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Regulatory affairs on health Canada

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ABSTRACT

Regulatory affairs (RA), also called government affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods). Regulatory affairs (medical affairs) professionals (aka regulatory professionals) usually have responsibility for the following general areas: Ensuring that their companies comply with all of the regulations and laws pertaining to their business. Working with federal, state, and local regulatory agencies and personnel on specific issues affecting their business. i.e. working with such agencies as the Food and Drug Administration or European Medicines Agency (pharmaceuticals and medical devices); The Department of Energy; or the Securities and Exchange Commission (banking).Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e. describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.

Keywords: European Medicines Agency, Sarbanes-Oxley compliance, Food and Drug Administration

INTRODUCTION

A pharmaceutical regulatory affairs and quality operations associate makes sure that medical devices and pharmaceuticals are tested and are ready for distribution. You follow regulatory standards in Canada and any country where you export your product. You may work for a pharmaceutical company or for a governmental or non-governmental agency. You may also be called a Regulatory Affairs Specialist.

Generally, pharmaceutical regulatory affairs and quality operations associates

1. Design and execute clinical trials with quality control.
2. Assess products under strict guidelines and keep proper documentation.
3. Track and maintain regulatory correspondence and submissions.
4. Use different strategies to meet changing regulations.

5. Review and observe worldwide quality control guidelines.
6. Audit tracking programs.
7. Report and document when there are problems with medical devices or products.
8. Provide good manufacturing practice (GMP).
9. Communicate effectively with managers and people at regulatory bodies.
10. Do technical writing and data entry.
11. Make sure that the product you represent is safe, meets all standards and is ready for market.

As Canada's national authority responsible for the regulation of health products and foods, the Health Product and Food Branch [1] (HPFB) is responsible for a broad scope of health protection, promotion and disease prevention activities that affect the everyday lives of Canadians. Regulation plays an important role in protecting the interests of Canadians and is an essential tool used by governments to achieve public policy objectives. Regulation is one of the prime tools used by the Branch to fulfill its mandate and the Branch is engaged in a wide variety of regulatory activity. The Regulatory Affairs Team in the Office of Regulatory and International Affairs [4] (ORIA) leads the Branch to determine its regulatory agenda and manages the horizontal, cross cutting regulatory work to help ensure consistency across the Branch. Examples of this work include: Smart Regulation, Legislation Renewal, Electronic Review and Product Categorization. [1, 2, 3]

Smart Regulation

Smart Regulation is a Government of Canada regulatory reform initiative that will result in regulations that are more relevant and effective in safeguarding the health and safety of Canadians, ensuring a healthy environment, and, creating the conditions for an innovative and competitive economy. Smart Regulation advances objectives that the federal government has in recent public policy documents, in particular Strengthening Public Sector Management and Budget 2005. The Smart Regulation[2] Report on Actions and Plans, released in March 2005, describes the government's plan for the implementation of Smart Regulation, and highlights many of the regulatory initiatives already underway by departments and agencies. It will be periodically updated in order to report on progress. ORIA[4] has the lead in HPFB on this initiative [5, 6, 7]

Legislation Renewal

Health Canada is conducting a comprehensive review of its health protection legislation with a view to replacing outdated statutes with a new health protection legislative regime, better adapted to modern technology and society. The main objectives of the legislation review are to modernize and strengthen the legislation to help better protect Canadians against health risks, and provide policy direction in the area of health protection.

The ORIA is the HPFB lead on Legislation Renewal. ORIA leads and manages Branch involvement in the initiative by developing and contributing to policy analysis on a variety of topics; creating and maintaining a Branch Governance Structure and Working Groups; representing the Branch at departmental committees; and upholding Branch needs and perspectives [7, 8, 9].

Regulatory transparency and openness

The Government of Canada is making more data and information available to Canadians than ever before. Canadians are also being offered more opportunities to participate in discussions on government policies and priorities [10, 11].

This Framework will

- Help Canadians to better understand how and why our decisions are made. They can use this information to make well-informed decisions on their health and the health of their families.
- Assist industry to be better positioned to comply with current regulatory requirements and plan for upcoming regulatory changes.

Office of the Comptroller General

The Comptroller General of Canada is responsible for providing functional direction and assurance government-wide for financial management, internal audit, investment planning, procurement, project management, and the management of real property and materiel.

The Office of the Comptroller General supports the Comptroller General of Canada by working to ensure that sound policies, standards and practices are in place; by overseeing performance and

compliance across the federal government; and by maintaining and building vibrant professional communities through a range of recruitment and development activities.

Office of the Chief Human Resources Officer

The Office of the Chief Human Resources Officer (OCHRO) supports the Treasury Board in its role as the employer by driving excellence in people management and ensuring the appropriate degree of consistency across the public service. OCHRO[5] fulfills this mandate in a manner that is compatible with primary deputy head accountability and responsibility

Expenditure Management Sector

The Expenditure Management Sector (EMS) [8] provides a central focus for the functions that support and strengthen the Secretariat's role in the government's broader expenditure management system. EMS's work covers the entire expenditure management cycle—from expenditure analysis, forecasting and expenditure management strategies, policies and operations through to results-based management, evaluation, strategic reviews, Estimates production, accountability, and reporting to Parliament.

EMS plays a strong integration role in planning and coordinating expenditure management initiatives and in providing a whole-of-government perspective on matters related to the management of direct program spending and compensation within the federal government.

Government Operations Sector

The Government Operations Sector [11] supports the Treasury Board in its role as management board and budget office. The Sector provides analysis and advice on management capacity and risks, strategic resource allocation, and effective program design in a portfolio that includes central agencies, Agents of Parliament, many Crown corporations and Public Works and Government Services Canada. As well, the Sector provides policy advice and analysis on corporate governance to Crown corporations and the small agency community [12,13].

Chief Information Officer Branch

The Chief Information Officer Branch [7] (CIOB) provides strategic direction and leadership in the pursuit of excellence in information management, information technology, security, privacy and access to information across the Government of Canada. To facilitate this work, CIOB also provides support and guidance on capacity building and project management and oversight.

PRIORITIES AND PLANNING

Priorities and Planning (P&P) is responsible for key policy and planning activities that underpin both government-wide management excellence and efficient and effective corporate governance within the Secretariat. Specifically, P&P works with all departmental sectors to ensure that Treasury Board policy advice is coordinated and consistent. It does so by playing both an integrative role and a challenge function in advancing the strategic management priorities of the Secretary and the President of the Treasury Board. P&P also provides leadership for governance and planning processes within the Secretariat to ensure coherence in corporate priorities, progress on key files, clear accountabilities, and continuous improvement.

Social and Cultural Sector

The Social and Cultural Sector supports the Treasury Board in its role as management board of the Government of Canada and as budget office in the government-wide expenditure cycle. As such, the Sector performs due diligence reviews of Memoranda to Cabinet and Treasury Board submissions from federal organizations and provides advice to the Treasury Board regarding resource allocation, risks, and policy compliance. This work supports sound decision making, value for money, compliance with rules and policies, and alignment with Government of Canada priorities and objectives. The Sector also assists in the production of government Estimates documents and parliamentary reports.

In addition, the Sector provides strategic advice, guidance and support to federal organizations in their implementation and application of Treasury Board policies, government priorities, risk management strategies, and performance management. It also supports organizations seeking commonly sought authorities and approvals from the Treasury Board (e.g., financial and expenditure authorities, project and program approvals).

The Sector deals with over 30 federal organizations that cover a variety of responsibilities including Aboriginal issues, health, culture, parks, heritage, human resources and skills development, labour, social development, veterans affairs and housing. The Sector also works closely with other central agencies.

Strategic Communications and Ministerial Affairs

Strategic Communications and Ministerial Affairs [9] (SCMA) provides briefings, correspondence and ogistical support for Treasury Board meetings, parliamentary affairs, Cabinet business and dealings with other government departments and non-governmental organizations. SCMA manages and coordinates Treasury Board meetings; coordinates the Secretariat's access to information and privacy activities; and tracks the President's and the Secretary's correspondence, and assists in preparing replies.

SCMA is also responsible for developing internal and external communications products and providing services in consultation with subject matter experts (e.g., communications strategies and plans, speeches and speaking notes, scenario notes for ministerial events, media advisories, news releases, questions and answers, and news conferences). It ensures a web presence for the President, the Treasury Board and the Secretariat and prepares department-wide messages, including messages from the President of the Treasury Board.

In addition, SCMA develops and implements government-wide policy instruments related to communications and corporate identity, and monitors compliance by government departments and agencies [14,15].

Regulatory Affairs Sector

The Regulatory Affairs Sector, transferred in July 2006 from the Privy Council Office, supports the Treasury Board in its role as the Queen's Privy Council for Canada by providing advice to the Governor General and managing the government's regulatory function. The Sector also provides leadership on federal regulatory policy and the *Cabinet Directive on Streamlining Regulation* [12] (CDSR).

As such, the Sector is engaged in two key functions: (1) supporting government priorities through continuous improvement of policy; and (2) advising Treasury Board ministers on Governor in Council (GIC) submissions.

The Sector delivers on its mandate by undertaking policy research and analysis, and developing policies and associated frameworks; providing reliable and timely advice to federal organizations on regulatory policy interpretation and application; reviewing regulatory and non-regulatory GIC submissions (except for appointments), ensuring that submissions adhere to the CDSR and that relevant information is provided for decision making; contributing to learning programs that strengthen the regulatory capacity of all government organizations, particularly the understanding of regulatory policy requirements; and brokering the resolution of issues through interdepartmental coordination and horizontal policy management [16, 17]

International Affairs, Security and Justice Sector

The International Affairs, Security and Justice Sector (IASJ) supports the Treasury Board in its role as the management board and budget office of the Government of Canada. As such, IASJ [15] performs due diligence reviews of Memoranda to Cabinet and Treasury Board submissions from federal organizations and provides advice to the Treasury Board regarding resource allocation, risks, and policy compliance. This work supports sound decision making, value for money, compliance with rules and policies, and alignment with Government of Canada priorities and objectives.

In addition, IASJ provides strategic advice, guidance and support to federal organizations in their implementation and application of Treasury Board policies, government priorities, risk management strategies, and performance management. It also supports client organizations seeking commonly sought authorities and approvals from the Treasury Board (e.g., financial and expenditure authorities, project and program approvals).

IASJ works with the federal departments and organizations responsible for international affairs, immigration, international development, defence, justice and security.

Internal Audit and Evaluation Bureau

The Internal Audit and Evaluation Bureau [17] (IAEB) provides independent, objective assurance and evaluation services that are designed to add value to the management of the Secretariat's programs and operations. IAEB conducts its work in accordance with the *Policy on Internal Audit*, the Institute of Internal Auditors International Professional Practices Framework and the *Policy on Evaluation*. It aims to assist the Secretariat in meeting its objectives and the expectations of the *Federal Accountability Act* through a systematic, disciplined approach to improving the effectiveness of risk management, control and governance processes.

Human Resources Division

The Human Resources Division (HRD) is responsible for providing strategic human resources advice, guidance and services to the Secretariat's senior management, managers, supervisors and employees.

HRD provides advice, research, analysis and other services to senior management on corporate talent management, unions, demographic profiling, and organizational health indicators.

HRD provides comprehensive and timely advice, guidance and services to employees, managers and supervisors on classification, recruitment, staffing and resourcing, official languages, labor management, employment equity and diversity, training and learning and development, awards and recognition, career planning, compensation and benefits, and human resources information management.

In addition, HRD [5] supports the development, maintenance and operation of PeopleSoft and associated reporting systems for the Central Agency Cluster, which comprises four federal organizations: the Secretariat, the Canada School of Public Service, the Department of Finance Canada, and the Privy Council Office

Corporate Services Sector

The Corporate Services Sector (CSS) assists the Secretary of the Treasury Board in the internal administration of the Secretariat. Its various directorates provide internal corporate services to the Secretariat and certain shared services to the Department of Finance Canada, the Canada School of Public Service, and the Privy Council Office. The CSS provides support in the areas of financial management, security, information management, information technology, and facilities and materiel management.

Legal Services Branch

The Legal Services Branch provides strategic legal advice to the Treasury Board in its roles as employer, budget office and management board of the Government Canada, as well as to the President of Treasury Board, the Secretariat, and the Canada School of Public Service. It is also responsible for representing the Treasury Board as employer for the core public administration and separate agencies and deputy heads before specialized tribunals and courts of law

WHAT HEALTH CANADA REGULATES

Health Canada oversees product safety for Canadians. Find out about the types of products we regulate to help reduce risks to human health and safety and to the environment.

WHAT HEALTH CANADA DOES AS A REGULATOR

Evaluating and approving products

Health Canada regulates a wide range of products.

For many products, we review their safety before they can be sold in Canada. We allow them on the market only if rigorous science-based assessments confirm that their benefits outweigh their risks when used properly. They include products like:

- Pesticides
- Food additives
- Infant formulas
- Medical devices
- Drug and health products (including natural health products)
- Novel foods, including genetically modified products

For other types of products, we set strict rules that industry must follow. Products must meet our requirements before they can be sold.

Setting requirements and providing guidance

Health Canada sets rules for a broad range of products sold in Canada. This can include rules for their:

- Use ,Import, Labeling, Packaging, Advertising, Manufacturing, Environmental safety

These rules are set out in laws and regulations. We also produce guidance documents, policies and standards to help companies understand the rules and their responsibilities more clearly.

Our requirements go beyond product safety. For example, we also

- Develop guidelines for drinking water and air pollution
- Develop food and nutrition standards to help protect the safety and quality of food
- Develop measures to manage health risks from chemicals found to be harmful to human health
- Restrict tobacco advertising and ban the use of additives that contribute to making tobacco products attractive
- We also communicate regularly with businesses to make sure they know about the rules that apply to their industry.
- We also work with other government departments that help enforce the rules we set, such as the:
- Canada Border Services Agency
- Canadian Food Inspection Agency

WORKING WITH PARTNERS

Health Canada helps to protect your health and safety by actively working with a range of partners, including

- Industry associations, International organizations, Scientific and research communities
- National regulators in other countries, Provincial, territorial and local governments
- Non-government organizations (like patient advocacy, and consumer and user groups)

Our work with these groups includes

Communicating product safety information

- Addressing safety issues that affect multiple countries
- Participating in international standard-setting efforts to provide a Canadian perspective [16]
- Getting the best advice on policies and standards through external advisory bodies and external experts
- Supporting other levels of government and non-government regulatory bodies in delivering their mandates

MONITORING SAFETY

For as long as a product is available in Canada, we:

- Monitor for safety concerns
- Make sure industry takes the appropriate steps to protect Canadians if a safety issue arises
- Report to Canadians on adverse reactions (side effects) and reports received about:
    - pesticides, health products, cosmetics and consumer products

When the science informing our regulations evolves, we review the risks and take steps to manage them. This may include changing the regulations and guidance, as needed.

Enforcing compliance

When we set rules, we also need to make sure they are followed.

Industry is responsible for understanding and following the rules designed to keep you safe. Health Canada's role is to work closely with partners to monitor compliance and take action when necessary.

Our compliance and enforcement groups work with other agencies, such as the Canadian Food Inspection Agency.

We verify compliance by

- Testing products on the market, Doing inspections (both scheduled and unannounced)
- Working with regulators around the world on product risks, Following up on:
    - Complaints, incident reports, adverse reactions (side effects)

If a company fails to comply, we have a range of options. The department chooses the most appropriate compliance option based on the risk and history of compliance. These options include:

- Working with the company to help bring it back into compliance

- Taking more severe actions to address high-risk issues and prevent future non-compliance, such as:
  - Prosecution, financial penalties, removing products from retailers
- Banning the company from selling products or operating in Canada in very serious cases
- Drug and health product inspections, which allows you to:
  - do your own search for inspections ,browse lists of inspections in Canada and at foreign sites
- Consumer product enforcement summary reports, which inform you about products reviewed by Health Canada that met or failed to meet safety requirements
- Quarterly reports on complaints received about consumer products and cosmetics
- Compliance and enforcement information for pesticides, which includes enforcement bulletins
- Compliance and enforcement of the Marihuana for Medical Purposes Regulations, which addresses:
  - inspection data summaries, customer complaints summaries
- Annual compliance and enforcement reports, including:
  - drug and health products ,medical use of marijuana, pesticides

Communicating about health risks

We use a variety of ways to communicate about health risks as part of our work to engage and inform Canadians.

We also encourage Canadians to report safety incidents to both the manufacturer and Health Canada. This will allow us to follow up and take appropriate action.

How science is used to support regulatory decisions

Health Canada uses the most up-to-date science to inform its regulatory decisions. Our scientists are essential in making all of these decisions. For example, they:

- Do risk assessments to identify health and safety issues that need to be addressed
- Give input on draft guidance documents, regulations and legislation
- Review evidence for many new products to determine benefits and risks, and decide if they should be allowed for sale
  - we review a broad range of products, such as:
- vaccines, medications, novel foods, including genetically modified products
- Review research from around the world to understand new risks and how to protect Canadians
- Collaborate with peers around the world to develop and improve on scientific approaches
- Analyze adverse reaction (side effects) and incident reports related to product use to:
  - look for patterns ,recommend actions to protect the public

The risk assessment process

Risk assessments are a main part of Health Canada's decision-making process. Risk assessments are done to:

- Review the benefits and risks of products or substances, Re-evaluate products based on new science or other information, Understand the risks from exposure to substances in our environment, Assess information we have collected from inspection or incident reports
- Consider information about consumer behavior that might affect the benefits and risks of a product or substance

We use them to

- Identify the health and environmental risks linked to substance exposure
- Estimate the level of risk
- Determine how to reduce or manage a risk, like:
  - setting limits, correcting a non-compliance with our regulations

In a risk assessment, we aim to answer questions about a substance or product, such as

- Are there benefits?, Can it be harmful?, How harmful is it?
- What level of exposure causes harm (either from short- or long-term exposure)?
- What levels of exposure are possible in the situation being assessed?

- Are specific groups more sensitive (such as pregnant women and children)?

Our experts study all of the available science and make recommendations on the level of benefit or risk. This helps us decide what actions are needed.

For more information on Health Canada's risk assessment process, see *A Primer on Scientific Risk Assessment* [20] *at Health Canada*.

Here are some examples of how this process works in specific areas

- Pesticide review in Canada
- Chemical substances risk assessment
- Food-related health risk assessments
- Consumer products, cosmetics and risk assessment

Health Canada's research

Health Canada's scientists

- Conduct research as part of their work to:
  - help improve overall scientific knowledge
  - develop new scientific methods to benefit Canadians
  - better understand emerging health and safety issues
  - support Health Canada's contributions to standards and guidelines
- Help interpret the latest science to inform policy decisions
- Are actively involved in research across a wide range of fields
- Publish their research for the benefit of the broader scientific community in peer-reviewed journals
- This research has led to many important discoveries. For example, our researchers:
- Were the first to discover how acrylamide [21], a possible cancer-causing substance, forms in fried foods
- Studied environmental chemicals to better understand possible effects of exposure during pregnancy on infant health
- Developed new methods to more quickly detect bacteria in food
  - these methods have now become the industry standard
- Measured and studied noise generated by wind turbines to better understand potential health impacts

Engaging Canadians in regulatory work

- We regularly engage Canadians on regulatory topics as part of our decision making. Consultations help us make sure our decisions consider a range of views.

Consultations that help inform future regulatory decisions

We seek input from experts and stakeholders to help inform decisions, guidance and policies that support our regulatory work.

These consultations are

- Outside of the formal federal regulation-making process
- Can involve different types of activities and documents in the regulatory system

We may seek the views of interested groups through

- Roundtables
- Advisory committees
- Online consultations and surveys
- Meetings with regulated parties (like industry) and stakeholders [22]

Consultations on proposed regulations and amendments to existing regulations

Consultations are used to inform and finalize the regulations that govern our regulatory work. These follow a formal federal regulation-making process done through the *Canada Gazette*, which is the federal government's official newspaper.

The 2-step process gives us opportunities to hear a wide range of views

1. Before the formal *Canada Gazette* process begins (pre-consultation)
2. Through the formal *Canada Gazette* process

Step 1: Pre-consultation

We will often engage the scientific community and affected groups before we begin drafting a proposed regulation. This lets us make sure we have the latest information and a range of views.

Step 2: *Canada Gazette* process

We publish the proposed regulations in the *Canada Gazette*. This allows you to comment on the proposed regulations.

Based on the comments we receive, we will:

- Adjust and finalize the proposal
- Publish the final regulations in the *Canada Gazette*[22] (along with a summary of the comments received)

Getting involved

Are you interested in being consulted on upcoming issues? We have a Stakeholder Registry that lets you sign up for topics you are interested in. You will be notified when we consult on those topics.

As well, our consultations are published on the consulting with Canadians web page.

For more information and to get involved in regulation making through the *Canada Gazette* process:

- Visit the *Canada Gazette*
- Read about how the federal government makes regulations

Health Canada also publishes a forward regulatory plan that lists our upcoming regulatory projects. This informs Canadians about our work in developing regulations.

Informing Canadians about health issues

Health Canada keeps up to date on science and research. We use this knowledge to provide Canadians with information to help them make informed decisions about health and safety. We do this through:

- Regulations, Online tools, Outreach, Responses to information requests

Regulations

Through regulations, we require that information be made available so that you can make informed choices. This includes:

- Food labels that:
- contain ingredient lists
- declare potential food allergens
- Cosmetics that list all of their ingredients
- this lets you avoid ingredients you may be sensitive to
- Nutrition labels that help you make healthy food choices
- Drug labels that are easy to read and understand
- this makes you aware of risks and allows you to avoid mixing medications that should not be used together
- Pesticide labels that explain how to safely use the product

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- Pesticides, Food additives, Infant formulas, Medical devices, Drug and health products (including natural health products),Novel foods, including genetically modified products

For other types of products, we set strict rules that industry must follow. Products must meet our requirements before they can be sold.

CONCLUSION

- Health Canada's safety review concluded that there is very limited evidence of ischemic colitis linked with the occasional use of pseudoephedrine at recommended dose and duration, in the absence of other risk factors. Pseudoephedrine [23] and several other types of medications are known to cause narrowing of blood vessels (vasoconstriction), so a risk of ischemic colitis cannot be ruled out entirely in susceptible people (e.g. those with other underlying conditions, etc.).
- Health Canada will publish an article in the Health Product Info Watch to raise awareness and to encourage healthcare practitioners to ask their patients about the use of health products containing pseudoephedrine.
- Health Canada will continue to monitor safety information involving pseudoephedrine, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action if and when any new health risks are identified.

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