Your Health & Safety - Our Priority

Health Canada
Health Products and Food Branch

July 2004

Involving You

I am pleased to introduce this new-look version of *Involving You* - the Health Products and Food Branch (HPFB) newsletter.

We are committed to ongoing improvement and expansion of this publication to help keep our stakeholders and all interested Canadians in touch with our activities and plans.

This edition spotlights some of our recent successes in promoting greater international cooperation, including the signing of a new Memorandum of Understanding with the Therapeutic Goods Administration of Australia. The report on these achievements - together with an article on increased nutrition information on food labelling - reflects our commitment to new approaches to regulatory development through what is known as Smart Regulation principles. These principles are being applied through a number of initiatives, many under the umbrella of the Therapeutic Access Strategy (TAS). Through TAS, HPFB is working to ensure the safety, quality, effectiveness, appropriate use, affordability and ready accessibility of human drugs and related products.

This issue also contains an Internet link to the HPFB Strategic Plan for 2004-2007. The Strategic Plan is our roadmap for anticipating, understanding and responding to changes to the regulatory environment brought about by globalization, public health trends and technological and scientific advances. The document represents a major milestone in HPFB's evolution as an organization committed to providing world-class delivery of its regulatory mandate and to meeting the needs of its diverse public.

It is my hope that *Involving You* readers are enjoying a happy and healthy summer.

Diane Gorman, Assistant Deputy Minister - Health Products and Food Branch

MOU Signed With Australia

A Memorandum of Understanding (MOU) to enhance information sharing and facilitate cooperation on the regulation of therapeutic products for human use was signed in Ottawa on April 14, 2004 by the Health Products and Food Branch (HPFB) and the Therapeutic Goods Administration (TGA) of Australia's Department of Health and Ageing.

The move opens the door to shared information and joint cooperation on clinical trials, marketing applications for therapeutic products, product testing for biological products, compliance and enforcement activities, and other issues. Both HPFB and TGA will ensure that confidential information is protected.

The MOU was signed by Diane Gorman, HPFB's Assistant Deputy Minister, and Terry Slater, National Manager of Australia's TGA.

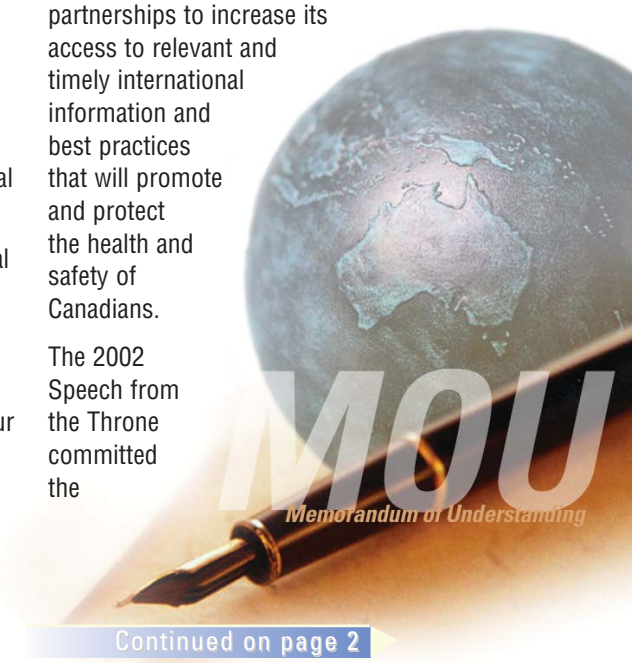
"Our Branch is very pleased to put in place a formal arrangement that sets out future steps with the Therapeutic Goods Administration," Ms. Gorman said. "This Branch has worked with the TGA on a number of issues and the level of collaboration, information sharing and understanding between our two organizations has allowed for very productive and positive outcomes."

Mr. Slater said "the MOU with Canada could give rise to improved and faster decision-making and reduce costs to industry in both countries, while giving greater confidence to consumers about the quality, safety and efficacy of the products on their respective markets."

The MOU took effect immediately and is valid for 10 years. It creates a formal link between the Australian and Canadian regulatory agencies. The MOU can be found on Health Canada's Web site at: www.hc-gc.ca/english/media/releases/2004/mou_april2004.htm.

HPFB continues to develop formal international partnerships to increase its access to relevant and timely international information and best practices that will promote and protect the health and safety of Canadians.

The 2002 Speech from the Throne committed the



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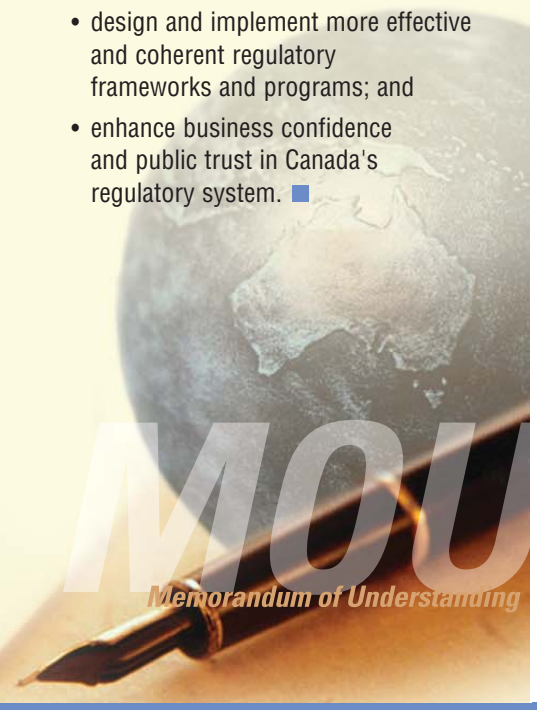
Government of Canada to accelerate reforms in the regulatory process for drug approvals to ensure that Canadians have faster access to the safe drugs they need. The 2003 Budget identified $190 million to address this issue.

The MOU between HPFB and Australia's TGA is in accord with a federal government commitment to a fundamental and critical shift in perspective that embraces what is called Smart Regulation. Smart Regulation is based on the principle that the regulatory system is part of a complex global system that requires governments and government departments and agencies to work better together towards common goals.

Smart Regulation is intended to:

- support key national social, environmental and economic priorities;
- achieve high standards in the way government, businesses and individuals protect the health and safety of citizens and the environment;
- support a competitive economy that attracts investment, supports innovation and generates jobs, and positions Canada internationally as a place to do business;
- help citizens, businesses and governments take advantage of new knowledge and technologies;
- make better use of government resources;
- design and implement more effective and coherent regulatory frameworks and programs; and
- enhance business confidence and public trust in Canada's regulatory system. ■



Smart Regulation

Smart Regulation principles, which factored into the Memorandum of Understanding with Australia, are currently being applied in many Health Products and Food Branch initiatives, including new regulations for food labelling and increased international regulatory cooperation.

International Regulatory Cooperation in HPFB

The health of Canadians is influenced more than ever before by international factors.

The expanding movement of people and goods around the world has dramatically increased the risk of spreading infectious diseases. Because of its extensive expertise in health product and food safety, Canada is often asked to work collaboratively in sharing its knowledge with the rest of the world.

As part of its mandate to take an integrated approach to managing the risks and benefits to health-related products and food, the Health Products and Food Branch (HPFB) actively participates in a number of different international and regional fora. This ensures that HPFB is aware of new policies and issues that may affect the health of Canadians and also permits the Branch to share information on Canadian health issues with the rest of the world. The Branch is often asked to send representatives to sit on the committees of international agencies to share ideas with other international regulators.

Besides its involvement with multilateral organizations, HPFB manages a number of bilateral projects that mobilize staff and other Canadian health experts to help build the capacity of other countries by sharing expertise and transferring knowledge on diverse health issues. Each year, HPFB also receives official delegations and visitors from around the world who are interested in learning more about how the Branch regulates health products and food.

Much of the work to develop these bilateral relationships is done by formalized agreements with other countries through "Memoranda of Understanding" (MOUs). These arrangements are designed to facilitate cooperation and coordinate action between the Branch and jurisdictions in other countries. For example, HPFB has signed two MOUs in the past year - one with the U.S. Food and Drug Administration and another with the Therapeutic Goods Administration of Australia (see related article) to share and exchange information on a range of therapeutic products.

HPFB is increasingly affected and challenged by health issues beyond its borders. Responding to this complex environment requires active participation internationally to help protect and enhance the health of Canadians. Because international cooperation is a key direction in our strategic plan over the next three years, HPFB is engaging and partnering with other regulatory agencies wherever possible to improve regulatory processes and best practices. The prime objective is to ensure the safety, quality, and efficacy of products. ■

Food Labels Take on a Brand New Look

Canadian consumers today are taking an active role in making informed choices about the foods they eat. Many consumers regularly refer to the nutrition information listed on food labels when they're shopping. This hasn't always been an easy task though, as this information is sometimes missing on some food labels. When it is available, it is sometimes hard to read or inconsistent in its form.

Now new regulations developed by HPFB will require food manufacturers to include more nutrition information on food labels using a clear and consistent format. While manufacturers have until 2005 to comply, the ***Nutrition Facts*** table has already started to appear on food labels. Check out what's new:

- The ***Nutrition Facts*** table will be mandatory on almost all pre-packaged foods.
- ***Nutrition Facts*** has an easy-to-read format and looks the same from product to product.
- ***Nutrition Facts*** contains information on calories and at least 13 core nutrients.

More information on nutrition labelling is available by calling 1-800-O-Canada (1-800-622-6232) or by visiting: www.healthcanada.ca/nutritionlabelling . ■

Nutrition Facts
Per 125 mL (87 g)

Amount	% Daily Value
Calories 80	
Fat 0.5 g	**1** %
Saturated 0 g + Trans 0 g	**0** %
Cholesterol 0 mg	
Sodium 0 mg	**0** %
Carbohydrate 18 g	**6** %
Fibre 2 g	**8** %
Sugars 2 g	
Protein 3 g	

Vitamin A	2 %	Vitamin C	10 %
Calcium	0 %	Iron	2 %

Strategic Plan Unveiled

The Health Products and Food Branch (HPFB) Strategic Plan for 2004-07 is now available on HPFB's Web site.

The plan identifies five key strategies linked to overall government commitments that will guide Branch organizational activities over the next three years. They are:

- Transforming our efficiency, effectiveness and responsiveness as a regulator.
- Providing authoritative information to support healthy choices and informed decisions by Canadians.
- Increasing our responsiveness to public health issues and our vigilance over safety and therapeutic effectiveness.
- Improving our transparency, openness and accountability, to strengthen public trust and stakeholder relationships.
- Building a nationally based, flexible organization that has the capacity to fulfill its mandate and priorities in a changing environment.

"The Strategic Plan will serve as a constant yardstick against which we will make informed choices about our priorities and resources, put in place performance measures, and track and report on progress and accountabilities," explained HPFB Assistant Deputy Minister Diane Gorman. "Ultimately, it serves as our tool for demonstrating progress against our commitment to serving Canadians more effectively and efficiently now and into the future."

She said the plan allows both the Branch and its stakeholders "to share a common understanding of where we want to go and how we can work together to get there."

The Strategic Plan can be found on the Web at www.hc-sc.gc.ca/hpfb-dgpsa/strat_plan_e.html . ■

Announcements on Web

As part of a commitment to openness and transparency, the Health Products and Food Branch (HPFB) is continually increasing its efforts to keep stakeholders aware of its activities.

The HPFB Web site has an *Announcements* section that lists recent appointments to senior positions in the Branch. Those interested in keeping abreast of changes as they occur should periodically check this section. Please visit the HPFB site at www.hc-sc.gc.ca/hpfb-dgpsa and click on *Announcements*. ■

Public Advisory Committee Update

The Health Products and Food Branch (HPFB) Public Advisory Committee (PAC) met on May 28 and 29, 2004 in Montreal, Quebec.

The Committee provided advice on key considerations for Health Canada for regulating Somatic Cell Nuclear Transfer (SCNT) technology and its use in food-producing livestock animals. (SCNT is the form of cloning that was used to produce "Dolly" the sheep.) The members stressed the importance of Health Canada's role in steering this technology to ensure the health and safety of Canadians. Based on PAC's advice, a public-oriented document will be prepared to highlight Health Canada's role and key challenges. The Committee emphasized the importance of further review of the ethical issues surrounding this technology.

PAC also examined the topic of plant molecular farming (PMF). This technique involves using genetically modified plants to produce substances that the plants typically do not produce naturally, such as industrial compounds or therapeutics. Members said they preferred that PMF not be allowed in food crops. However, if it was allowed, then strict containment according to international standards should apply. PAC suggested further consideration be given to potential impacts on the farming industry and to the importance of the federal government working collaboratively to minimize any potential environmental health risks. The Committee's advice will be presented at Health Canada's workshop on PMF to be held later this year. The workshop is the next step in the Department's policy-making process regarding PMF.

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Advisory Committees at Work

A new Scientific Advisory Committee on Oncology Therapies has begun work, an Expert Advisory Committee on Cells, Tissues, and Organs Regulation is being set up, and the Expert Advisory Committee on Blood Regulation has a new chairperson.

The new **Scientific Advisory Committee on Oncology Therapies (SAC-OT)** was added to the Therapeutic Products Directorate's growing list of standing committees in therapeutic specialties. This committee is to provide the Health Products and Food Branch with timely scientific, technical and medical advice on issues generated from the regulation of drugs used for the treatment of cancer.

The committee's mandate includes pre- and post-market issues related to products regulated by both the Therapeutic Products Directorate (TPD), the Biologics and Genetic Therapies Directorate (BGTD) and Marketed Health Products Directorate (MHPD), all of which are part of the Health Products and Food Branch.

"As products are brought into the global market, regulatory issues are becoming increasingly complex and include considerations of safety, efficacy and quality of submitted evidence," explained TPD Director General Dr. Robert Peterson. "Risk benefit analysis and subsequent decision-making on evidence from clinical trials must be taken within a Canadian context that respects our legal framework."

The committee has both core and ad hoc members selected for their medical/scientific/technical expertise or experience. Core members are permanent members for the duration of their terms while ad hoc members are invited by the Chair to serve for a specific topic or group of topics appropriate to their expertise. Representatives of patient groups are included to add their perspectives on the effects of therapies as part of the ongoing commitment to increase patient/consumer involvement.

Involvement of the scientific, medical and consumer communities in regulatory decision-making is expected to enhance the drug review process by improving transparency and broadening the knowledge base upon which decision-making is made. Although the committee is a source of advice and recommendations, the decision-making responsibility remains with Health Canada.

The new **Expert Advisory Committee on Cells, Tissues, and Organs Regulation** will work closely with the Biologics and Genetic Therapies Directorate (BGTD). The committee's mandate is to provide BGTD with timely regulatory and safety advice on issues concerning human cells, tissues and organs as therapeutic products intended for transplantation. Names of the Chair and members will be announced soon.

Dr. Lindsay Nicolle has been appointed chair of the **Expert Advisory Committee on Blood Regulation (EAC-BR)**. She succeeds Dr. Noni MacDonald, Dean of Medicine at Dalhousie University, who chaired the committee for the past eight years.

Dr. Nicolle is Professor of Internal Medicine and Medical Microbiology at the University of Manitoba and Consultant in Adult Infectious Diseases at the Health Sciences Centre and Winnipeg Regional Health Authority.

The EAC-BR provides timely advice on medical and scientific issues relevant to federal responsibilities within the national blood system.

There has also been a move to expand public participation on this committee through the involvement of St. John Ambulance, the Hemophilia Society of Canada, and the Canadian Mental Health Association. This is in line with HPFB's strengthened commitment to transparency and engagement of patient and consumer organizations in Branch decision-making. The EAC-BR now consists of three lay representatives and 12 technical experts. ■

Adverse Reaction Reporting

Health Canada received 9,209 new domestic reports of suspected adverse reactions (ARs) to drugs and other health products in 2003. For the most part, ARs were reported by health professionals (pharmacists, physicians, nurses, dentists, coroners and others), either directly to Health Canada or indirectly through another source.

A steady increase in the reporting of ARs has been noted over the past five years with 7.5 per cent more reports in 2003 than in 2002.

The Canadian Adverse Drug Reaction Information System (CADRIS) is a computerized database that houses Canadian suspected adverse reactions which have been reported to Health Canada's Canadian Adverse Drug Reaction Monitoring Program (CADRMP). The program collects AR reports for pharmaceuticals, biologics (including blood products, as well as therapeutic and diagnostic vaccines), natural health products, and radiopharmaceuticals. Adverse reaction reports are submitted by health professionals and laypersons on a voluntary basis, either directly to Health Canada or through manufacturers.

Of the AR reports received, 6,414 (69.6%) were classified as serious. A serious AR is defined in the *Food and Drugs Act and Regulations* as "a noxious and unintended response to a drug which occurs at any dose and requires inpatient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death."

HPFB thanks all who have contributed to the program and encourages the continued support of post-marketing surveillance through AR reporting. ARs may be reported by using the toll-free telephone (866-234-2345) and fax (866-678-6789) lines. The forms for reporting are available on the Web at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_report_e.html#forms .

The Canadian Adverse Reaction Newsletter - published quarterly in January, April, July and October of each year - is a reputable source of adverse reaction information and is available on the Web at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_newsletter_e.html .

More HPFB Initiatives

The Health Products and Food Branch is forging ahead with a broad variety of initiatives to improve the rate of reporting and the availability of information on the post-market use of therapeutic products. Several examples:

- Health Canada's five Regional Adverse Reaction Centres across Canada collect adverse reaction reports from health professionals and consumers and promote the adverse reaction reporting program. Two new Centres will be added to this network in 2004.
- HPFB is collaborating with the Canadian Pediatric Society and the Children's and Women's Health Centre of British Columbia on an initiative to identify serious and life threatening adverse reactions in children. The initiative will include data collection, analysis and publication of results.
- The Branch is now working to implement the Canadian Medication Incident Reporting and Prevention System (CMIRPS), in cooperation with the Canadian Patient Safety Institute, the Canadian Institute for Health Information, the Institute for Safe Medication Practices Canada, and the Canadian Coalition on Medication Incident Reporting and Prevention. Watch for more on this in an upcoming issue of *Profiles in Progress*.
- Consumers and health care professionals have said they want an easy-access means through which they can report adverse reactions and receive information about the safety of health products in the marketplace. Health Canada is in the planning phase of developing a single window Web site to centralize the collection of adverse reaction information and disseminate new health product safety information such as advisories and warnings. The Web site will be designed, developed, and tested over the next several months before being launched in 2005.

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Members also delivered concrete advice on how the Health Canada Framework on Biotechnology can be improved. For example, they suggested a need for further clarity on safety measures, outcomes and benefits. Members reiterated that while innovation is important, safety should not be compromised. Based on their input, the Branch will revise the current draft and produce a separate document geared to a public audience.

The committee toured the laboratories at Health Canada's headquarters in Longueuil, Quebec. Lucie Myre, Health Canada's Regional Director General in Quebec, delivered a presentation on the role of Health Canada in the Quebec region. Jean Lambert, Director General of the Health Products and Food Branch Inspectorate, addressed the roles of the Inspectorate. Participants said they appreciated the first-hand look at the product investigation process.

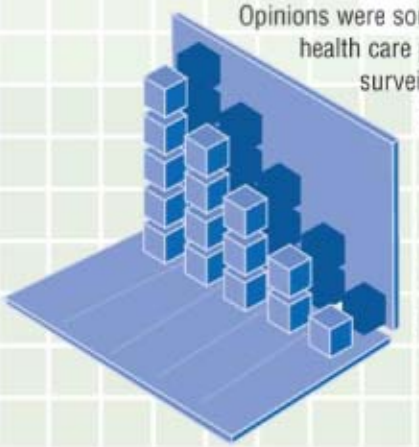
Wayne Busch, PAC Chair, and Dominic Bergeron, PAC Vice Chair, accepted nominations by PAC members to retain their current positions for the remainder of their first three-year terms, ending November 2005.

The next Public Advisory Committee meetings will be held in Ottawa on October 1-2, 2004 and February 18-19, 2005.

Adverse Reaction Reporting (con't)

National Survey

Risk communication tools for adverse reactions were analyzed in a national survey recently completed by Decima Research.



Opinions were sought from Canadians, including health care professionals, on post-marketing surveillance of marketed health products (prescription drugs, non-prescription drugs and natural health products) available in Canada. Respondents provided important information on the effectiveness of Health Canada's methods used to communicate health product safety information.

This feedback included perceptions of health product safety and health risks posed by adverse reactions (ARs), as well as awareness, use of, familiarity and satisfaction with available sources of new health product safety information, views on mandatory AR reporting by health care professionals, and views on patient informed consent before AR reporting.

The survey results will be used to evaluate the effectiveness of Health Canada sources of new drug safety information (e.g., *Dear Health Care Professional* letters, Public Advisories and the *Canadian Adverse Reaction Newsletter*) and will provide direction for improvements and baseline data for future evaluations. This report is available at:

www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_adr_reports_e.html .■

Health Fact Sheets Available

Health Canada maintains a series of timely fact sheets intended for the general public, the media and special interest groups.

The *It's Your Health (IYH)* series covers a wide range of health issues. Topics cover diseases, the environment, food, lifestyles, and consumer products as well as medical treatments, devices and drugs. These articles also include Internet links and references to more information. Each article is written in consultation with Health Canada's scientists and experts and may also be reviewed by national experts outside the department. Please note - *IYH* does not provide diagnoses or treatment recommendations and should not be used in place of medical advice, instruction and/or treatment. Specific health questions should be referred to your physician or appropriate healthcare professional.

Those interested in keeping on top of the most recent information Health Canada has to offer on pertinent health and safety issues may subscribe to the *It's Your Health* notification service. Subscribers to this service will be informed via email whenever a new *It's Your Health* fact sheet is available on the Web. To subscribe go to www.hc-sc.gc.ca/english/iyh/subscribe.html .

The fact sheets are available in print form and on the Health Canada Web site by clicking on *It's Your Health* at the top of the home page at www.hc-sc.gc.ca .■

Contact Us

If you are interested in particular issues and would like to be kept informed of upcoming opportunities to participate please contact the Office of Consumer and Public Involvement (OCAPI).

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Involving You is produced by the Office of Consumer and Public Involvement (OCAPI).

It is one of a variety of ways we hope to encourage more informed involvement of Canadians in decisions about health priorities, policies and programs of the Health Products and Food Branch (HPFB) and other Health Canada branches with similar regulatory responsibilities.

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