

Direct-to-Consumer Advertising (DTCA)

Health Products and Food Branch (HPFB)
Office of Regulatory and International
Affairs (ORIA)

CAPRA Symposium, February 24, 2004



Objectives

- ❑ Provide information on the status of DTCA policy work and consultation activities.

- ❑ Promote discussion to inform the review of DTCA policy:
 - Evidence needed to make an informed decision about DTCA;
 - How to provide information to enable the public to make informed decisions about their health.



Overview

- ❑ Context.

- ❑ Status of Policy Work on DTCA:
 - Policy Analysis.
 - Consultations.

- ❑ DTCA Policy Review: Next Steps?

Context

Food and Drugs Act

- ❑ 1949 advertisement prohibition to the general public as a treatment, preventative or cure for conditions listed to Schedule A (PART I, 3.(1)).
- ❑ Example: Cancer, depression, heart disease, asthma.

Food and Drug Regulations

- ❑ 1978 amendment allowing ads to mention name, price and quantity. (Section C.01.044).
- ❑ *Help-seeking* announcements and *reminder* ads.
- ❑ Provisions against Deception.

Context (Cont'd)

□ Why the pressure for review?:

- Cross-border exposure: 1997 U.S. legislative changes, Internet.
- Socio-economic changes.
- Monitoring and enforcement capacity.



Status of Work on DTCA

Policy analysis.

Consultations.

DTCA Policy Analysis

Policy Analysis

- ❑ Health Transition Fund study: *An Assessment of the Health System Impacts of DTCA of Prescription Medicines.*
- ❑ Study of international jurisdictions, literature reviews and identification of research gaps.

Policy Analysis (Cont'd)

Health Transition Fund study (2002):

- Literature review of empirical research on the effects of DTCA:
 - Association between DTCA and cost increases;
- Expert survey on DTCA involving stakeholders from Canada, the United States, and New Zealand:
 - DTCA increases spending on prescription drugs and frequency of physician visits;



Policy Analysis (Cont'd)

- Comparative survey of impact of DTCA on patient/doctor interactions and prescribing practices (Vancouver and Sacramento):
 - Patients exposed to DTCA requested more advertised drugs;
 - Physicians more likely to express ambivalence about treatment choices when prescribing a requested drug;

Policy Analysis (Cont'd)

- Examination of the economic basis of DTCA and its potential impacts in Canada:
 - No conclusive data that brand-specific DTCA leads to more competitive pricing or health care savings relative to existing disease awareness campaigns.



Policy Analysis (Cont'd)

International jurisdictions:

- **EU:** DTCA is prohibited. October 2002, European Parliament rejects DTCA, requests a comprehensive consumer/patient information strategy.
- **Australia:** DTCA is prohibited. Advertising of non-prescription drugs and medical devices is permitted; pre-approval systems in place.
- **New Zealand:** DTCA is permitted but currently undergoing review.
- **United States:** DTCA has grown rapidly, especially for “blockbuster” drugs, with the highest ROI.



Policy Analysis (Cont'd)

Identification of research gaps:

- ❑ A large body of literature suggests that DTCA increases demand and use of prescription drugs.
- ❑ Significant gaps remain regarding causal linkages and potential impacts of DTCA on the Canadian population as a whole.

Policy Analysis (Cont'd)

Research Gaps:

- ❑ *Whether increased use of prescription drugs constitutes a positive or negative health impact:*
 - Prescription medication may be beneficial when used as directed. However:
 - Risk of unnecessary use.
 - Risk of inappropriate use.

- ❑ *Risks associated with new and innovative drugs:*
 - Performance and side-effects outside the context of the small controlled clinical studies;
 - DTCA is usually most intense for new products.

Policy Analysis (Cont'd)

- ❑ *Optimal means to ensure that patients can make informed health choices:*
 - Does the impact of DTCA on patient habits differ from that of public education/objective information?

- ❑ *Costs to health care system.*
 - Issue of sustainability.

Consultations

Consultations

- ❑ TPP consultations on DTCA: 1996, 1998, 1999.
- ❑ First round of Legislative Renewal consultations.
- ❑ As part of the second round Legislative Renewal consultations, in fall 2003 Health Canada organized national stakeholder workshops on advertising of health products:
 - Montreal (November 20-21)
 - Toronto (November 27-28)
 - Ottawa (December 4-5)

Consultations (Cont'd)

- ❑ Objective of Legislative Renewal Consultations on Advertising:
 - Provide information to stakeholders on the draft proposal for a new Canada Health Protection Act;
 - Obtain feedback from key stakeholders on issues pertaining to the advertising of health products as outlined in the proposed;

- ❑ A broad range of stakeholders: Consumer and community groups, academia, patient groups, health professional associations, and industry (pharmaceutical and advertising industries,) and pre-clearance agencies.

Legislative Renewal Consultations

(Cont'd): Key Messages

General:

- Health and safety is the highest priority.
- Develop a solution for drug advertising adapted to the Canadian situation and promote Direct-to-Consumer Information and Direct-to-Consumer Education (as opposed to advertising).
- The status quo is not tenable. Greater control is needed.
- Important role for Health Canada.

Consultations (Cont'd): Key Messages

Deception:

- Eliminate deception.
- Clarify and tighten definitions for deception and promotion.
- Establish criteria for balanced information and valid data.

Consultations (Cont'd): Key Messages

Monitoring and enforcement:

- Need for effective, transparent and timely monitoring and enforcement (for advertising or the dissemination of information).
- Need for effective sanctions for violations for either advertising or the dissemination of information?
- Role for independent third party bodies in pre-clearance, monitoring and enforcement.



Consultations (Cont'd)

- ❑ Public Advisory Committee (PAC) consultations (February 21, 2004).
- ❑ Objective: To obtain feedback on how drug advertising might be better controlled in light of comments received from recently held Legislative Renewal consultations.



DTCA Policy Review: Next Steps?

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- ❑ Consultations findings will be used to inform policy analysis.

Key questions and considerations:

- ❑ DTCA of prescription drugs:
 - Analysis needed regarding the potential impacts of DTCA in Canada?
 - How can these data be obtained?
- ❑ Other health products.
- ❑ Other Advertising issues.

DTCA Policy Review: Next Steps? (Cont'd)

- ❑ Cross-border exposure:
 - Difficulty of distinguishing between Canadian and foreign ads;
 - Drugs often have the same name in Canada and the U.S.: A U.S. ad may have an impact in Canada;
 - DTCA on the Internet.

