Health Canada Santé Canada

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Fall 2006

INVOLVING YOU

Health Products and Food Branch

STRONGER Directorate Created

The Health Products and Food Branch (HPFB) has merged its Policy and Strategic Planning Directorate and the Office of Regulatory and International Affairs to create a new Policy, Planning and International Affairs Directorate.

"By consolidating two strong organizations, we expect to be able to further strengthen the Branch's policy capacity, increase our ability to leverage existing resources, and improve our responsiveness to emerging priorities," explained Assistant Deputy Minister Neil Yeates.

Mr. Yeates said the new directorate has emerged in response to an increasing emphasis in HPFB's work on strategic policy analysis and development, international affairs, federal-provincial-territorial (FPT) relations and engagement with the Health Portfolio and other federal partners. He said these areas are critical to the Branch's success in its Blueprint for Renewal initiative, the continued implementation of the HPFB Strategic Plan and Smart Regulation and Legislative Renewal initiatives, participation in the National Pharmaceuticals Strategy and other FPT initiatives, and in efforts to strengthen international regulatory cooperation.

New Consumer Advertising Guidelines

After comprehensive consultations with external stakeholders, the Health Products and Food Branch's Marketed Health Products Directorate has issued the final Consumer Advertising Guidelines for Marketed Health Products.

Advertising guidelines apply specifically to advertising of nonprescription drugs and natural health products

The guidelines were created as a way to provide advertisers and advertising pre-clearance agencies, who review and approve advertising, with clear guidance on the federal regulatory requirements for advertising under the *Food and Drugs Act and Regulations*, the Natural Health Product regulations and other Health Canada policies and guidelines. The revised guidelines replace the 1990 Consumer Advertising Guidelines and were developed in collaboration with Advertising Standards Canada and members of the Branch Advertising Working Group.

Of particular importance, Section 2.21 of the guidelines clarifies the regulatory requirements for communicating risk information in consumer advertising. The new guidelines will require advertisers to consistently include information that encourages the consumer to read product labels, and in cases where risks have been identified for a product, to include a general cautionary statement. Where new risks have been identified but do not yet appear on a product label, there are additional requirements. Inclusion of improved risk information in advertising will allow consumers to make more informed health product choices.

The Guidelines, which will be updated on an as-needed basis, are available at www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index_e.html. They are effective immediately but the clarifications outlined in Section 2.21 will take effect April 1, 2007 to allow industry to adjust its advertising material.

In this issue

Canada

UPDATE Progressive Licensing

The Health Products and Food Branch (HPFB) Progressive Licensing Framework is steadily taking shape.

As noted in the summer edition of *Involving You*, the objective is to develop a modern drug licensing framework, based on sound evidence and risk management, that supports access to promising new drug therapies while continuously monitoring and reassessing potential safety, quality, efficacy and effectiveness concerns throughout the life-cycle of a drug.

A number of milestones have been achieved as work progresses. One very successful workshop brought together a variety of individuals in July 2006. It confirmed that a number of the concepts of progressive licensing are supported by industry, health professionals, researchers and patient groups. Many bilateral meetings have also been held with stakeholders to raise awareness of the project and obtain early feedback regarding the drug regulatory process and more are planned.

The project team is now continuing to develop the key concepts of progressive licensing and is planning more workshops that are tentatively scheduled for the winter of 2007. These workshops will take a more in-depth look at framework concepts new to drug regulation in Canada.

The project team is also developing an electronic tool that will help explain the present regulatory system and how a new framework will incorporate modern thinking around drug regulation, such as addressing extraordinary need drugs and post-market activities. This electronic tool will be made available to internal and external stakeholders on the Health Canada Web site this winter.

Public Input Policy *Developed*

The Health Products and Food Branch (HPFB) is developing a policy to strengthen its capacity to involve the public in decision making that in the past was limited to scientific experts.

Becoming a world-class regulator means promoting a more open and transparent system where the involvement of the public and stakeholders contributes to better overall quality of decision making and effective regulation in the public interest.

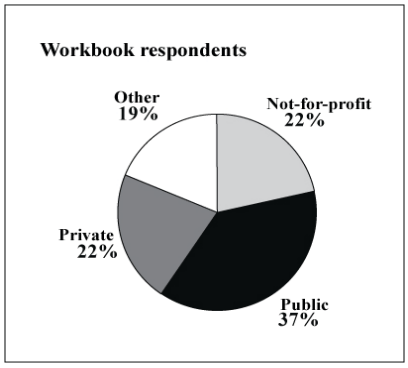
The Policy on Public Input into the Review of Health Products is one element of the Branch's efforts to renew its approach to regulating health products and food (see Blueprint for Renewal article on page 4). It supports the consideration of public input in HPFB's review of the safety and effectiveness of health products under the *Food and Drugs Act*, by describing when and how to seek public input.

The policy will allow the Branch to better identify, assess and manage risks by expanding the evidence pool and perspectives on decisions about health products. And, by providing accessible information about the science underpinning our decisions, the policy will help to bring more transparency to HPFB's decision-making processes.

Involving Canadians

From July to September, HPFB's Office of Consumer and Public Involvement (OCAPI) invited stakeholders from across the public, private and not-for-profit sectors to complete an online workbook to learn more about the policy and provide input on selected topics.

OCAPI has made the workbook results available at www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index_e.html. In the coming months, watch for further consultation updates and next steps for the policy.



Clinical Trial *Consultations Update*

The transparency of clinical trials has become an important issue in Canada and abroad. Patients, health professionals, researchers, and regulators want greater access to information on clinical trials to help them make more informed decisions.

Public & Stakeholder Consultations

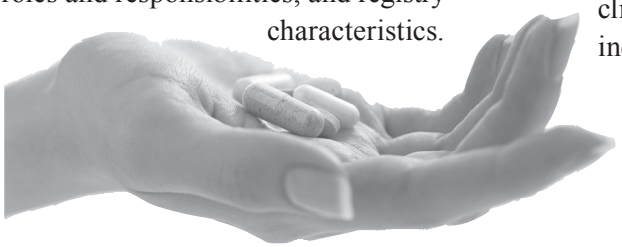
Input from recent public and stakeholder consultations on the registration and disclosure of clinical trial information is now being reviewed by an External Working Group.

The working group plans to make a final recommendation to Health Canada on how to improve access to clinical trial information in Canada.

In addition to the recent consultation findings, the working group is also taking results of previous consultations and international activities into account.

Electronic Consultation

The most recent input came this summer through an electronic consultation based on the External Working Group's preliminary list of options. The consultation used a workbook format which allowed participants to read through information and facts before responding to questions. Topic areas included the purpose of registration in Canada, types of trials to be registered, timing of registration, disclosure of results, roles and responsibilities, and registry characteristics.



A report on the consultation has been developed and will be posted on the Health Canada Web site.

Improving Public Access

The External Working Group first met in late April 2006 and focussed on developing a preliminary list of options for improving public access to clinical trial information. The group has 13 members including academics, health professionals, patient and consumer groups and industry representatives. The working group's terms of reference, membership, and other information are now available on the Health Canada Web site at www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/sci-consult/ewg-ct/index_e.html.

This recent work builds on consultations held in June 2005 which identified the needs and requirements for clinical trial registration. Consultations included three one-day workshops in Halifax, Ottawa, and Vancouver and an online questionnaire. Participants included academics, community and consumer groups, industry, research ethic boards, research ethicists, patient organizations, health professionals, medical journal editors, and public funding agencies. The report on the workshops and questionnaire are available at www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/proj/enreg-clini-info/2005-consult/index_e.html.

A ***clinical trial*** is an investigation of a drug for use in humans and involves human subjects. It determines the level of safety and efficacy of a drug, what dosages are most effective, and what side effects a drug may cause.

Clinical Trials Manual ON THE WEB

A clinical trials manual now posted on the Health Canada Web site offers comprehensive guidance to all stakeholders on filing clinical trial applications.

Created by the Therapeutic Products Directorate's Office of Clinical Trials in consultation with the Biologics and Genetic Therapies Directorate and the Inspectorate, the manual helps minimize the many inquiries received daily. The manual includes a Frequently Asked Questions section.

The information provided in the manual is for clinical trials that involve the use of pharmaceutical, biological or radiopharmaceutical drugs in humans. It does not apply to clinical trials involving medical devices and natural health products.

A clinical trial application includes documentation to support the objectives and goals of a proposed clinical trial and data to support the quality of the drug to be tested. Both the clinical and quality components of the application are reviewed and must be satisfactory before Health Canada issues a "No Objection Letter." The approval of local or institutional research ethics boards must also be obtained before a clinical trial is initiated. Changes to an authorized application must be submitted to Health Canada as an amendment or a notification.

The manual can be found at www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_intro_e.html .

Launch of Blueprint for Renewal Consultations

Transforming Canada's approach to regulating health products and food

The Health Products and Food Branch's Blueprint for Renewal initiative, aimed at modernizing Health Canada's approach to regulating health products and food, was officially launched in October.

A discussion document has been posted on Health Canada's Blueprint Web site (www.healthcanada.gc.ca/hpfb-blueprint), as well as an e-consultation workbook. The Branch has invited a broad selection of stakeholders to provide their views on the vision and objectives of the Blueprint by completing the workbook.

Regional Meetings

In addition to the e-consultation, we are moving ahead with a series of regional meetings with key stakeholders in November. The stakeholders include health professionals, academics, patients, consumers, and industry.

The first of seven sessions with Neil Yeates, Assistant Deputy Minister of the Health Products and Food Branch, took place in Toronto on November 3 with stakeholders from the Ontario-Nunavut region. The schedule included similar meetings in Halifax, Winnipeg, Montréal, Ottawa, Vancouver, and Edmonton.

Left to right, Anthony Sangster, Health Canada's Regional Director General for Ontario and Nunavut, Susan Gardner-Barclay, Acting Director General of HPFB's Office of Consumer and Public Involvement, and HPFB's Assistant Deputy Minister Neil Yeates at the Toronto regional meeting.

Canada's Regulatory System

"The Blueprint for Renewal is intended to guide the modernization of the Canadian regulatory system and achieve a vision as an internationally recognized regulatory leader," Mr. Yeates noted in the Blueprint document now on the Health Canada Web site.

Central to the vision, he explained, Health Canada will need to have an adaptable and sustainable regulatory system that:

- helps Canadians improve their health outcomes through timely access to safe, effective and high-quality health products and food;
- strengthens safety oversight through a product lifecycle approach;
- sustains and improves regulatory efficiency and predictability, while maintaining Health Canada's high standards for safety;
- is accountable, open and transparent to stakeholders and the public; and
- contributes to better aligned regulatory and reimbursement decision making.

Vision

"Our primary goal in the development and implementation of the Blueprint's vision will be the protection of the health and safety of Canadians," Mr. Yeates stressed.

"This is a long-term vision that will require time and effort to be fulfilled."

Besides seeking the views of Canadians on the Blueprint's overall plan, HPFB will also hold a number of thematic consultations over the coming months and year on various Blueprint initiatives key to the renewal. They include a progressive licensing framework for pharmaceuticals and biologics; a renewed external charging framework that will stabilize the Branch's resources and cover the regulation, licensing and post-market surveillance of health products; and a regulatory modernization strategy for food and nutrition.

HPFB will report progress on the Blueprint for Renewal on its Web site. For more information on the renewal efforts, visit www.healthcanada.gc.ca/hpfb-blueprint.

HPFB Helps Make Nutrient Guide More Accessible

HPFB's Office of Nutrition Policy and Promotion is pleased to announce the release of the summary report of eight publications on Dietary Reference Intakes (DRIs).

The summary will serve as a practical guide to health professionals in Canada and the United States. And for the first time, the summary will be published in a language other than English. The French version will be available next spring.

The Dietary Reference Intakes – a definitive resource about nutrient requirements for healthy people – were developed by the Food and Nutrition Board of the Institute of Medicine (IOM) in response to increasing scientific knowledge on the role of nutrients in human health.

The eight reports on DRIs – in English only – took 10 years to develop and total over 5,000 pages. Support from the Canadian nutrition community and industry for harmonizing Canadian and U.S. standards allowed Canadian scientists to participate on standing committees and nutrient expert panels. The size, complexity and cost of these eight reports and the fact that they were not available to French-speaking people in their language, made them inaccessible to a large segment of Canadians interested in nutrition.

Copies of the easy-to-use ***Dietary Reference Intakes*** summary may be ordered through the National Academies Press Web site at www.nap.edu .

Recognizing the groundbreaking nature of the reports and their value to the nutrition community, HPFB and the Food and Nutrition Board of the IOM partnered in 2005 to create a single volume that would summarize the DRIs, their uses and interpretation, and extend the reach of the original reports to a wider audience.

This summary report recasts essential ideas from the original reports in an accessible and more compact form. It provides information on how much of each nutrient healthy people need, why they are important, and how to use nutrient reference values.

The DRIs may be used in applications that require accurate, practical and up-to-date information, such as assessing and planning diets for individuals and groups, establishing nutrition standards for food assistance programs and nutrition labeling, designing nutrition education programs, developing new products for industry and evaluating the adequacy of food supplies in meeting national nutritional needs.

Developing dietary guidelines that define and promote healthy eating among Canadians is a priority at Health Canada and the Department has used the DRIs to strengthen its dietary guidance. For example, in revising Canada's Food Guide to Healthy Eating, Health Canada used the DRIs as well other scientific dietary direction linking food patterns and chronic disease. A new and improved version of the Food Guide is expected to be released in early 2007.

Organizational Changes in HPFB

A number of organizational changes have occurred in the Health Products and Food Branch over the past few months.

Karolyn Lui has been appointed HPFB Regional Director, Ontario and Nunavut Region. Ms. Lui brings a broad perspective and extensive experience to her new role, having worked in HPFB for 15 years in various positions in science, regulatory policy and management. As part of the Career Assignment Program (CAP), a federal Public Service development program, Ms. Lui completed a number of senior-level assignments in the last three years in Health Canada and in other federal departments. As the Associate Director of the Policy Bureau, Therapeutic Products Directorate, she led the regulatory development of Canada's Access to Medicines (Drugs for Africa) Regime. More recently, she completed an assignment in the Regulatory Affairs and Orders in Council Secretariat of the Privy Council Office, where she was responsible for the government's public risk management framework and the Smart Regulation and Healthy Canada Theme Table initiatives. Ms. Lui holds degrees in Biochemistry and Nutrition/Pharmacology.

Dr. Ken Sato, Acting Director General of the Office of Biotechnology and Science, has retired. Dr. Sato was instrumental in providing leadership in the areas of biotechnology, science, and the Science Library Network. As part of HPFB's efforts to strengthen the role of science advice in the Branch, the Biotechnology Group has been transferred to HPFB's Biologics and Genetic Therapies Directorate. It now reports to Dr. Elwyn Griffiths, Associate Director General, under the leadership of Dr. Pierre Charest, Director General.

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After many years of dedicated service to the Food Directorate, **Paul Mayers** has left HPFB to join the Canadian Food Inspection Agency, where he will be leading the Meat Inspection Reform Initiative.

Daniel Chaput joined the Food Directorate as the Associate Director General and brings with him significant and diversified experience in leading science-based regulatory organizations. He began his public service career in 1983 as an analytical chemist with Environment Canada and moved to more senior positions with Agriculture and Agri-Food Canada and then with the Pest Management Regulatory Agency of Health Canada. Most recently, he was the Director General, Directorate of Operational Strategies with the Canadian Nuclear Safety Commission. Mr. Chaput holds a B.Sc. in chemistry from l'Université de Sherbrooke and a MPA from l'École nationale d'administration publique.

Diana Dowthwaite was appointed Director General of the HPFB Inspectorate. Ms. Dowthwaite first came to Health Canada and the Inspectorate in April 2004 as the Associate Director General of the Inspectorate. She later assumed the duties of Director of the Compliance and Enforcement Coordination Division and had been leading the Inspectorate as Acting Director General since February 2006. Before joining Health Canada, Ms. Dowthwaite worked at Public Works and Government Services Canada, where she managed and directed public affairs, media relations and communications files. Ms. Dowthwaite holds a BA in Public Relations from Mount Saint Vincent University in Halifax.

Science Advisor *for HPFB*

The Health Products and Food Branch (HPFB) has created the position of Science Advisor to deal with science policy and support risk management.

Dr. David Clapin, former Associate Director General of the Marketed Health Products Directorate, has been appointed to the Ottawa-based post and reports directly to the Assistant Deputy Minister.

As head of the Office of Science and Risk Management, the Branch Science Advisor provides a focal point for strategic science planning and science policy, and for consistency in the Branch's approach to benefit and risk decision making. The Advisor helps ensure that consistent standards and levels of scientific evidence are employed, and that effective risk management principles and practices are used to fulfill HPFB's mandate. He also provides coordination and advice on international, national, federal, and departmental science and technology issues that affect the Branch.

Dr. Clapin has been leading work on "real world safety and effectiveness" as part of the National Pharmaceuticals Strategy and will continue with this project while it is in the developmental phase. He has extensive experience in HPFB in pharmaceuticals and medical devices and has served as an advisor to the Food Directorate and as the Health Canada coordinator for the Canadian Biotechnology Strategy.

Dr. Clapin believes a more coordinated, strategic and planned approach to science communication is needed to raise awareness of Health Canada's science and research activities; support the use, transfer and exchange of internal and external knowledge; and enhance transparency and openness.

A graduate of the University of Ottawa in biochemistry (BSc, PhD) and of Carleton University, where he studied public administration (MPA), Dr. Clapin completed five years of post-doctoral studies in the field of neuroscience and neurotoxicology at institutions in Canada and the United States. He is certified by the American Board of Toxicology and is also a Eurotox Registered Toxicologist. Since joining the federal public service more than 18 years ago, Dr. Clapin has held a variety of positions related to risk management programs for human health and safety and is a graduate of the Health Canada Science Management Development Programme.

... the Branch Science Advisor provides a focal point for strategic science planning and science policy, and for consistency in the Branch's approach to benefit and risk decision making.

Fact Sheet on Adverse Reaction Newsletter

Health care professionals and consumers interested in learning more about the Canadian Adverse Reaction Newsletter will find a useful new fact sheet on the Web.

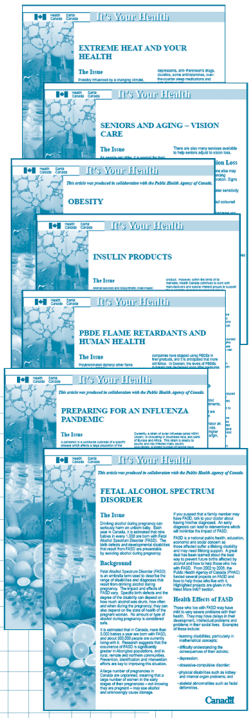
The fact sheet contains information on the scope, purpose, features, target audience and distribution of the newsletter as well a brief explanation of adverse reactions.

The Canadian Adverse Reaction Newsletter is a reputable source of information on suspected adverse reactions to Canadian marketed health products occurring in humans. It is one tool Health Canada uses to disseminate newly identified safety information before comprehensive benefit-risk evaluations and regulatory decisions are undertaken. The newsletter, launched in January 1991 and produced by the Marketed Health Products Directorate, is published quarterly in January, April, July and October.

The fact sheet and newsletter are available on Health Canada's MedEffect Web site at www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/index_e.html.

It's Your Health

Each *It's Your Health (IYH)* article is written in consultation with Health Canada's scientists and experts and may also be reviewed by national experts outside the department. *IYH* does not provide diagnosis or treatment recommendations and should not be used in place of medical advice, instruction and/or treatment. These fact sheets are posted on the Web at www.hc-sc.gc.ca/iyh-vsv/index_e.html.



Extreme Heat and Your Health - *New*
www.hc-sc.gc.ca/iyh-vsv/environ/heat-chaleur_e.html

Seniors and Aging - Vision Care - *New*
www.hc-sc.gc.ca/iyh-vsv/life-vie/seniors-aines_vc-sv_e.html

Obesity - *New*
www.hc-sc.gc.ca/iyh-vsv/life-vie/obes_e.html

Insulin Products - *Updated*
www.hc-sc.gc.ca/iyh-vsv/med/insul_e.html

PBDE Flame Retardants and Human Health - *New*
www.hc-sc.gc.ca/iyh-vsv/environ/pbde_e.html

Preparing for An Influenza Pandemic - *New*
www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/pandem_e.html

Fetal Alcohol Spectrum Disorder - *New*
www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/fasd-etcaf_e.html

REPORTING Adverse Reactions online

Health Canada's *MedEffect* Web site has been updated to accept online reports of suspected adverse reactions to health products marketed in Canada.

Now, in addition to reporting methods that include mailing reports or using the toll-free fax or telephone numbers, health care professionals and consumers can submit reports of adverse reactions online. When an online report is submitted, the system will generate a file that you can print and store electronically. Information on the identity of the patient or the person reporting an adverse reaction is protected under the *Access to Information Act* and the *Privacy Act*.

Under-reporting of adverse reactions is a well-known global issue. International studies have estimated that only one to 10 per cent of all reactions are reported. Health professionals have identified barriers which include the inconvenience and difficulty of reporting. The new user-friendly on-line reporting form will make the process more convenient and should contribute to increased reporting of adverse reactions.

Visit the *MedEffect* Web site (www.healthcanada.gc.ca/medeffect) to submit a report online and see the latest advisories, adverse reaction information and other reporting initiatives.

Recent Warnings or Advisories

Health Canada helps protect Canadians from potential health hazards by releasing warnings and advisories on food, drugs, medical devices, natural health products and consumer products.

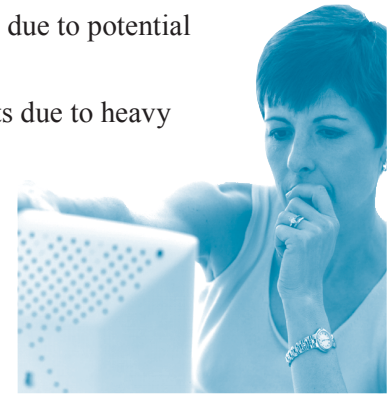
The following is a list of some recent warnings or advisories posted on the Health Canada Web site at www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/index_e.html. New postings and updates appear on a regular basis.

September

- Health Canada advises about missing dosage information on the veterinary drug product PENPRO
- New information regarding uncommon psychiatric adverse events for all ADHD drugs
- Health Canada warns consumers not to use natural sex enhancer Libidus due to potential health risks
- Health Canada advises against use of the Ayurvedic medicinal product Jambrulin due to lead content
- Health Canada is advising Canadian farmers about missing dosage information on some Selenium-E veterinary drug packages

October

- Health Canada is advising consumers not to use a specific lot of Neutragel sodium fluoride gel due to mould contamination
- Health Canada warns consumers about counterfeit Lifescan blood glucose test strips
- Health Canada warns consumers not to use unauthorized intravenous health products due to potential health risks
- Health Canada advises consumers not to use two unauthorized natural health products due to heavy metal contamination



November

- Health Canada advises consumers not to use four unauthorized natural health products that claim to treat serious diseases
- Health Canada advises consumers not to use unauthorized products for sexual enhancement due to potential health risks

Contact Us

If you are interested in particular issues and would like to be kept informed, 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.

It is just 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).

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