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# Marketed Health Products Directorate: Retrospective

## The First Five Years | 2002-2007



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we can improve  
health product  
safety

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Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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# Table of Contents

<b>Foreword</b> .....	<b>3</b>
<b>Origins</b> .....	<b>5</b>
Marketed Health Products Directorate Who's Who. ....	7
<b>Marketed Health Products Directorate and the Health Product Life Cycle</b> .....	<b>8</b>
Market Authorization .....	8
Surveillance and Inspection .....	9
Adverse Reaction Reporting .....	9
Responses to Adverse Reaction Reporting .....	10
International Collaboration .....	11
Stakeholder Relations .....	12
<b>Spreading the Word</b> .....	<b>13</b>
MedEffect™ Canada Web Site .....	13
MedEffect™ e-Notice .....	13
Canadian Adverse Reaction Newsletter .....	13
Canada Vigilance Online Database .....	13
Canada Vigilance Regional Offices .....	14
Media Contacts .....	14
Product Monographs and Labels .....	14
Risk Communications .....	15
Guidelines .....	16
<b>By the Numbers</b> .....	<b>17</b>
Marketed Health Products Directorate Growth .....	17
Adverse Reaction Reports .....	17
Risk Communications .....	18
MedEffect™ e-Notice .....	19
Advertising .....	20

<b>Early Successes</b> .....	<b>21</b>
Partnering .....	21
Adverse Reaction Monitoring Centres Transitioned to Canada Vigilance Regional Offices .....	21
Canada Vigilance .....	22
Expert Advisory Committee on the Vigilance of Health Products .....	22
International Activities .....	23
Being Proactive .....	24
Business Transformation .....	24
Increased Scientific Capacity .....	25
Office of Paediatric Initiatives .....	26
Reaching Out .....	26
Education and Promotion .....	26
Publications .....	26
<b>Working Together</b> .....	<b>27</b>



## Foreword

It gives me great pleasure to present the story of the first five years of the Marketed Health Products Directorate (MHPD), including the circumstances that led to its creation within the Health Products and Food Branch of Health Canada in 2002, and the work that it now does to help improve health product safety in Canada.

In this special summary report, we provide an overview of the federal health product regulatory system in general and, in particular, MHPD's post-market surveillance/vigilance work within that system.

The Directorate monitors health products federally authorized for sale and, with branch colleagues, manages risks when emerging safety information and adverse reactions – undesirable, unintended effects – are reported. We describe the risk communications vehicles that keep you up to date on health product information. We also provide statistics to illustrate how we've grown, from an initial staff of 62 to 130 in 2006-2007.

In the last chapter, "Early Successes," we describe some examples of early accomplishments. Details on objectives, themes and projects can be found in our recently published strategic plan: *Planning for Our Future: Federal Regulatory Post-Market Surveillance Strategy 2007-2012*.<sup>1</sup>

Directorate employees, both in the National Office (located in Ottawa) and in the seven Canada Vigilance Regional Offices, are dedicated to the important work of continuing to strengthen health product safety.



This report has been written for patients, consumers, health professionals, research organizations, industry, health departments of various levels of government, health and industry associations, and the general public – in short, anyone with an interest in health product safety. We trust that you will find it informative.

Be sure to look for the 2007-2008 annual report, scheduled for release later this year!

Christopher Turner, MD, FRCPC  
Director General  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada

<sup>1</sup> [http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/strategy\\_strategie\\_surveillance-eng.php](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/strategy_strategie_surveillance-eng.php)



Front: Christopher Turner, Marketed Health Products Directorate - Director General and Acting Director, Marketed Biologicals, Biotechnology and Natural Health Products Bureau; and Christiane Villemure, Associate Director General and Director, Bureau of Strategic Initiatives and Planning. Back from left to right: Heather Sutcliffe, Director, Marketed Health Products Safety and Effectiveness Information Bureau; Cindy Evans, Director, Therapeutic Effectiveness and Policy Bureau; Marc Berthiaume, Director, Marketed Pharmaceuticals and Medical Devices Bureau; and Vicky Hogan, Director, Office of Risk Management and Science.





## Origins

The Marketed Health Products Directorate (MHPD) is part of the Health Products and Food Branch (HPFB), which regulates the sale of human health products sold in Canada, including:

- biological products that include biotechnology, blood products, radiopharmaceuticals and vaccines;
- medical devices;
- natural health products; and
- pharmaceuticals.

After a product has been authorized for sale and is on the market, additional information about its use comes to light. Post-market surveillance (or health product vigilance, as it is often called) monitors risks and benefits of that product to the population.

Since its creation in 2002, Health Canada's MHPD has been:

- playing a leadership role in coordinating post-market surveillance activities for all human health products;
- conducting independent post-market surveillance activities for specific product lines;
- collaborating on surveillance activities related to vaccines and blood components with the Public Health Agency of Canada and other HPFB directorates;
- working with other partners such as the Canadian Institute for Health

Information (CIHI), the Institute for Safe Medication Practices Canada and the Canadian Patient Safety Institute (CPSI) in developing the Canadian Medication Incident Reporting and Prevention System (CMIRPS);

- collecting and monitoring adverse reaction reports from consumers, health professionals and industry;
- independently analyzing marketed health product safety data;
- conducting benefit/risk assessments of marketed health products;
- providing independent scientific and clinical input to decisions and recommendations affecting the entire branch;
- communicating product-related risks to health professionals and the public;
- providing regulatory oversight to health product advertising; and
- developing and implementing policies to effectively monitor marketed health products.



Canadian federal vigilance practices originated in the 1960s, after the thalidomide tragedy generated calls for greater government drug oversight. There are now more than 22,000 pharmaceutical and biological products, 50,000 natural health products and close to 82,000 medical devices on the market.

The potential for unexpected and rare adverse reactions continues to be a challenge, as is the potential for interactions among drugs and other health and food products. The demand for earlier access to new products also focuses more attention on post-market surveillance and vigilance activities.

Federal regulatory developments, increased international standardization and cooperation, advances in information availability, increasingly complex therapeutic regimens, developments concerning individualized medicines and devices, and public expectations have all contributed to a need for more rigorous monitoring of marketed health products. The emerging concern about the therapeutic effectiveness of products on the market is also a pressure, and it highlights the increasing amount of information and knowledge that needs to be managed by stakeholders and incorporated into MHPD's activities.



## Marketed Health Products Directorate Who's Who

MHPD's five bureaus and two offices collaborate to oversee the post-market safety of federally regulated and marketed health products:

- The Marketed Health Products Safety and Effectiveness Information Bureau works through the Canada Vigilance Program (which includes seven regional offices) to collect, process and monitor adverse reactions and to identify potential safety risks.
- The Marketed Pharmaceuticals and Medical Devices Bureau and the Marketed Biologicals, Biotechnology and Natural Health Products Bureau investigate safety risks and review the benefit and risk balance of marketed health products in their respective areas of responsibility.
- The Therapeutic Effectiveness and Policy Bureau is responsible for policy and regulatory development; coordinating international liaison in post-market surveillance; risk communication, including responsibility for the MedEffect™ Canada Web site; regulatory oversight of advertising; developing methodologies for marketed health product monitoring and assessment regarding therapeutic effectiveness; patient safety initiatives, including developing CMIRPS in partnership with CIHI, The Institute for Safe Medication Practices and CPSI; and stakeholder relations and outreach.

- The Bureau of Strategic Initiatives and Planning is responsible for strategic and operational planning activities; supporting the Expert Advisory Committee on the Vigilance of Health Products; business transformation; project management; and quality, performance and information management.
- The Office of Risk Management and Science is responsible for managing the risk process within MHPD, for setting science and research priorities pertaining to the post-market surveillance/vigilance program, and for introducing the capabilities of new scientific evaluative programs within Health Canada.
- The Office of Paediatric Initiatives coordinates the development of paediatric information and raises awareness of federal regulatory issues related to health products and food as they affect children and adolescents, pregnant and lactating women, and nursing babies. This Office is hosted within MHPD but adopts a Branch perspective in all its activities.

*Health Canada is committed to a more open and transparent regulatory system in which the involvement of patients, consumers, health professionals, industry and researchers contributes to better overall quality of decision making.*

2007–2012 Strategic Plan, Health Products and Food Branch





# Marketed Health Products Directorate and the Health Product Life Cycle

The regulation of drugs is undergoing rapid worldwide change in response to advances in pharmaceutical sciences and drug development, and changes in public expectations. MHPD is a key player in the Progressive Licensing Project, which addresses part of HPFB's *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food*.<sup>2</sup>

The Project will eventually support more regular information collection for federal regulatory post-market surveillance activities through the use of modern tools. These tools might include Pharmacovigilance Plans submitted to Health Canada prior to market authorization or in response to a safety signal, Risk Mitigation Plans, and Periodic Safety Update Reports. Consequently, MHPD will be contributing directly to the continued safety and therapeutic effectiveness of health products as product knowledge is accumulated over time.

## Market Authorization

New therapeutic products can be sold in Canada after successfully passing a federal regulatory review process to assess their safety, efficacy and quality. Responsibility for this review process rests with the product-specific directorates within HPFB, including the Biologics and Genetic Therapies Directorate, the Natural Health Products Directorate and the Therapeutic Products Directorate.

For some products – human drugs and some medical devices in particular – pre-clinical and clinical studies gather information on the product's safety and efficacy in humans, in accordance with internationally accepted principles of good clinical practice. When a product receives a favourable review, the manufacturer is granted authorization to sell it in Canada.

HPFB's Inspectorate leads compliance and enforcement activities before and after products are authorized for sale. "Establishment licensing" ensures that manufacturers comply with Good Manufacturing Practices or equivalent standards for drugs, medical devices and natural health products. All establishments that are engaged in fabrication, packaging, labelling, importation, distribution or wholesale, or the operation of a testing laboratory, are required to hold an establishment licence unless expressly exempted under the *Food and Drugs Act and Regulations*.<sup>3</sup>

<sup>2</sup> <http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/blueprint-plan/index-eng.php>

<sup>3</sup> [http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi\\_reg-eng.php](http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi_reg-eng.php)



## Surveillance

Federal regulation of therapeutic health products continues even after the products reach the marketplace. MHPD leads the monitoring, identification and assessment of human health product safety risks, with the participation of other HPFB directorates.

Information gathered after a product reaches the market may create a need to re-evaluate the benefit/risk profile, the quality of the product, or whether it should still be authorized for sale.

The responsibility Market Authorization Holders (companies authorized to market health products) have for monitoring the safety and therapeutic effectiveness of their products, extends to the post-market as well. They must advise stakeholders, including consumers, health professionals and regulators, of changes in the benefit/risk balance of their products.

## Adverse Reaction Reporting

Before a product is marketed, knowledge of its safety and efficacy is limited to its use in clinical trials. These trials identify likely adverse reactions (ARs) or undesirable effects. The predicted reactions are rare, and the controlled conditions of clinical trials often do not reflect how the product will actually be used. Continued monitoring of ARs in the post-market phase – or adverse incidents in the case of medical devices – is thus essential for maintaining a comprehensive safety and effectiveness profile of health products available to Canadians.

Patients, health professionals, manufacturers, federal and provincial/territorial health product regulatory authorities and the World Health Organization (WHO) all monitor suspected ARs. Voluntary reporting by health professionals and consumers of suspected reactions is an important source of information about previously undetected ARs. Mandatory reporting by Market Authorization Holders provides both domestic and foreign AR information to Health Canada.

Under-reporting of ARs is an internationally recognized challenge. MHPD works with stakeholders to facilitate reporting and the use of new information about product risks. Partnerships with non-governmental AR monitoring programs, as well as provincial/territorial initiatives, are valuable sources of additional information that facilitate individual therapeutic choices and appropriate health system interventions.



# Surveillance and Inspection

## Responses to Adverse Reaction Reporting

MHPD's clinical and scientific staff members review the AR reports, either as individual reports or as summary cumulative reports filed by industry, and then prioritize them based on risk. Working with the reports and other available evidence, staff may then determine the likelihood of a cause-and-effect relationship between the health product and reported ARs.

When appropriate, the benefits of the product relative to its risk may also be re-examined. Market Authorization Holders are expected to update the safety profile of their marketed health products after the AR assessment. Should they not act on their own, they will be asked to do so by Health Canada. MHPD has developed the capacity to conduct independent scientific evaluations, which was one of the intentions when it was created in 2002. This capacity permits independent post-market surveillance/vigilance assessment and contributes to federal regulatory decision-making that is free from conflict of interest.

Actions taken following an AR assessment will vary depending on a number of factors: the nature, seriousness and frequency of the reaction; the intended use of the health product; the benefit from its use versus the risks and the availability of alternative therapies; and the acceptability of these actions in the affected population or sub-population.

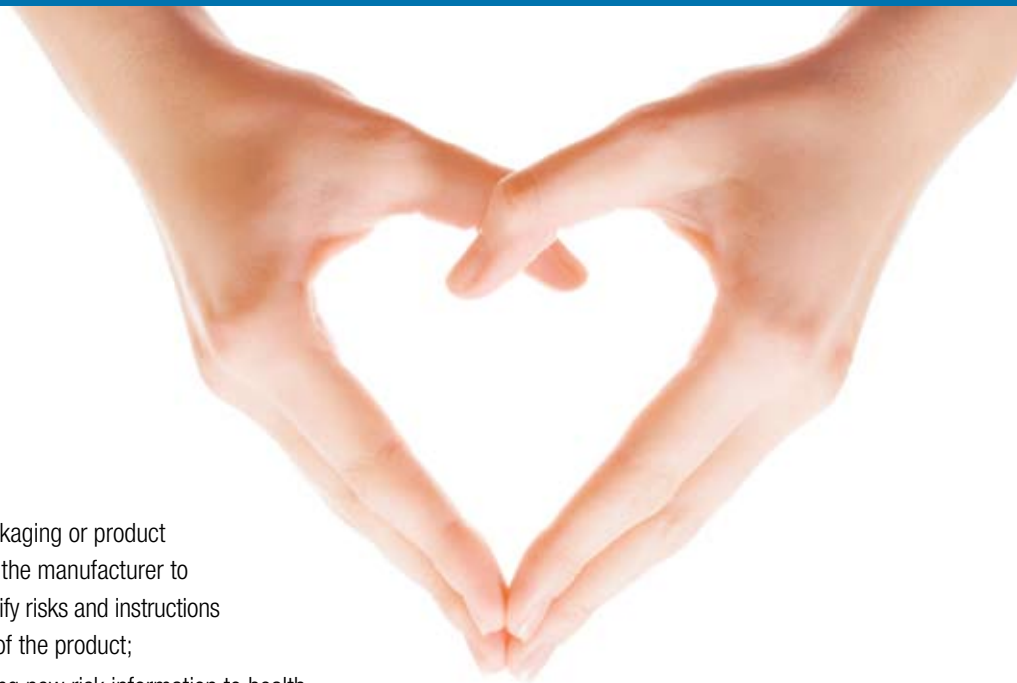
Possible actions vary from the continuing observation of health products at one end of the spectrum, to cancelling the marketing authorization in Canada at the other, or any of the following actions in the interim:

- comprehensive reassessment of the risk-and-benefit profile of the health product;

- altering packaging or product labelling by the manufacturer to clearly identify risks and instructions on the use of the product;
- disseminating new risk information to health professionals and consumers; or
- undertaking risk communications through Health Canada's warnings, advisories, public alerts, foreign products alerts, etc.

Industry-issued communications on all health products which alert health professionals and the public to new safety information, are prepared in conjunction with Health Canada and are posted on the MedEffect™ Canada Web site<sup>4</sup>. Details on the various communication vehicles developed to inform health professionals and the public may be found in the next chapter, "Spreading the Word."

<sup>4</sup> [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)





## International Collaboration

MHPD staff collaborates with leading foreign regulatory partners through Memoranda of Understanding (MOUs), especially regarding the effective sharing of confidential and personal information on regulated product safety.

A regular video/teleconference with federal regulatory partners in the United States, New Zealand and Australia enables the sharing of ongoing federal regulatory post-market surveillance/vigilance issues. Where possible, MHPD and its MOU partners collaborate on risk communications requiring simultaneous action to reduce public confusion.

Health Canada has been contributing to the development of ICH<sup>5</sup> internationally harmonized guidelines since before MHPD's creation in 2002.

The focus of the ICH has been on the technical requirements for medicinal products containing new drugs. The vast majority of those new drugs and medicines are developed in Western Europe, Japan and the United States. As a result, when the ICH was established, it was agreed that its scope would be confined to registration in those three regions. Canada is an observer to the ICH, provides active members to ICH expert working groups that develop harmonized guidelines and, where possible, applies ICH standards.

Date MOU Signed	Country/Region	Name of the Organization
December 2007	European Union	European Commission's Directorate-General Enterprise and Industry & European Agency for the Evaluation of Medicinal Products
October 2006	Switzerland	Swissmedic
September 2006	Singapore	Health Science Authority
November 2003	Australia	Therapeutic Goods Administration
November 2003	United States	Food and Drug Administration
September 1999	China	State Food and Drug Administration of China

<sup>5</sup> ICH – The International Conference on the Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

## Stakeholder Relations

Stakeholders are individuals and groups that affect and are affected by post-market surveillance work (see below). Both external and internal stakeholders are important.

For greater effectiveness in its regulatory work, MHPD regularly collaborates and consults with its principal stakeholders through participation in various Directorate and Branch-wide meetings with industry associations, patient and consumer groups, and advertising standards agencies. In 2007, the Directorate undertook a 360°

evaluation with stakeholders as part of its five-year re-evaluation; also, staff received training to strengthen their focus on effective stakeholder relations, and some procedures were reviewed.

Following a further assessment of stakeholder relations, MHPD will focus its efforts on more meaningful engagement with its stakeholders by obtaining and analyzing more data, raising its profile, undertaking timely consultations and simplifying the feedback reporting process.





# Spreading the Word

This chapter provides an overview of the principal communication vehicles that Health Canada uses to inform Canadians about health product safety.

## MedEffect™ Canada Web Site

Since 2005, the MedEffect™ Canada Web site has been providing centralized access to new health product safety information, as well as serving as a mechanism for reporting ARs. It is the place where descriptions of all MHPD programs and initiatives may be found, and it contributes to building awareness about the importance of reporting ARs to Health Canada. It also describes how this information is used to identify and communicate potential safety risks.

## MedEffect™ e-Notice

MedEffect™ e-Notice is a free service that helps subscribers stay on top of health professional and public communications, advisories, warnings and foreign product alerts for health products that Canadians use every day.

Consumers, patients and caregivers, as well as health professionals, can subscribe to MedEffect™ e-Notice by visiting [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect). Subscribers receive the latest health product information posted by Health Canada in their e-mail in-box.

## Canadian Adverse Reaction Newsletter

The *Canadian Adverse Reaction Newsletter* (CARN), a quarterly publication since 1991, alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. CARN provides subscribers with early information on suspected ARs to health products before comprehensive risk/benefit evaluations and regulatory decisions are undertaken.

CARN is available on the MedEffect™ Canada Web site by subscribing to the MedEffect™ e-Notice.

## Canada Vigilance Online Database

On a quarterly basis, the MedEffect™ Canada Web site is updated with the latest adverse reaction reports, so that the public has access to ARs that have been reported to Health Canada. The information on the MedEffect™ Canada Web site is a subset of the actual data contained within the Canada Vigilance AR database.



## Canada Vigilance Regional Offices

Regional offices are responsible for the collection of AR reports submitted by health professionals and consumers. The reports are then reviewed for completeness before being forwarded to the Canada Vigilance National Office in Ottawa for further analysis. Each regional office is also responsible for:

- increasing health professional and consumer awareness of and participation in the Canada Vigilance Program;
- improving communication between the AR program staff and individuals who report ARs;
- providing guidance on AR reporting in order to maximize the quality of reports; and
- directing Canadians to Health Canada sources of new safety information regarding Canadian marketed health products.

## Media Contacts

Health Canada Media Relations supports MHPD staff in their responses to media inquiries about the continued safety of marketed health products in Canada. Contacts with the media generally focus on how and what kind of ARs to report, as well as the appropriate use of AR information.

## Product Monographs and Labels

MHPD contributes to the Branch Product Monograph (PM) working group. The PM is a factual, scientific document on a drug product, which describes the properties, claims, indications and conditions of use of the drug product and is devoid of promotional material. It contains information that may be required for the optimal, safe and effective use of the product.

Manufacturers are required to provide Health Canada with a detailed PM, along with their drug submission. The PM is used by the manufacturer to inform physicians, pharmacists, dentists, nurses and other health professionals, as well as the general public, of the authorized conditions of use of the drug.

Health Canada is moving forward with its initiative to make PMs publicly available on its Web site.<sup>6</sup>

<sup>6</sup> [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/proj/monograph-rev/notice\\_pm\\_avis\\_mp-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/proj/monograph-rev/notice_pm_avis_mp-eng.php).





## Risk Communications

The communication of emerging health product safety information to the public and health professionals acts as a bridging mechanism for label changes and updates to product monographs (PMs). Health Canada, like other federal regulators internationally, fulfills its mandate by bringing the information to the point of care (health practitioners) so that informed decisions can be made.

MHPD works with the Department's corporate communications staff in the Public Affairs, Consultations and Regions Branch when preparing Health Canada Warnings, Advisories, Foreign Product Alerts and Information updates. When such information is disseminated by Health Canada and the Market Authorization Holders, other groups in the health system become involved.

Health organizations may develop clinical practice guidelines and continuing medical education materials, and drug formulary regimes may review various standards and drug reimbursement plans in order to update usage and prescription practices. In addition, certain professional journals may summarize new safety information to facilitate use by their members, and certain patient groups may draw their members' attention to new safety information through newsletters or local publications (sometimes in languages other than English and French when there is a need).

Current risk communication vehicles for the public include:

- public warnings;
- public advisories;
- public communications;
- foreign product alerts;
- information updates;
- *It's Your Health*; and
- fact sheets and backgrounders.

Current risk communication vehicles for health professionals include:

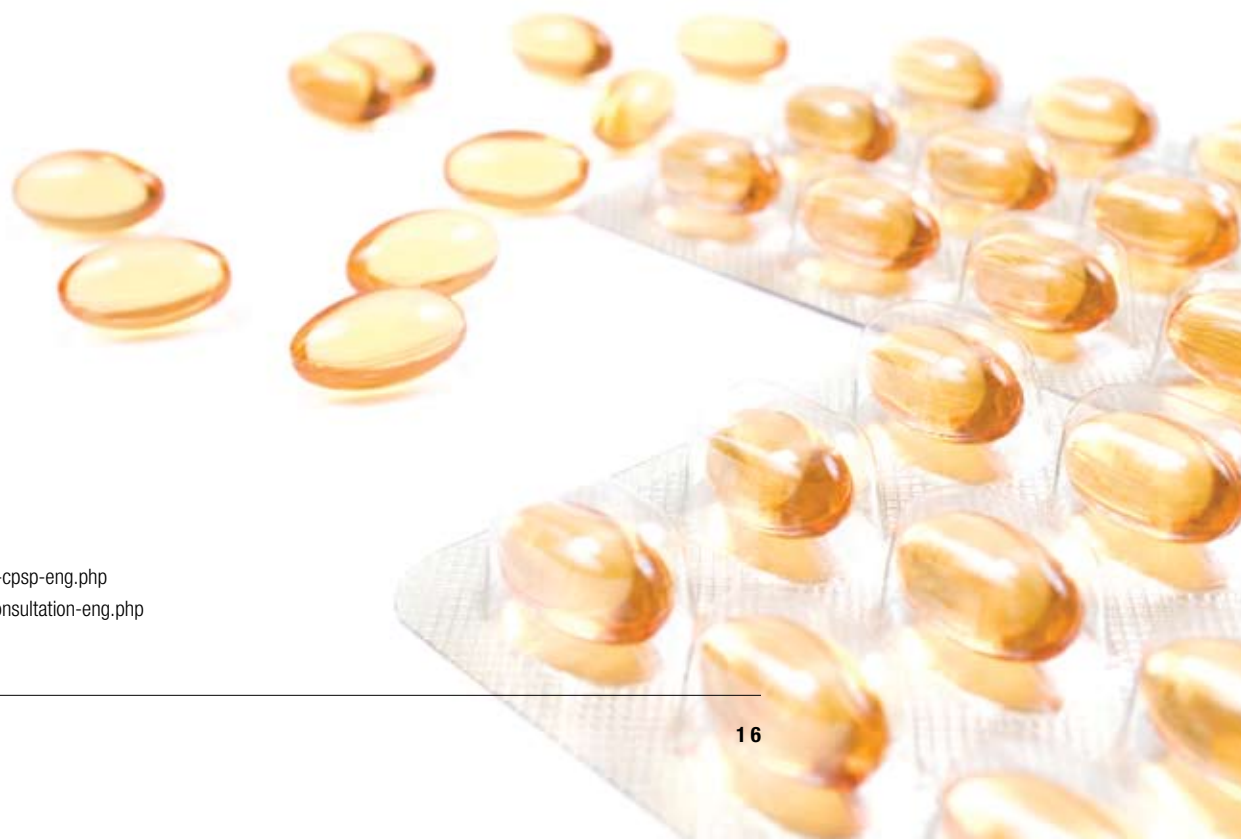
- "Dear Health Professional" letters;
- "Notice to Hospitals"; and
- the *Canadian Adverse Reaction Newsletter*.

*Canada's Food and Drugs Act and regulations authorize Health Canada to regulate the safety, efficacy and quality of therapeutic products.*

## Guidelines

The MedEffect™ Canada Web site contains the following guidelines developed and issued by MHPD after consultation with the public.

- Guidelines for the Canadian Pharmaceutical Industry on Reporting Adverse Reactions to Marketed Drugs (Vaccines Excluded) Issued: 2001-07-01 – currently in effect
- Guidelines – Voluntary Reporting of Suspected Adverse Reactions to Health Products by Health Professionals and Consumers Issued: 2006-05-11 – was posted for consultation and amended
- Consumer Advertising Guidelines (for non-prescription drugs, including natural health products)<sup>7</sup>
- Guidelines for Market Authorization Holders on industry-issued health professional communications and public communications<sup>8</sup>
- Description of Current Risk Communication Documents for Marketed Health Products for Human Use - Guidance Document, which describes situations where Health Canada and/or the Market Authorization Holders consider the development and dissemination of risk communication documents regarding health products marketed in Canada Issued: 2007-06-11<sup>9</sup>

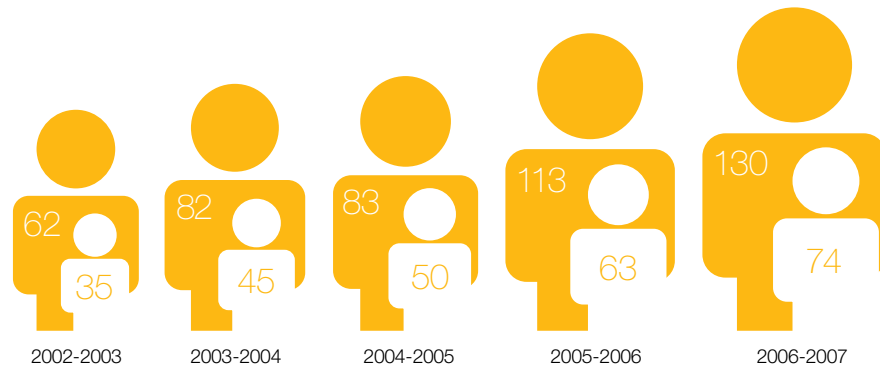


<sup>7</sup> <http://www.hc-sc.gc.ca/dhp-mpps/advert-publicit/index-eng.php>

<sup>8</sup> [http://www.hc-sc.gc.ca/dhp-mpps/medeff/advisories-avis/guide-ld/guid-dir\\_indust\\_hppc-csp-eng.php](http://www.hc-sc.gc.ca/dhp-mpps/medeff/advisories-avis/guide-ld/guid-dir_indust_hppc-csp-eng.php)

<sup>9</sup> [http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/guide/triggers-elements\\_consultation-eng.php](http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/guide/triggers-elements_consultation-eng.php)

## By the Numbers



MHPD Full-Time Employees

### MHPD Growth

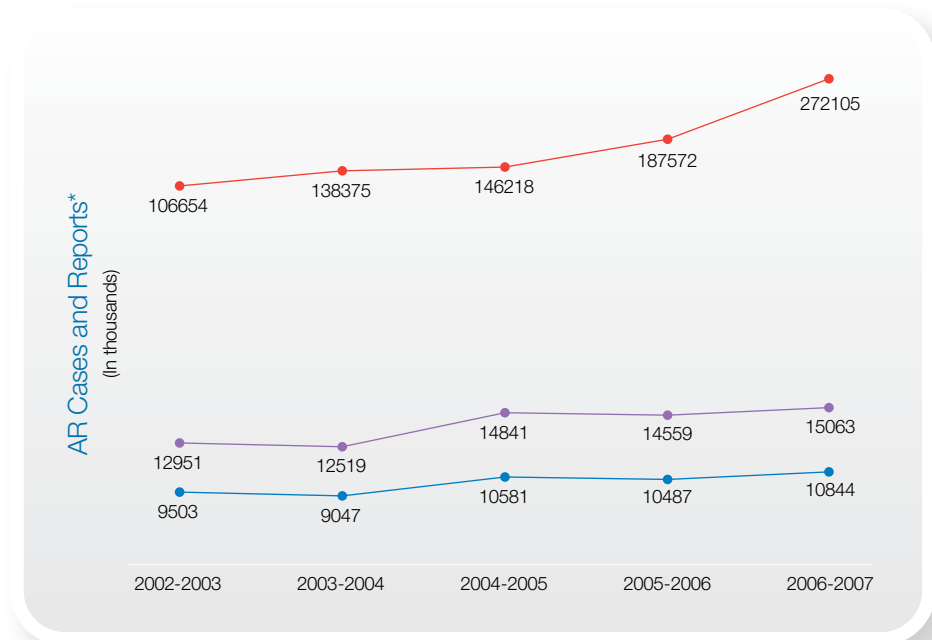
MHPD's full-time staff has more than doubled in the last five years to meet its increasing responsibilities. As the graph at left illustrates, in 2006-2007 57% of MHPD's staff were scientific and medical specialists, with the balance being policy analysts, project managers and support staff.



### AR Reports

The chart at right shows the number of domestic and foreign AR reports received from 2002 to 2007.

MHPD continues the work of those who were among the founding members of the WHO International Drug Monitoring program in 1968. Canada is one of 180 member countries and is ranked fourth in the rate of submission of domestic AR reports to the WHO vigilance database, which is located at the Uppsala Monitoring Centre in Sweden.



● Domestic Cases\* (Initials)
 ● Domestic Reports (Initials and Follow Ups)
 ● Foreign Reports (Initials)

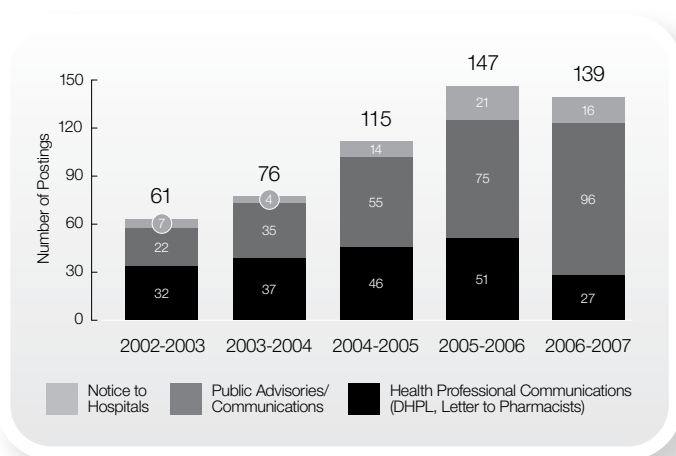
\* Cases result from the merge of initial, follow-up and duplicate reports.



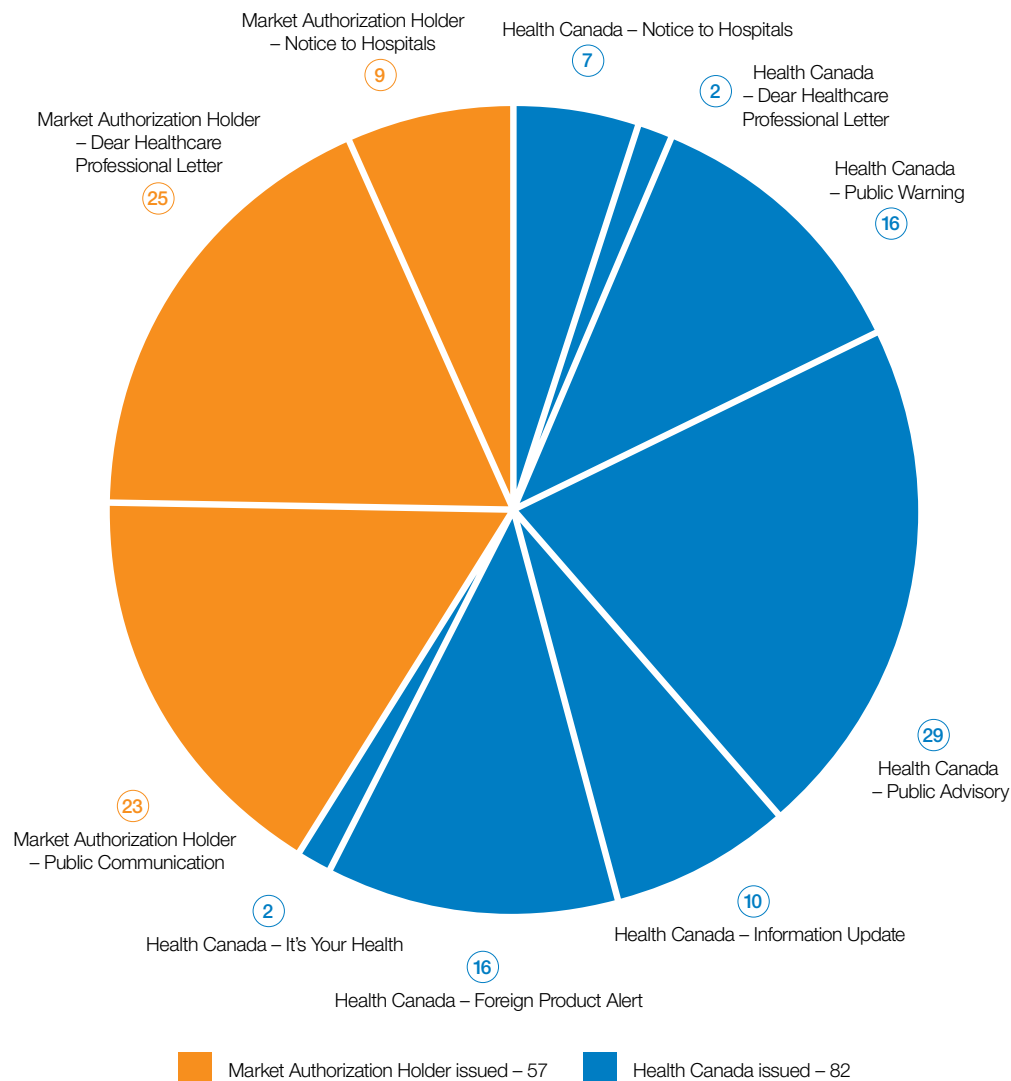
## Risk Communications

In 2002-2003, 61 warnings or advisories were issued. In 2006, 139 warnings, advisories and other risk communications were issued. As the volume of risk communications has risen, so too have the quantity and sophistication of the metrics associated with them. While a description of the various risk communication vehicles can be found on the Health Canada Web site,<sup>10</sup> the following bar graph shows the rise in quantity and type of risk communications posted to the site since MHPD's creation. The pie chart illustrates risk communications postings for fiscal year 2006-2007, organized by issuer and type.

Baseline and follow-up surveys of the media, public and health professionals concerning risk communications and AR information have been conducted and posted to the MedEffect™ Canada Web site, as well as used to inform continuous quality improvement.



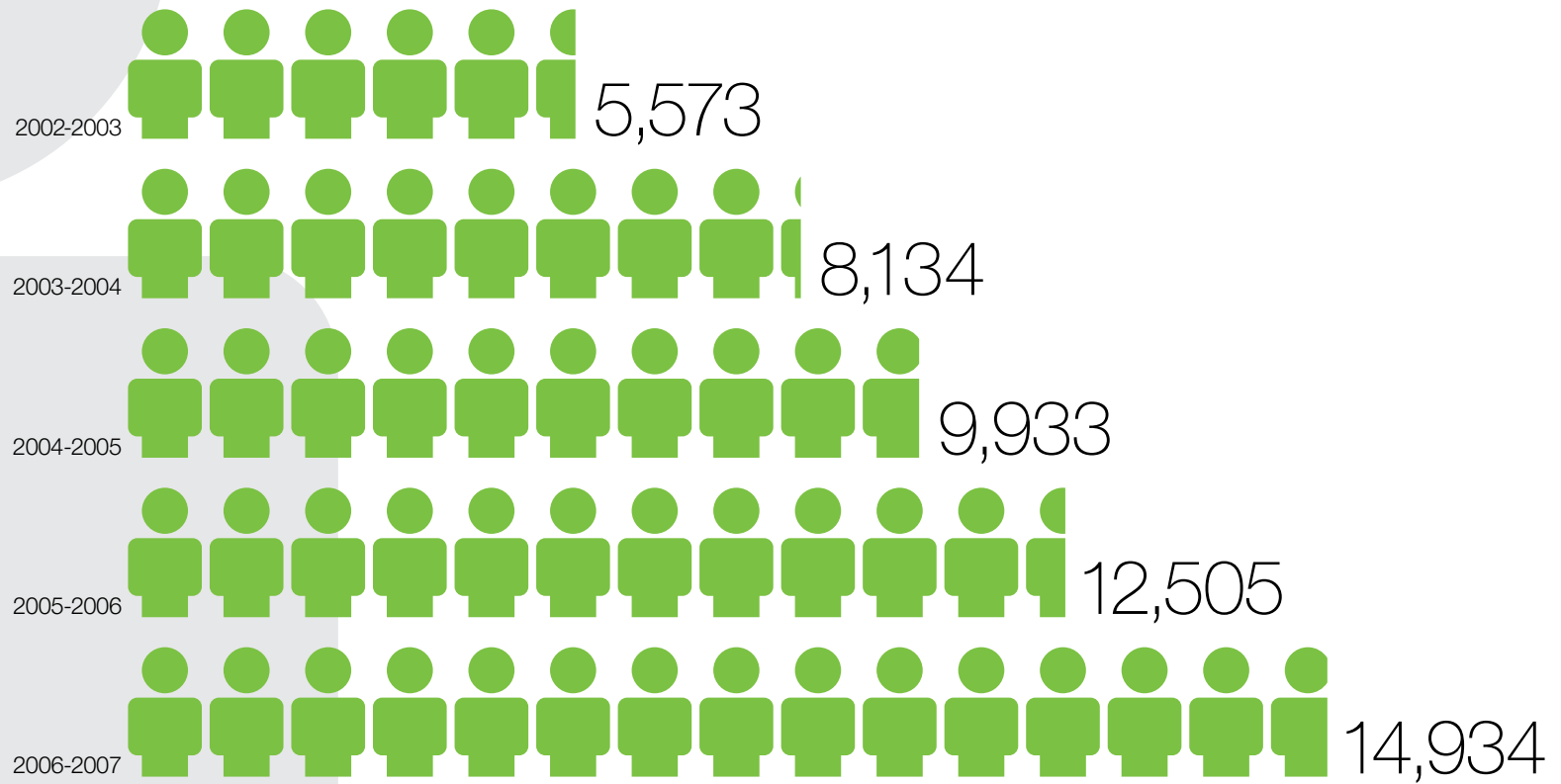
## MHPD Postings to Health Canada Web Site 139 Risk Communications Postings in 2006 – 2007



<sup>10</sup> <http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fact-feuille-eng.php>

## MedEffect™ e-Notice

The number of subscribers to the MedEffect™ e-Notice service has grown steadily from 2,574 in 2001-2002 to 14,934 in 2006-2007.



## Advertising

In October 2006, MHPD finalized the Consumer Advertising Guidelines for Marketed Health Products (for non-prescription drugs and natural health products) to replace the outdated 1990 Consumer Drug Advertising Guidelines.

The new guidelines include enhanced requirements aimed at providing fair and balanced information on the risks and benefits of non-prescription drugs and natural health products in consumer advertising. Initially, there was overall support for the draft guidelines, but a consensus was not reached on the requirements for the communication of risk information. Extensive stakeholder consultation, including a roundtable discussion, occurred in 2005 and 2006.

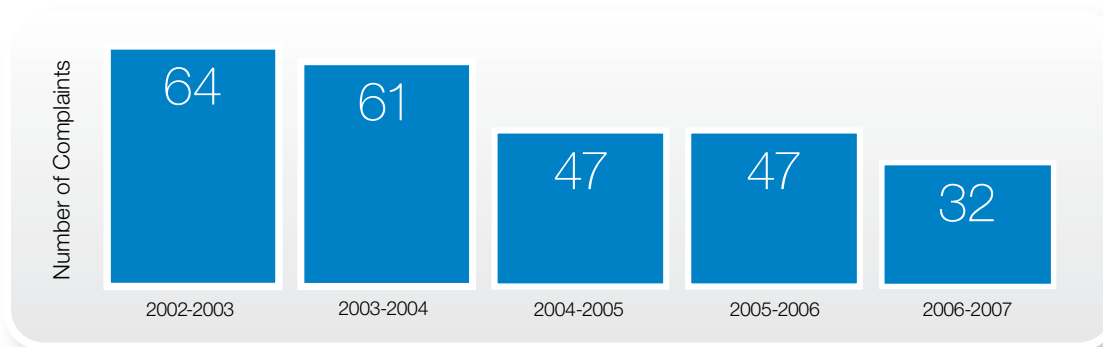
These events allowed the full range of interested parties to voice concerns and work collaboratively to propose options and arrive at finalized guidelines. The intention is to establish a system that increases consumer awareness of the importance of considering the risk/benefit

profile of health products before using them. Health Canada and the Non-Prescription Drug Manufacturers Association of Canada conducted research to measure baseline levels of population awareness, to determine the impact of prominently displaying the “general cautionary statement” in health product advertising.

All parties are currently monitoring the application of the guidelines to achieve the mutual goal of increasing consumer awareness with regard to the safety profile of non-prescription drugs and natural health products.

The following graph illustrates the decrease in advertising complaints referred to MHPD for resolution since 2002. While MHPD is still analyzing the factors contributing to the decrease, a better understanding by stakeholders of the regulatory requirements and related policies may be a contributing factor.

### Advertising Complaints Assessed by MHPD



# Early Successes

Five years on, we can now direct our attention to the future. We have come a long way since 2002 in capacity and service delivery and have much to be proud of. At the same time, however, we are humbled by the realization that much remains to be done and that a federal regulator should not attempt to work alone. MHPD has an opportunity to systematically add to the available information to facilitate informed decision-making by patients and their health providers. Reaching this goal requires a clear strategy.

MHPD's forward-looking agenda, outlined in *Planning for Our Future: Federal Regulatory Post-Market Surveillance Strategy 2007-2012*, focuses on three strategic themes:

- Partnering
- Being proactive
- Reaching out

We are working diligently in these three areas and are pleased to share some of our early accomplishments here. Please look for success updates in our 2007-2008 Annual Report.

## Partnering

MHPD's partnering projects are designed to build solid stakeholder relationships that capitalize on information, knowledge and the work of other organizations in Canada and around the world. Partnering also serves to promote AR reporting, develop new sources of information, set up international collaboration with other regulatory agencies, and establish an Expert Advisory Committee on the Vigilance of Health Products for ongoing external advice.

## AR Monitoring Centres Transitioned to Canada Vigilance Regional Offices

Health Canada opened five Regional AR Monitoring Centres in 1991, staffed by contractors. In 2005, two more centres opened, in Alberta and Manitoba, bringing the total to seven. In 2006-2007, MHPD completed the transition of the Regional AR Monitoring Centres from a contractor-based model to an employee-based model, and renamed the centres, the Canada Vigilance Regional Offices.

By having Health Canada employees located in offices across the country, MHPD has increased its collection capacity for post-market surveillance AR reports. Moreover, it is now in an ideal position to facilitate the education and appreciation of post-market surveillance, which is required to continue the momentum achieved to date.

## Canada Vigilance

In autumn 2007, Health Canada announced “Canada Vigilance” as the new name for the Canadian Adverse Drug Reaction Monitoring Program. Canada Vigilance, a program of MedEffect™ Canada, is Health Canada’s post-market surveillance program that collects and assesses AR reports for the following marketed health products:

- pharmaceuticals,
- biologics,
- natural health products, and
- radiopharmaceuticals.

Central to the Canada Vigilance Program is its AR database. The Canada Vigilance database consists of a core application for collecting, coding, assessing and reporting both domestic and foreign AR data. It is a signal-detection and data-mining tool, and one of its modules automatically routes AR cases to specialists and assessors. The database is fully compliant with the International Conference on Harmonisation’s (ICH’s) technical requirements and is bilingual.

## Expert Advisory Committee on the Vigilance of Health Products

The establishment of the Expert Advisory Committee on the Vigilance of Health Products (EAC-VHP) is part of a series of measures to modernize the regulatory system so that departmental decision-making

is more open, transparent and accountable to stakeholders and the public. The EAC-VHP held its inaugural meeting in November 2007.

The EAC-VHP’s mandate is to provide the Health Products and Food Branch (HPFB) with ongoing external expert strategic and policy advice on:

- post-market surveillance activities;
- educational programs;
- risk communication processes;
- regulatory advertising oversight issues; and
- strengthening management and business practices.

It also provides a mechanism for members of the public to have their views heard by a committee, who in turn incorporates these view when providing advice to the Branch. Incorporating the views of citizens and stakeholders is critical for effective regulation in the public interest.





## International Activities

MHPD is engaged in developing better collaboration and work-sharing opportunities with other regulators internationally. This approach is consistent with that of the HPFB of Health Canada.

To date, MHPD:

- has been an observer in the ICH of Technical Requirements for Registration of Pharmaceuticals for Human Use and applied their post-market surveillance standards in the development of the Canada Vigilance database;
- has participated in the Council for International Organizations of Medical Science VIII working group report on signal detection development and in the International Society on Pharmacovigilance;
- has held regular four-way video-conference meetings with the U.S. Food and Drug Administration (FDA), Australian Therapeutic Goods Administration (TGA) and New Zealand Medsafe, to share and discuss drug safety risk information;
- has participated in Senior Officials meetings with international MOU partners: FDA, TGA, Singapore Health Sciences Authority, Chinese State Food and Drug Administration (SFDA), Swissmedic and, more recently, with the European Medicines Agency;
- has been the official member country representative in the WHO Programme for International Drug Monitoring;
- has participated in training related to AR reporting and Canada Vigilance for officials in China as part of the Plan for Action between HPFB and SFDA; and
- has given presentations on the Canadian Post-Market Surveillance/ Product Vigilance System to other foreign regulators and stakeholders from countries such as South Korea, Brazil, South Africa and Mexico.



## Being Proactive

Proactive surveillance projects will enable MHPD to focus on early, preventive actions that make the most of limited resources. In being proactive, MHPD will also strive to make post-market surveillance more transparent and understandable by sharing methodologies, programs and results with stakeholders.

## Business Transformation

Various activities to modernize post-market surveillance have led to:

- the publication of a post-market surveillance five-year strategy: *Planning for Our Future: Federal Regulatory Post-Market Surveillance Strategy 2007-2012*;
- work with the Canadian Paediatric Society and the Children's and Women's Hospital of British Columbia to investigate the feasibility of active surveillance methodologies for increasing the reporting of ARs. An evaluation of the initiative is currently being completed and results will contribute to discussions on potential new surveillance approaches;
- the introduction of project management methodologies in MHPD monitoring and evaluation practices, as well as the creation and staffing of permanent project manager positions;
- the set-up of a performance management framework, with greater management oversight that will result in better information about post-market surveillance activities, their impacts and improved service;

- a commitment to continuous improvement through the formal introduction of quality systems in MHPD, modelled on the ISO 9001 and National Quality Institute Performance Excellence Program standards;
- progress towards establishing requirements for industry to submit pharmacovigilance plans, risk mitigation plans and periodic safety update reports;
- the gradual elaboration of a post-market surveillance framework that (when complete) will describe key responsibilities, area-of-activity and management accountabilities, and that will include an associated pharmacovigilance toolkit; and
- consultations with provinces and territories regarding mandatory reporting of serious ARs by hospitals and the shared use of information for regulatory and health systems uses.

*Did you know? The number of subscribers to the MedEffect™ e-Notice grew from 5,573 in FY 2002-2003 to 14,934 in FY 2006-2007.*





## Increased Scientific Capacity

A key success factor for improved surveillance and more effective risk management is increased scientific capacity. With recent investments in therapeutic product safety, MHPD was able to increase its number of employees by 36%, from 113 in 2005-2006 to 154 in 2007-2008.

The Directorate makes it a priority to support staff members in their achievement of higher education diplomas. MHPD accommodates employees with flexible work hours, so that they can further their studies.

MHPD has worked to develop and promote best pharmacovigilance practices through its participation in the organizing committee of the University of Ottawa's Workshop on Pharmacovigilance (January 2007) and by working with academia on the 2007 Symposium on Vigilance, and the 2007 Knowledge Translation Workshop. In addition, the Directorate made regular contributions to various industry, health professional, academic and consumer conferences.

*Did you know that only 51 percent of physicians and 87 percent of pharmacists report being familiar with AR reporting?*

## Office of Pædiatric Initiatives

Since 2005, the Office of Pædiatric Initiatives (OPI) has been raising awareness of children's health and safety issues related to health products and food. OPI leverages international best practices on pædiatric issues, serves as a central point for stakeholders on pædiatric regulatory affairs, and provides leadership and senior management advice on pædiatric matters.

OPI's key accomplishments to date include:

- promoting the Branch work to advance patent exclusivity, resulting in a patent extension of six months for products that included pædiatric investigations;
- completing the framework to establish an external Pædiatric Expert Advisory Committee; and
- compiling a comprehensive inventory of pædiatric activities and raising awareness of pædiatric issues within HPFB.

Updates on OPI's work will be published in MHPD's 2007-2008 Annual Report.

## Reaching Out

To enhance its visibility and efficiency, as well as to ensure good stakeholder engagement, MHPD continuously looks to develop mechanisms to encourage the participation of stakeholders in post-market surveillance activities. Involving stakeholders in our work leads to better, more durable outcomes.

<sup>11</sup> <http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/index-eng.php>  
<http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/index-eng.php>

## Education and Promotion

Recent efforts by MHPD led to the development of specific modules to educate medical doctors, naturopaths, other health professionals and consumers on how to report ARs, and the integration of these modules into course curriculum or continuing education programs. Additional modules are planned on how to use AR information. The modules will supplement fact sheets that will be posted on the MedEffect™ Canada Web site.

In October 2007, at the seventh annual meeting of the International Society of Pharmacovigilance in Bournemouth, U.K., MHPD staff led a team that won third prize for its poster "Evaluation of an Adverse Reaction (AR) Reporting Education Program (curriculum)." The poster was developed jointly by MHPD and the Natural Health Products Directorate and was one of 169 entries submitted by more than 30 countries.

## Publications

A list of MHPD reports and publications by topic are available on the Health Canada Web site.<sup>11</sup>



International Society of Pharmacovigilance Award recipients

From left to right: MHPD's Karen Pilon, Susanne Reid and Jane McAuley, with Carol Toone of the Natural Health Products Directorate.





## Working Together

Health Canada's goal is to help Canadians maintain and improve their health. By partnering, being proactive and reaching out, MHPD, the federal government and external stakeholder partners can address new challenges to the health and safety of Canadians and keep pace in a rapidly changing environment.

Optimism, commitment and enthusiasm, coupled with our accomplishments to date, convince us that post-market surveillance and vigilance can make a positive difference for Canadians.

Together we can improve health product safety!