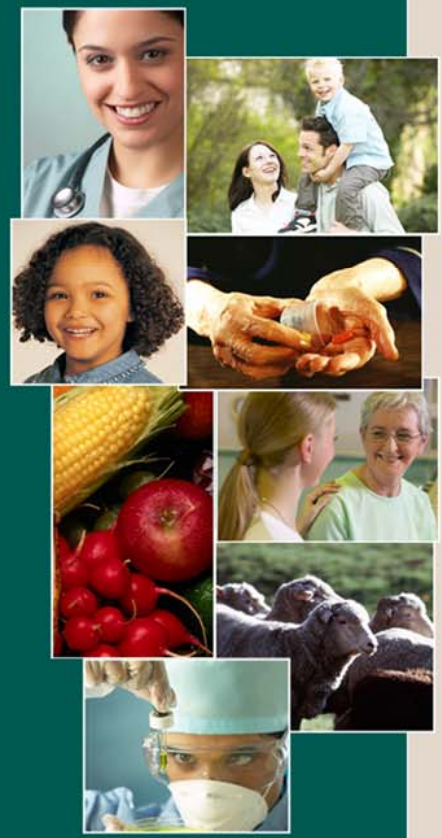
Attachment B

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)

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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.