should have a stand alone slogan, such as "No drug is 100% safe for everyone", that links to the checklist (above). There was agreement that financing such a national campaign would be a good use of tax dollars and credible to the public if supported by government. But at the same time it was agreed that there are several partners involved to ensure responsible use and these include manufacturers, advertisers, government, health professionals and consumers.

Opinions were expressed that the risk warnings in advertising of prescription drugs used in the US are not effective and that a similar approach in this country would not be appropriate, even for nonprescription drugs and NHPs. At the same time, however, it was agreed that if there are known risks about a particular product, that omitting to make consumers aware of those risks is misleading and indeed breaches the principle of "truth in advertising". The group agreed to the principles that:

i. Consumers should always be advised to read the label and to verify with a health professional when uncertain;
ii. If the information on the label changes, such as during a safety advisory, advertising should be used to warn the public;
iii. If there are known risks, a general statement around risks of products and that they may not be suitable for everyone should be included to this effect
iv. The notice should link to an independent, publicly credible source of detailed, plain language information about the product, so that the "average consumer" can make an independent determination as to the appropriateness and safety of the product

A suggestion was also made with regards to the development of a formula, based upon the degree or percentage of potential risk posed to the general population. This percentage could then be used to instruct the portion of the advertisement (air time or white space) that should relate to an explanation of risks. The majority of the group believed this was a good approach in principle, but felt the practical application to be somewhat daunting.

The group agreed that where there are known risks, it may be possible to classify the "level of risk" on a scale. The three-level scale of high, moderate and low was suggested. It was then suggested that wording for a number of specific messages, which would be directly included in

advertisements, be developed for each of the three levels of risk categories. Manufacturers / advertisers would then be able to choose the message from the list depending upon how their particular product had been rated. Although the majority of participants endorsed this approach some felt that this would be overly complicated and difficult to administer.

The group agreed that the misuse of nonprescription drugs and NHPs can be a serious problem for specific populations, but that to list these populations in the advertisement would be very challenging and that it might cause confusion and create fear amongst consumers. The group agreed that, where a product causes a potential risk for certain populations (i.e. high-blood pressure sufferers, children or seniors), that regulators, manufacturers and advertisers should work through the agencies, institutions or associations that represent those populations to make them aware of the potential risks.

4. Summary of Plenary

After the small group discussions concluded, there was a plenary session. This session had two components. During the first component, the small group facilitators reported the results of their discussions, invited their participants to add any clarification necessary and then opened the floor to questions from members from the other two groups. After each group had presented and explained their findings and options, the facilitators challenged all participants to use the results of the small group discussions to identify overarching alignment between the three small groups. After all questions had been answered, the second component of the plenary session was to focus on next steps.

Participants agree with the need to finalize the Guidelines and engaged in a discussion about how to finalize Section 2.21. The group was able to agree upon several principles and portions of options that had been developed in small groups.

There is consensus that consumers have the right to be and should be informed about both the merits and potential risks of a product before they purchase it.

Participants also agreed that advertising should play a role in raising general awareness of the “responsible use” of these products. This led to a discussion about raising awareness of the potential risks of specific products within specific populations and how advertising can be connected to awareness-raising and to consumer education. It was agreed that it would be very difficult to include detailed information about specific risks to individual populations in all forms of advertising (except in the case of a public safety advisory). At the same time it was recognized that advertising of products that carry known risks should be the vehicle to inform consumers that they need to seek more information before making the decision to purchase that product.

There was consensus that advertisements of products that have known risks should direct consumers to read the label and that all known risks should be listed on the label. It was also agreed that the Guidelines adequately address the situations when there is a safety advisory or where the label information is inaccurate or out-of-date, in order to protect the safety of the consumer.

The group did agree that certain nonprescription drugs and NHPs that are known to have no risks (the example of lip balm was used) should be exempted from the requirements of Section 2.21.

There was discussion but no agreement as to which categories of nonprescription drugs and NHPs (i.e. where there is no caution or criticality of dosage) could be exempted or whether exemptions should be on a case-by-case basis.

It was agreed that getting information about product risks to health care professionals has been a problem in the past and that manufacturers, advertisers, consumer groups, health care professionals and regulators should work together to solve this problem.

Lastly it was agreed that there is significant merit to developing a national “responsible use” campaign. It was agreed that representatives from the stakeholder groups noted above should discuss how to develop and launch such a campaign.

As a Certified Professional Facilitator and a member in good standing with the International Association of Public Participation I am bound by the values and code of ethics of these associations. I verify that the information contained in this report to be true to the best of my knowledge and reflects the nature of discussion, dissension and agreement that was present on this day with these participants [Attachment D].

Original signed by

Richard Delaney, MPA, CPF
President, Delaney and Associates Inc.

Attachment A

Roundtable Discussion on Consumer Advertising Guidelines for Marketed Health Products

The information below was generated by the facilitators from the one-pagers that were provided by roundtable participants. Not all participants submitted papers. The points outlined in sections 2-4 below are summaries of points made in the various papers and are used to define the "central questions" (section 5) to be discussed during the roundtable. Section 6 contains other points of view that were included in the discussion papers, but are outside the scope of the workshop and, as such, are not included in the discussion framework (section 5) for this event. The vast majority of submitters noted in their documents that they agree or strongly agree with the principle that providing fair and balanced information helps consumers to make better self-medication decisions, based upon both benefit and risk information.

1. Who submitted one-pagers?

- Advertising Standards of Canada
- Association of Canadian Advertisers
- Best Medicines Coalition
- Canadian Association of Broadcasters
- Canadian Association of Naturopathic Doctors
- Canadian Cosmetic, Toiletry and Fragrance Association
- Canadian Health Food Association
- Canadian Magazine Publishers Association (Magazines Canada)
- Canadian Medical Association
- Canadian Pharmacists Association
- Canadian Public Health Association
- Groupement provincial de l'industrie du medicament
- Institute of Canadian Advertising
- NDMAC
- Option Consommateurs
- Pharmaceutical Advertising Advisory Board
- Women and Health Protection

2. What potential impacts from Section 2.21 were identified?

- Advertisers would be required to provide more detailed information than is presently required.
- Consumers may increasingly seek information directly from the manufacturer / distributor.
- Consumers may increasingly seek information through their health professional.
- More information about the risks of NHPs could be provided.
- Misunderstanding about the safety of natural health products and concern about interactions between NHPs and nonprescription and prescription drugs.
- Consumers may become more likely to report adverse side effects.
- The new approach may over-emphasize risks and create an incorrect public perception of risk.
- Unwarranted consumer fear may be created.
- The ability for advertisers to effectively promote products may be impeded.
- Increased information about risks / side effects might lessen advertising effectiveness.
- Mass media is not effective with target populations or considering needs of vulnerable populations (e.g. elderly, visually impaired, illiterate etc).
- Additional resources may be required to develop and review warning information.
- Advertising costs may increase.
- Consumers may become confused from information overload and potential misinterpretation.

- "Spill" from U.S. advertisers may cause confusion.
- Promotional activities might move to other, "uncontrolled" channels.
- Consumers may seek professional advice and opt for prescription solutions thus increasing publicly funded healthcare costs.
- With only the most relevant risk information in advertising, consumers may be lulled into a false sense of security and may be less likely to read details on the label or insert.
- Sales of OTC, NHP and cosmetics might decline.
- Cosmetic products are low risk.
- Manufactures may shift advertising away from "mass media" to print media in order to meet the requirements.
- Revenue to mass media from OTC, NHP and cosmetics manufacturers may decline.
- In a global marketplace, advertising that was created for the U.S. or EU markets may become unsuitable if Canadian standards exceed "international" standards.
- Canadian competitiveness in this market may be negatively impacted.
- Some cosmetics may drop health care properties (i.e. SPF) to avoid the requirement of Section 2.21.
- Those products advertised under the enhanced standards are likely to be perceived by consumers as being more unsafe that those that do not comply with the voluntary guideline.
- Advertisers may abandon the voluntary guidelines, leading to a reduced standard for the advertisement of risks.
- The incidence of non-compliance to the voluntary guideline may increase.

3. What alternatives were proposed?

- Consumer information and education versus advertising as a conduit for the communication of risk.
- Change attitudes and behaviors of consumers through aggressive education of patients and consumers (e.g. more resources and emphasis on programs such as Be Medwise)
- Use the "black box" for certain drugs that require special precautions.
- Identify only those cohorts / populations to whom the product poses a serious risk.
- Direct consumers to seek additional information before use (from their health care provider), if they suffer from conditions that may react adversely with the product.
- Develop and use an established communication message that is recognized by consumers and will encourage them to be attentive to the information that is provided
- Direct consumers with high-risk conditions to consult their physician or pharmacist.
- Detailed risk information needs to be provided on the product monograph.
- Monographs should be included on the Health Canada website or other objective website.
- Create a credible and unbiased source of information about all products.
- Provide information through existing organizations
- Provide detailed information on risk through inserts, 1-800 #'s and websites.
- Promote consumer education of the information that is already available.
- Establish a government-run campaign that encourages consumers to read labels and educates children about the dangers of misusing OTC and NHP products.
- Exempt Category IV Personal Care products.
- Exclude cosmetic-like products.
- Limit the requirement to ingested products.
- Make labels and inserts more user friendly.
- State the consumer group that could be at risk on labels, monographs and in advertising; for example: "Not suitable for patients with high blood pressure."
- Where significant risk exists, make the product available only by prescription.
- Create a regulation that outlines a standard for the inclusion of risk-related information.

- Publish the revised guideline without section 2.21 until a resolution (amongst stakeholders) can be achieved.
- If product is being advertised after a safety advisory has been issued, advertising must carry the safety advisory.

4. What are some of the associated issues?

- Defining "fair and balanced" should be the first step
- Issue of need and value of risk information on product labels for NHPs should be addressed first.
- Are we sure that there is a problem with the current approach?
- Do we have sufficient information on the nature of the problem in order to make a decision? For example, in the area of health claims and risks or international standards or frameworks for NHPs.
- Public opinion polls do not constitute "scientific research" per se. These polls need to be verified in a scientific way.
- What portion of the population must be exposed to potential serious risk for it to be a serious risk to the population as a whole?
- Does the proposed section meet the test of "fair balance"?
- The requirement should include the need to make consumers aware of the dangers of prolonged use and potential for overdose.
- Advertisement is for awareness, not education.
- Is Canada exceeding standards for risk notification in advertising?
- Would the guideline still apply if the regulatory amendments liberalizing Section 3 and Schedule A were to be accepted?
- Need a review and analysis of the quality of non-prescription drug advertising, and the link between knowledge and use of medication in other countries.
- Need a review of patient/consumer understanding of product monograph and label information.
- Need criteria for determining what and when risk information should be placed on product labels.

5. What are the central questions for discussion at the roundtable?

- How to balance the need to provide fair and balanced representations in advertising to consumers about the benefits and risks of health products (nonprescriptions drugs and natural health products) while preserving the ability to effectively advertise the products?
- When is it appropriate to include risk information in advertising?

6. What issues, that are outside the scope of the roundtable, were identified?

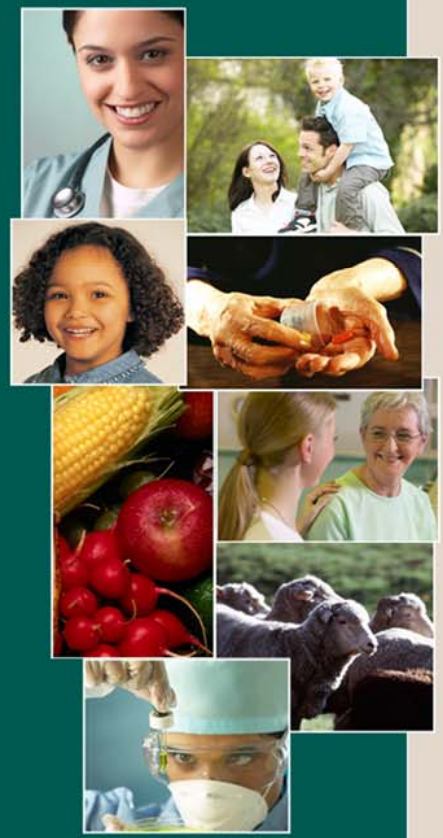
- Switches from prescription to non-prescription drugs
- Different and contradictory information that promotes and encourages unhealthy lifestyles
- Banning the advertising of newly approved products for a specific time after introduction
- Health Canada Legislative Renewal
- Direct-to-Consumer Advertising (DTCA)of prescription drugs
- Pre-clearance advertising systems

Attachment B

Health Products and Food Branch

Your Health and Safety - Our Priority

Marketed Health Products Directorate



Consumer Advertising Guidelines for Marketed Health Products

Roundtable Discussion on Risk Information Communication (Section 2.21)

June 28, 2006

Ann Sztuke-Fournier, B.Pharm

Health Canada Santé Canada

Canada

Outline

- Purpose of Roundtable
- Background – Food & Drugs Act
- Proposed Section 2.21
- Considerations
- Education and advertising
- Conclusion

Purpose of Roundtable

- Gain a mutual understanding of different perspectives on the application of the proposed Section 2.21.
- Explain Health Canada's proposed approach to Section 2.21.
- Provide Health Canada with viable options to be taken into consideration as HC finalizes the guidelines.

On what basis is risk information needed ?

Section 9(1) of the Food and Drugs Act

"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 character, value, quantity, composition, merit or safety"

Why Include Risk Information in Advertising ?

- Concept already existed in the 1990 Consumer Drug Advertising Guidelines.
- HPFB`s mandate is to minimize health risk factors while maximizing safety provided by the regulatory system for health products.

Why Include Risk Information in Advertising ? …cont`d

- Consistent with HPFB mandate to promote conditions that enable Canadians to make healthy choices and provide information so that they can make informed decisions about their health.
- Need to explore how advertising can play a complementary role to other forms of communications to consumers, while minimizing impact on industry.

How is the goal of Section 9(1) achieved?

- By developing guidelines which outline Health Canada's acceptable practices in terms of providing balanced information on benefits and risks in advertising.
- Over the years the concepts which already existed in previous guidelines need to be clarified to adapt to evolving environment and changes in technology.

What are Guidelines?

- Guidelines are administrative instruments not having force of law and, as such, allow for flexibility in approach.
- Alternate approaches to the principles and practices described in a guideline **may be** acceptable provided they are supported by adequate scientific justification.

What are Guidelines? …Cont'd

- Meant to provide assistance to industry and interested stakeholders on **how** to comply with the policies, governing statutes and regulations.
- They also serve to provide review and compliance guidance, thereby ensuring legislative requirements are implemented in a fair and effective manner.

Proposed Section 2.21

- Part I: Consumers should **always** be advised to read the product label, to follow directions of use, and be provided with accessible sources of additional information.
- Part II: Consumers should be advised of risk information (side effects, drug interactions), of contraindications for certain population groups, **when applicable/appropriate**, and they should be invited to discuss with a health professional for additional advice.
- Part III: Consumers should be provided with access to new product safety information **if the label has not yet been updated following the issuance of a safety advisory.**

Considerations

- Precautionary Principle: need for a decision in the face of scientific uncertainty
- International perspectives: best practices, concept of “fair balance”
- Observational data: literature, surveys, AR reports
- Given findings, regulator needs to take a policy decision.

International Perspectives

- **Countries considered: United States, Australia, United Kingdom, New Zealand, European Union**
  - Most countries have requirements that advertisements for OTCs must be truthful, non-deceptive, fair & based on evidence, and some specify that omission of information is misleading;
  - Most countries require that advertising must include minimal requirements (read the label, use only as directed);
  - Some have additional requirements; e.g., if symptoms persist consult a health professional, advertising should support safe use, may include a reference to a disease-related Website.

International Perspectives ...cont`d

New Zealand:

- Country with most significant requirements.
- Additional requirements include:
- Where appropriate, ads must state information about precautions, contra-indications and adverse effects;
- Ads must inform consumers that there are risks, that further information is available, and that the appropriate use of the product should be discussed with a health professional.
- Some categories of over-the-counter medicines require specific warnings in advertising: e.g., NSAIDS – Do not use if you have stomach ulcers, Sedating anti-histamines – May cause drowsiness (avoid alcohol and driving), pseudoephedrine – may cause increased heart rate.

Literature and Survey Findings

- Increases in switches (prescription to nonprescription status) (Cohen, BMJ 2005;330:39-41)
- Safety profiles not generated due to lack of pharmacy or medical records for nonprescription drugs (Bond, Drug Safety 2003; 26(15):1065-74.
- Self-medication can lead to misdiagnosis, improper use, drug interactions and polypharmacy (Carmel, Drug Safety 2001; 24(14) 1027-37.

Literature and Survey Findings

- Studies suggest that many emergency room and hospital visits could be avoided if consumers had better information on potential toxicity of acetaminophen. Larson, Hepatology 2005; 42(6);1364-72. Nourjah, Pharmacodepidemio Drug Safety 2005;Nov.18.
- Prints ads in consumer periodicals indicated that nonprescription drug advertisements lack information necessary for consumers to make informed purchase decisions. Sansgiry 1999

Literature and Survey Findings

- Although 91 % of Canadians recognize pharmacists as a good source of information on nonprescription drugs, only 38% got information from a pharmacist, while 62% cited the media and 51% cited advertising. Decima 2005
- Regarding the safety of drugs or health products they use, 29% of Canadians turned to advertising on TV, newspapers and/or magazines as a source of information. Decima Clinical Trial Survey 2006

Adverse Reaction data

- As outlined in the HC issue paper, reports of serious adverse reactions suspected to be associated with nonprescription drugs and NHPs do occur.
- Refer to tables -(e.g.,Acetaminophen, St-John's Wort, Pseudoephedrine)

Can advertising play a role in educating consumers on risk?

- Advertising of health products is a multimillion dollar business that impacts on consumer behaviour.
- Although nonprescription drugs and NHPs are generally safe, they can pose risks, particularly if used inappropriately.
- The public needs balanced benefit/risk representations to avoid erroneous impressions on health products.

Can advertising play a role in educating consumers on risk?...cont`d

- Health Canada is fully supportive of initiatives to further educate consumers on the safe use of products.
- Can the use of multiple strategies, including education campaigns and balanced product brand advertising, play a complementary role?
- We all have a social responsibility and this is an opportunity to be pro-active.

Conclusion

- The safe use of health products is a shared responsibility (regulator, industry, health professionals and consumers).
- Need to find mechanisms to present fair and balanced representations in advertising, **when appropriate**, in order to enable consumers to make informed decisions without imposing undue impediments to industry.
- Given research findings a decision is warranted.

Conclusion …cont'd

- Today's roundtable offers stakeholders the opportunity to identify viable options which will be taken into consideration as HC finalizes the proposed revised Consumer Advertising Guidelines, including the proposed Section 2.21.

Attachment C

Advertising Standards Canada
Les normes canadiennes de la publicité

Roundtable re Risk/Safety Communication

June 28, 2006

Overview

- About ASC
- ASC's role in advertising preclearance of nonprescription drugs and natural health products

Summary of Stakeholder Input re Section 2.21

- # of comments: 21
- Submitter Breakdown:
  - Academia (1)
  - Patient/Consumer groups (3)
  - Health Professionals (2)
  - Media (2)
  - Advertising Agencies (2)
  - Industry/Advertisers (10)
  - Advertising Preclearance (1)

Summary of Stakeholder Input: In Support of Section 2.21

- # of comments: 6
- Consensus that risk information should be communicated to consumers in nonprescription drug and NHP advertising
- All supported language in 2.21, and suggested additional requirements for inclusion

Summary of Stakeholder Input: In Support of Section 2.21

- Multiple comments received suggesting additional requirements:
  1. Ads should **include clinical trial information**
  2. Ads should **identify active ingredient**
  3. Ads should **include ADR information**

In Support of Section 2.21
1) Recommendations re Clinical Trials
(2 comments)

- Ads should communicate whether or not clinical trials have been conducted
- Ads should state which population groups product was tested on, as well as state that benefits and risks to other populations are unknown
- Ads should include information regarding duration of studies and sponsors

In Support of Section 2.21

2) Recommendation re Active Ingredient

(2 comments)

- Ads should include the name of the active ingredient

In Support of Section 2.21
3) Recommendation re ADR Reporting
(2 comments)

- Ads should advise consumers to report ADRs to health professionals or Health Canada
- Ads should include information regarding reporting ADRs to Health Canada

In Support of Section 2.21
Additional Recommendations
(1 comment)

- **Guidelines should:**
  - Provide technical parameters for verbal communication of risk information e.g. speed/cadence
  - TV/radio requirement to consult label in audio should also apply to internet
  - Include requirement that verbal message direct consumers to label **or health professional** to obtain risk information
  - Require that advertisements give equal weight to product risk and benefit

Summary of Stakeholder Input: Not In Support of Section 2.21

- # of comments: 15
- Agree with principle of informed consumer, but disagree that nonprescription drug and NHP product advertising is appropriate vehicle to achieve this
- No support for 2.21 as drafted

Summary of Stakeholder Input: Not In Support of Section 2.21

- Multiple comments were received on the following:
  1. **Request for evidence** re rationale for new requirement
  2. **Practicability** of advertising for presentation of risk information
  3. Guideline **overly expansive** for all self-care products

Not In Support of Section 2.21
1) Request for Evidence
(7 comments)

- Questions raised:
  - What precipitated need for 2.21?
  - What concerns exist with current nonprescription/NHP advertising?
    - » Is there evidence that advertising is resulting in product misuse and adverse health consequences?

Not In Support of Section 2.21
2) Practicability of Advertising to Communicate Risk
(11 comments)

- Advertising not the appropriate vehicle to communicate risk
  - Not possible to provide required information in many advertising media, i.e. TV, radio, out-of-home
  - Other more effective ways to communicate risk

(cont'd)

Not In Support of Section 2.21
2) Practicability of Advertising to Communicate Risk

- Could lead consumers to believe that the ad includes all important safety information
  - Concerns re subpopulation groups subject to less prevalent risks
- Potential for consumer over-reliance on advertising as sole information source
- Products supported by non-compliant advertising may be perceived by consumers as being "safer" than products supported by compliant advertising

Not In Support of Section 2.21
3) Guideline Overly Expansive
(4 comments)

- Guideline overly expansive for all self care products
- Question if application to all products would result in any health/safety benefit for consumers

Summary

- Consultation generated strong interest
- Full support for informed consumer, but no consensus re means to achieve
- Desire for additional dialogue

Advertising Standards Canada
Clearance Services

Les normes canadiennes de la publicité
Services d'approbation

Attachment D

Roundtable on Consumer Advertising Guidelines / Table ronde sur les Lignes directrices pour la publicité destinée aux consommateurs

2006-06-28

Participants:

Academia / Académiciens

1. University of Saskatchewan, Jeff Taylor

Patients and Consumers / Patients et consommateurs

2. Option Consommateurs, Nalini Vaddapalli
3. Canada's Association for the Fifty-Plus (CARP), Rolf Calhoun
4. HPFB Citizens' Network / Réseau de citoyens de la DGPSA, Claudine Larocque
5. Women and Health Protection / Action pour la protection de la santé des femmes, Joel Lexchin
6. Best Medicines Coalition, Lynn Macdonald
7. Centre for Science in the Public Interest, Bill Jeffery

Media / Média

8. Canadian Association of Broadcasters / Association canadienne des radiodiffuseurs, Elizabeth Roscoe
9. Canadian Magazine Publishers Association, Gary Garland
10. CBC/Radio-Canada, Sandra Wheaton

Advertising Agency / Agence de publicité

11. Institute of Canadian Advertising / Institut des communications et de la publicité, Catherine Shand

Industry and Advertisers / Industries et publicitaires

12. NDMAC, David Skinner
13. NDMAC, Gerry Harrington
14. Canadian Health Food Association, Joel Taller
15. Groupement provincial de l'industrie du médicament, Pierre Morin
16. Canadian Cosmetic, Toiletry and Fragrance Association, Susan Nieuwhof
17. Association of Canadian Advertisers / Association canadienne des annonceurs, Bob Reaume

Health Professionals / Professionnels de la santé

18. Canadian Medical Association / Association médicale canadienne, Millisent Toombs
19. Canadian Association of Naturopathic Doctors / Association canadienne des docteurs en naturopathie, Shawn O'Reilly
20. Canadian Pharmacists Association / Association des pharmaciens du Canada, David Crosbie

21. Canadian Public Health Association / Association canadienne de santé publique, Maureen Hartigan

Advertising Pre-Clearance Agencies / Agences de pré-approbation de publicité

22. Advertising Standards of Canada / Normes canadiennes de la publicité, Linda Nagel
23. Advertising Standards of Canada / Normes canadiennes de la publicité, Nicole Bellam
24. Pharmaceutical Advertising Advisory Board (PAAB) / Conseil consultatif de publicité pharmaceutique, Ray Chepesiuk

Regulatory Agency – Health Canada / Agence de réglementation / Santé Canada

25. Health Canada / Santé Canada, Neil Yeates
26. Health Canada / Santé Canada, Chris Turner

Non-participants:

Health Canada Technical Resource Staff / Personnes-ressources de Santé Canada

- Ann Sztuke-Fournier, MHPD, Manager, Regulatory Advertising and Risk Communications / DPSC, Gestionnaire, Section de la réglementation de la publicité et de la communication des risques
- Christophe Roy, MHPD, Advertising Regulatory Officer / DPSC, Agent de réglementation de la publicité
- Niyi Lawuyi, Inspectorate, Compliance & Enforcement Health Canada / Inspectorat, Agent de conformité

Observers / Observateurs de Santé Canada

- Susan Gardner-Barclay, OCAPI, Acting Director General / BPCP, Directrice générale intérimaire
- Sylvie Cantin, OCAPI, Director, Branch Services and Program Delivery / BPCP, Directrice, Livraison du programme et des services de la Direction générale
- Julie Pigeon, OCAPI, Project Lead / BPCP, chef de projet
- Joan Korol, MHPD, Regulatory Advertising Unit Head / DPSC, chef intérimaire de l'unité de la réglementation de la publicité
- Cindy Evans, MHPD, Acting Director, Therapeutic Effectiveness & Policy / DPSC, Directrice intérimaire, Division des politiques et de l'efficacité thérapeutique
- Michel Pariseau, Legislative Renewal Secretariat, Health Policy Branch / Secrétariat du renouveau legislatif, Direction générale de la politique de la santé
- Cynthia Boyd, OCAPI/BPCP

External Observer / Observateur externe

- ASC – Dora Gelntis, Clearance Analyst & Project Manager / NCP, analyste et gestionnaire de projet