

Health Products and Food Branch

Your Health and Safety - Our Priority

Marketed Health Products Directorate



Risk Communications For Marketed Health Products

University of Ottawa
Pharmacovigilance Workshop
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and Policy Bureau
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Health
Canada

Santé
Canada

Canada

Purpose

- To provide an overview of HPFB risk communication activities utilized for Marketed Health Products
- To identify challenge areas and future direction for risk communications activities

HC Risk Communications In Context

- Health Canada's mandate is to help Canadians maintain and improve their health
- Provision of risk communications:
 - Facilitates appropriate therapeutic choices by Canadians, and
 - Is essential to ensure that the benefits of health products distributed in Canada continue to outweigh the risks

Regulatory Support

- Regulatory intervention options are limited
 - stop sale (C.01.013)
 - Notice of Compliance Suspension (C.08.006)
 - clinical trial suspension (C.05.016)
 - product seizure (Section 23)
- Risk communications can mitigate a new safety issue, while not jeopardizing the benefit of product availability.

Shared Responsibility

- Health Canada
- Industry
- Healthcare Professionals
- Patients / Consumers
- Provincial Licensing Authorities

HC Issued Risk Communications

- Public Advisories and Warnings
- Foreign Product Alert
- Information Update
- Health Professional Communications (HPC) by HPFB
- Recall Listings
- Canadian Adverse Reaction Newsletter
- Its Your Health

Industry Issued Risk Communications

- Dear Investigator Letters
- Health Professional Communications (HPC)
 - Dear Health Care Professional Letters (DHCPL)
 - Notice to Hospitals (NtoH)
- Public Communications (PC)



Health Canada Santé Canada

Canada

Français	Contact us	Help	Search	Canada Site
Just For You	It's Your Health	Media Room	A-Z Index	Home

Health Canada **Drugs & Health Products**

- About Health Canada
- Consumer Product Safety
- Diseases & Conditions
- Drugs & Health Products
 - Adverse Reaction Information
 - Advisories, Warnings & Recalls
 - Biologics, Radiopharmaceuticals & Genetic Therapies
 - Compliance & Enforcement
 - Controlled Substances & Precursor Chemicals
 - Drug Products
 - International Activities
 - MedEffect
 - Medical Devices
 - Medical Use of Marihuana
 - Natural Health Products

Home > Drugs & Health Products > MedEffect

MEDEffect
Together we can improve health product safety

[View Advisories, Warnings and Recalls](#)

[Report a Problem or Reaction](#)

[Search the Adverse Reaction Database](#)

[Sign-up for MedEffect e-Notice](#)

- Topics**
- About MedEffect
 - Adverse Reaction Database
 - Adverse Reaction Information
 - Adverse Reaction Reporting
 - Advisories, Warnings & Recalls
 - Canadian Adverse Reaction Newsletter (CARN)
 - Consultations
 - Frequently Asked Questions
 - Learning Centre
 - MedEffect e-Notice Sign-up
 - Reports and Research
 - Resource Centre

Updates
[Some Ayurvedic medicinal products](#)

What's New
What's New

MedEffect e-Notice

- Subscribers:
 - receive notice of new postings for industry issued Health Professional & Public Communications, HC issued communications and CARN.
- MedEffect e-Notice:
 - New name replaced Health_Prod_Info (August 2005)

Summary of Subscribers to Electronic Mailing List

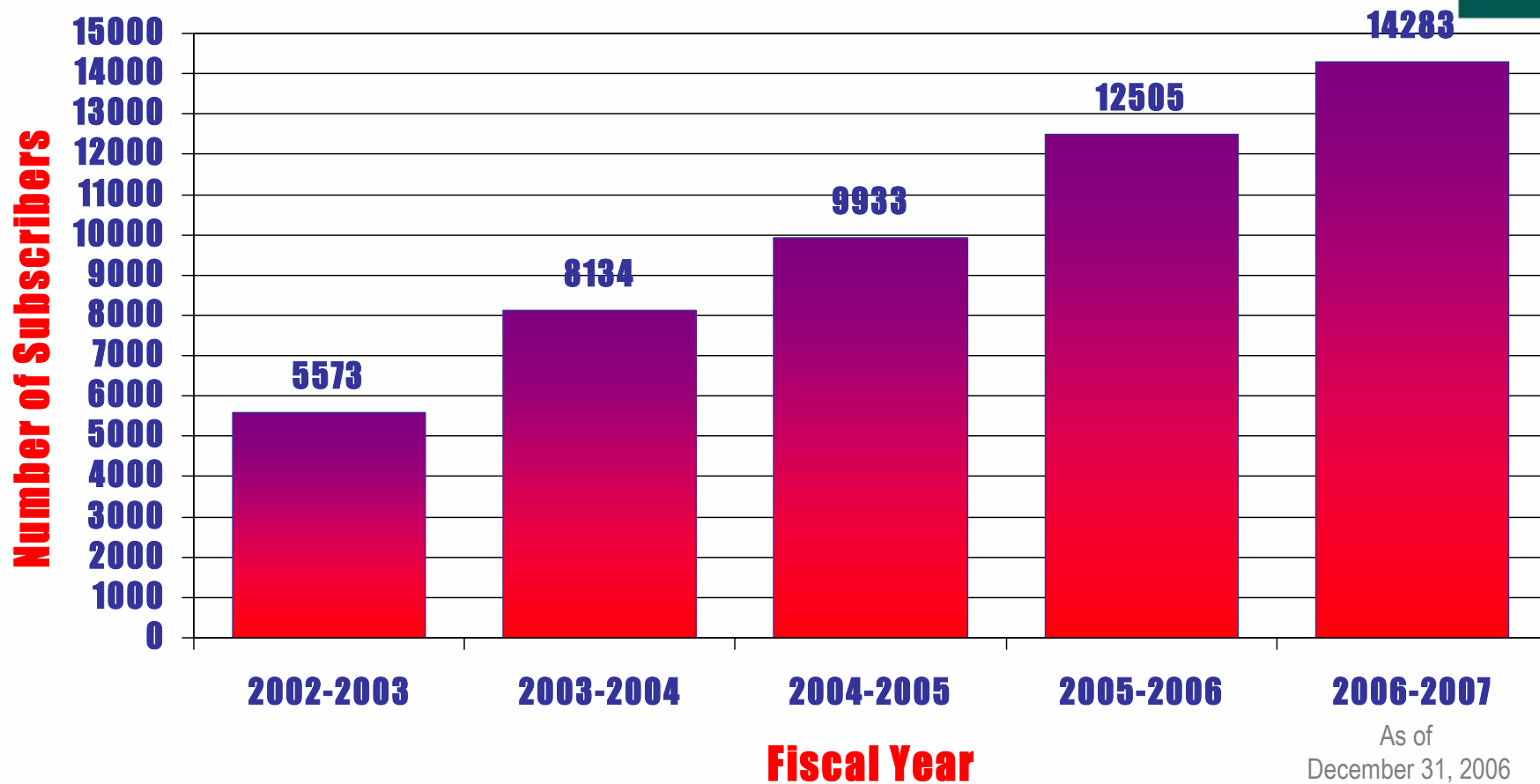
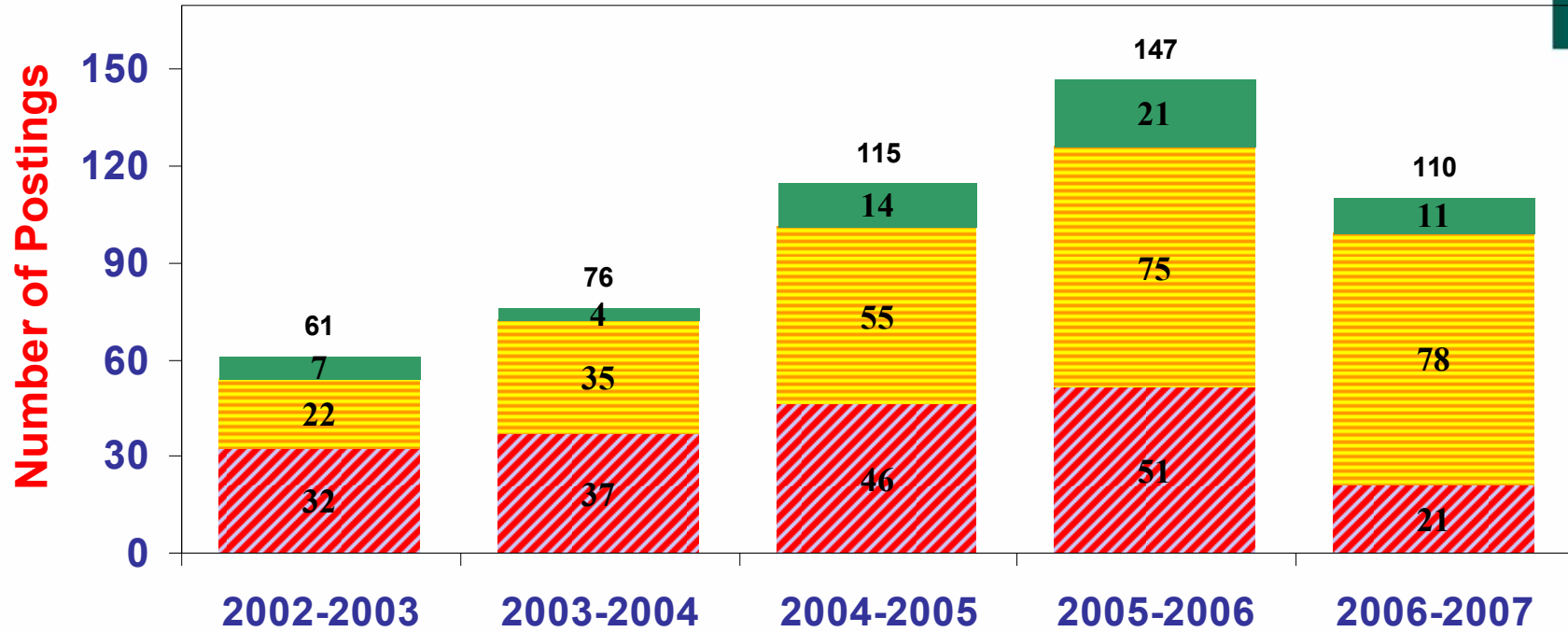


Chart of Risk Communications / Advisories Posted to the Health Canada Website by MHPD*



As of
January 15, 2007

- Notice to Hospitals
- Public Advisories/Communications
- Dear Healthcare Professional Letters

*includes those issued by HC and sponsors, for human products: pharmaceuticals, biologicals, medical devices & natural health products

HC issued products: Dissemination Strategy

- **Advisories & Warnings**
 - HC website posting
 - HC media e-mail list
 - MedEffect e-Notice
 - Canada Newswire Service
- **Foreign Product Alerts & Information Updates**
 - HC website posting
 - HC media e-mail list
 - MedEffect e-Notice
 - Canada Newswire Service (potentially for Information Updates)

Industry Issued Products: Dissemination Strategy

- Health Professional Communications & Public Communications
 - Mail out/fax out
 - Industry website posting
 - Association website posting
 - HC website posting
 - MedEffect e-Notice

Canadian Adverse Reaction Newsletter

- Targets **67,000** physicians via CMAJ
- Distributed through a hard copy mailing list to pharmacists and other stakeholders (**26,000**)
- New distribution to Canadian Association of Naturopathic Doctors (**1000**)
- Posted on Health Canada website
- Summaries published in Canadian Pharmacists Journal, Canadian Family Physicians Journal

Challenge: Regulatory Authority

- Health Canada and other key regulatory jurisdictions:
 - Authority to require issuance
 - Authority to require prior approval of content
 - Authority to require update of labelling (packaging, product monograph)

Challenge: Dissemination

- What distribution role for HC and other international regulatory jurisdictions?
- HC focus on content creation
- Identify partnerships to increase dissemination of health product safety information to targeted audiences
 - Promotion of MedEffect e-Notice
 - Website linkage
 - Mechanisms for systematic redistribution

Challenge: Tailoring the Message

- Maintain a comprehensive strategy to target all audiences
- Maximize interest to subscriber/reader
- Individual preferences
- Website of choice

Challenge: Uptake & Effectiveness

- Establish mechanisms to evaluate the effectiveness of current risk communication tools
- Overload versus transparency-what is the evidence?
- Creating a culture where awareness and incorporation of HC risk communications becomes a standard of practice

Any Questions?

Any Suggestions?

Additional Background

The slides which follow provide additional content, but will not be covered in detail during the presentation.

HC issued Advisories & Warnings

- **Public Warning:** Notice to inform that there is a high probability that the use of, or exposure to a product will cause serious adverse health effects or death, such that the public should stop using the product immediately
- **Public Advisory:** Notice to inform of possible serious health hazard and to enable public to make informed decisions concerning their continued use of the product

HC Issued

Latest Communication Tools

- **Foreign Product Alert:** Provides standard HC warnings about products which are not authorised for sale, not found on the Canadian marketplace but may have entered via personal importation or purchase over the internet. The alert provides details on identified foreign products in a table format.
- **Information Update:** Used when the risk of a product is lower, or where the product involved does not generally affect a large number of people. Can indicate the progress of HC's review or reinforce safety recommendations previously issued.

HC-issued Communications

Sample Public Advisory (PA)

The screenshot shows the Health Canada website interface. At the top, there are logos for Health Canada and Santé Canada, and the word "Canada" with a small Canadian flag. Below these are navigation links: Français (Just For You), Contact us (It's Your Health), Help (Media Room), Search (A-Z Index), and Canada Site (Home). A banner for "About Health Canada" features a photo of people. A left sidebar lists various categories under "About Health Canada". The main content area shows a breadcrumb trail: Home > About Health Canada > Media Room > Advisories, Warnings & Recalls > 2006. The title of the advisory is "Advisory" in large blue font. Below it, the date "2006-35" and "May 26, 2006" are listed, followed by "For immediate release". The main heading of the advisory is "New cautions regarding rare heart-related risks for all ADHD drugs" in blue. The text of the advisory begins with "OTTAWA - Health Canada has revised the prescribing and patient information for all drugs used for the management of ADHD (Attention Deficit Hyperactivity Disorder) and advises Canadians not to use them if they have high blood pressure."

Health Canada

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• About Health Canada •

Home > About Health Canada > Media Room > Advisories, Warnings & Recalls > 2006

Advisory

2006-35
May 26, 2006
For immediate release

New cautions regarding rare heart-related risks for all ADHD drugs

OTTAWA - Health Canada has revised the prescribing and patient information for all drugs used for the management of ADHD (Attention Deficit Hyperactivity Disorder) and advises Canadians not to use them if they have high blood

- Activities & Responsibilities
- Advisories, Warnings & Recalls
- Branches, Regions & Agencies
- Conferences & Events
- Estimates, Plans & Performance
- International Activities
- Media Room
- Ministers
- Public Involvement & Consultations
- Emerging

Healthcare Professional Communications

- **Health Professional Communication (HPC)**
A risk communication tool used to communicate new information about safety and therapeutic effectiveness of marketed health products to health care professionals in a timely manner. HPCs include, for example, DHCPLs (Dear Healthcare Professional Letters) and NtoHs (Notice to Hospitals)
- **Public Communication (PC)**
A risk communication tool used to communicate new health safety information to consumers, patients and the general public regarding marketed health products. A PC is the plain language version of a health professional communication on the same issue.

Industry-issued Communications

Health Professional Communications (HPC)

- Sample Dear Health
Care Professional
Letter (DHCPL)

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Eli Lilly Canada Inc., Bayer Inc., and Pfizer Canada Inc.**

Contact the company for a copy of any references, attachments or enclosures.

**Health Canada Endorsed Important Safety Information on
Cialis (tadalafil), Levitra (vardenafil hydrochloride) and Viagra
(sildenafil citrate)**

2006-06-19

Subject: Association of visual disturbances with the erectile dysfunction medication Cialis® (tadalafil), Levitra® (vardenafil hydrochloride) and Viagra® (sildenafil citrate).

Canadian Adverse Reaction Newsletter

- **Scope**
 - based on Canadian adverse reaction reports
 - factual review, national focus
 - no attribution of causality
 - useful mechanism to disseminate adverse reaction information before comprehensive risk/benefit evaluations are completed and before regulatory decisions are undertaken
- **Purpose**
 - disseminate information on serious unexpected ARs which may not yet be identified in PM or scientific references
 - raise awareness
 - prompt reporting of adverse reactions
 - feedback to health professionals

It's Your Health

- It's Your Health (IYH) is a series of articles, or fact sheets, that cover a wide range of health issues.
- Each IYH article is written in consultation with Health Canada or the Public Health Agency's scientists and experts, and may also be reviewed by national experts outside the department. These articles also include Internet links and references to more information.