

VETERINARY DRUGS DIRECTORATE
HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA

STRATEGIC PLAN

APRIL 2004 - MARCH 2007

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INTRODUCTION

The Veterinary Drugs Directorate's (VDD) Extended Management Committee met for their first retreat in October 2002 during which they established VDD's strategic direction for the next three fiscal years.¹ This meeting set the foundation for development of the 2003-2006 Strategic Plan, which underwent a rigorous process of revision and refinement prior to its approval on September 8, 2003. In keeping with VDD's commitment to transparency, the 2003-2006 Strategic Plan was subsequently posted on the VDD Web site.

The VDD Extended Management Committee met again in November 2003 with the purpose to review, validate and revise the 2003-2006 Strategic Plan. The discussions held at this meeting were used to update the Strategic Plan for the fiscal years 2004-2007, and to ensure that VDD continues to be properly aligned with Government, Department, Branch and stakeholder priorities in order to achieve its strategic objectives.

The process used to update the Strategic Plan for fiscal years 2004-2007 employed an extensive environmental scan to identify forces and influences that may affect the work of the Directorate over the coming years. The Extended Management Committee then set about to determine if the *Key Result Areas* (KRAs) were still appropriate, given the factors and influences that may be facing the Directorate. The revised *Key Result Areas* for VDD include (in no particular order): Effective and Responsible Management of Human & Financial Resources, International Cooperation/Harmonization, Public Involvement and Outreach, Policy & Regulatory Development and Timely Review of Submissions.

For each *Key Result Area*, managers were asked to review, validate and revise the strategic objectives along with the specific strategies required to achieve them. This was done taking into account progress made in the previous fiscal year, bearing in mind the factors and influences that may affect program delivery in the short and long term future.

This document outlines the strategic direction of the Veterinary Drugs Directorate for the fiscal years 2004-2007. It serves as a guide to aid the Directorate in setting appropriate priorities in order to achieve its strategic objectives. This Strategic Plan was approved by the Extended Management Committee on March 29, 2004.

ORGANIZATIONAL PROFILE AND HISTORY

The Veterinary Drugs Directorate was created in October 2001. It is one of several Directorates in the Health Products and Food Branch (HPFB) that reports to the Assistant Deputy Minister, HPFB. The mandate of VDD flows from the mandate of HPFB, and ultimately from the mandate of Health Canada.

HEALTH CANADA'S MANDATE

To help the people of Canada maintain and improve their health.

HEALTH PRODUCTS AND FOOD BRANCH'S (HPFB) MANDATE

¹ The fiscal year for the Veterinary Drugs Directorate extends from April 1 to March 31.

HPFB's mandate is to take an integrated approach to the management of the risks and benefits to health related to health products and food by:

- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,
- promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

VETERINARY DRUGS DIRECTORATE'S (VDD) MANDATE²

VDD is responsible for ensuring the safety of foods such as milk, meat, eggs, fish, and honey from animals treated with veterinary drugs. We also ensure that veterinary drugs sold in Canada are safe and effective for animals. Through this dual mandate, VDD contributes to the well-being of Canadians.

OUR VISION

VDD's vision is to be recognized nationally and internationally as an organization that embraces good science through teamwork based on leadership and mutual respect. VDD will also be recognized for its excellence in science-based decision making.

GUIDING PRINCIPLES

To guide the Veterinary Drugs Directorate towards its vision, and in keeping with the core principles of the Government of Canada³, VDD has adopted the following Guiding Principles:

- Transparency
- Accountability
- Financial Responsibility
- Ethical Conduct

Consideration of the four guiding principles above will be applied to all decisions and actions of the Veterinary Drugs Directorate. This will ensure sound decision making, and make certain that the best interests of Canadians are met in fulfilling VDD's mandate.

² The wording of the VDD's mandate is currently under review.

³ Documented in the press release: "Prime Minister Announces Appointment of Cabinet", December 12, 2003.

CORE ACTIVITIES

In fulfilling its mandate, VDD conducts a number of *Core Activities* (CA).

SCIENTIFIC ACTIVITIES

- CA 1 - Review of Industry Submissions - Including:
 - New Drug Submissions (NDS)
 - Supplemental New Drug Submissions (SNDS)
 - Abbreviated New Drug Submissions (ABNDS)
 - Supplemental Abbreviated New Drug Submissions (SABNDS)
 - DIN Applications (DIN)
 - Preclinical New Drug Submissions (also known as IND submissions)
 - Experimental Studies Certificates (ESC)
 - Emergency Drug Release (EDR)
 - Protocol Review (PR) and Notifiable Changes (NC)
- CA 2 - Establishment of Maximum Residue Limits (MRLs) and Administrative Maximum Residue Limits (AMRLs) for veterinary drugs in foods
- CA 3 - Pharmacovigilance
- CA 4 - Enforcement and Compliance Related Activities - Including: Health Risk Assessments (HRAs)
- CA 5 - Research and Surveillance
- CA 6 - Policy and Regulatory Development

OPERATIONAL AND SUPPORT ACTIVITIES

- CA 7 - Issues Management - Including: briefing notes, question period notes and advice to staff and partners
- CA 8 - Management - Including: performance measurement
- CA 9 - Process Support - Including: electronic review of submissions and external charging
- CA 10 - Planning and Reporting
- CA 11 - Public Involvement and Outreach

KEY RESULT AREAS

To optimize delivery of its mandate, VDD has identified the following *Key Result Areas* (in no particular order) :

- Timely Review of Drug Submissions
- Policy & Regulatory Development
- International Cooperation / Harmonization
- Public Involvement and Outreach
- Effective and Responsible Management of Human & Financial Resources

These Key Result Areas can effectively be related back to each scientific core activity. By applying the KRAs in this manner, VDD is able to conduct programs and activities according to its strategic plan. Strategic objectives related to each of the Key Result Areas as well as the specific strategies required to achieve them are elaborated below.

TIMELY REVIEW OF SUBMISSIONS

Under the *Canadian Food and Drugs Act and Regulations*, manufacturers who wish to sell veterinary drugs in Canada must receive approval from Health Canada's Veterinary Drugs Directorate. The Directorate also establishes Maximum Residue Limits (MRLs and AMRLs) for veterinary drugs used in food-producing animals. Manufacturers submit data to demonstrate/establish the safety of any residues in food from treated animals, as well as the safety and efficacy of the products for the treated animals.

To ensure timely access to safe and effective veterinary drugs, VDD needs to optimize every aspect of the evaluation and approval process.

Impact on Canadians

The timely review of submissions contributes to the health of Canadians by ensuring greater availability of drugs that when used in food-producing animals, are safe for humans consuming foods derived from treated animals. This will ensure more high quality and affordable food products. Timely access to safe and effective veterinary drugs for food-producing and companion animals will enable innovation, facilitate trade, increase investment, and contribute to building a 21st century Canadian economy.

Strategic Objectives:

- 1.1. Increase VDD's capacity by augmenting expertise and knowledge in emerging science areas.

Strategies:

- 1.1.1 Implement the Learning & Development Framework to provide employees with opportunities to improve their knowledge as well as their ability to work in teams and in partnerships. This includes offering regular scientific seminar opportunities for VDD staff.
- 1.1.2 Develop a succession plan and a staffing plan. This will allow VDD to better match

the knowledge and expertise of candidates with the Directorate's requirements for scientific and managerial knowledge and competencies.

- 1.2. Develop policies and processes which will facilitate the submission review process. Clear, explicit and documented policies, guidance documents and Standard Operating Procedures (SOPs) will allow for effective and efficient actions by all employees and greater compliance and understanding by external stakeholders. Once implemented, policies and guidelines will improve the efficiency and effectiveness in the review divisions by, for example, improving the quality of incoming files and allowing for rejection of inadequate submissions at the initial screening process.

Strategies:

- 1.2.1 a) Coordinate and develop policies, regulations, guidance documents, guidelines and SOPs across VDD to ensure consistency, and align those being developed with other directorates, branches, and departments. (This strategy requires VDD to collaborate and consult with partners and stakeholders.)

b) Establish an ongoing cycle of gap analysis in order to continuously focus the efforts of VDD on priority issues.
- 1.2.2 Apply enabling tools to facilitate review of submissions and improve timeliness (e.g., electronic submission reviews).
- 1.3. Increase international cooperation for harmonization of the technical requirements for registration of veterinary drugs and standards. The result will allow VDD to draw upon international expertise in order to assist, strengthen and expedite Canada's review process and standards setting activities.

Strategies:

- 1.3.1 Reassess our achievable level of participation in international organizations, taking into account our capacity, financial resources and progress made to date.
- 1.3.2 Implement an internal system that will track key participants, resource requirements, expected outcomes and performance indicators, to be used to evaluate each participation.
- 1.3.3 Enhance our bilateral relationship with the United States Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) and other jurisdictions.
- 1.4. Develop performance indicators for submission reviews.

Strategies:

- 1.4.1 Establish standards for submission review (included in the Management core activity, CA-8).

POLICY & REGULATORY DEVELOPMENT

Policy & regulatory development facilitates the implementation of the Directorate's strategic direction. Science-based policies directly contribute to protecting the health of Canadians by guiding decision making related to issues such as Antimicrobial Resistance and Extra-Label Drug Use (ELDU). Operational policies help VDD to harmonize procedures and support quality control.

Evidence-based decision making and policy analysis is fundamental in developing appropriate regulatory and non-regulatory mechanisms to protect and promote the health of Canadians. Regulatory development is undertaken using a Smart Regulations⁴ approach, which emphasizes appropriate instrument choice in order to protect Canadians, the public interest and enable innovation. Use of the Smart Regulations approach is exemplified through the adoption of Administrative Maximum Residue Limits (AMRLs), which have facilitated producers' ability to comply with, and regulatory agency's enforcement of residue limits for veterinary drugs in food, without having to wait for regulations to be promulgated.

Impact on Canadians

Policy and regulatory development within VDD is undertaken using evidence-based decision making and a Smart Regulations approach, which contributes to the Directorate's capacity for risk management. Policies that are explicit and transparent contribute to the health and safety of Canadians by ensuring that regulatory and risk-management decisions are made consistently. VDD also undertakes frequent policy and regulatory gap analyses to focus the efforts of the Directorate on priority issues, which helps foster a flexible organization with the capacity to fulfil its mandate and priorities in a changing environment.

Strategic Objectives:

- 2.1 The overall objective is to develop and implement policies, regulations, guidance documents, guidelines and SOPs to support all of VDD's core activities⁵.

Strategies:

- 2.1.1 a) Coordinate and develop policies, regulations, guidance documents, guidelines and SOPs across VDD to ensure consistency, and align those being developed with other directorates, branches, and departments. (This strategy requires VDD to collaborate and consult with stakeholders.)
 - b) Establish an ongoing cycle of gap analysis in order to continuously focus the efforts of VDD on priority issues.
- 2.2 Legislative Renewal affords the opportunity to examine the legislative and regulatory basis of existing policies and regulations, to assess and promote possible changes.

⁴ *Smart Regulations* is a government-wide approach to regulatory reform that has both protecting and enabling characteristics with the goal of promoting health, safety and sustainability, contributing to economic growth and reducing burden on business.

⁵ All policies are to be based on Health Canada's Decision Making Framework, and fit within the context of Health Canada's science-based approach to decision making to support its regulatory framework.

Strategies:

- 2.2.1 Review of current policies and regulations.
- 2.2.2 Identify constraints of current regulations.
- 2.2.3 Gap analysis in consultation with partners and stakeholders.
- 2.2.4 Develop and implement policy priorities.

INTERNATIONAL COOPERATION / HARMONIZATION

Achieving harmonization is important for public health reasons (e.g., ensuring quality of imports and domestic products through high standards) and for business (e.g., ensuring a level playing field in the global marketplace). To enhance harmonization with other jurisdictions, the Veterinary Drugs Directorate is an 'observer' in the *Veterinary International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medical Products (VICH)*⁶. Involvement in the VICH harmonization process allows VDD to participate on behalf of the Government of Canada in the VICH Steering Committee, as well as a number of technical working groups. Working together with partners such as the Canadian Food Inspection Agency (CFIA, also representing the Government of Canada on VICH) and the Canadian Animal Health Institute (CAHI, representing Canadian veterinary drug manufacturers on VICH), enables Canada to have guidelines for data requirements that are harmonized with other countries.

VDD also represents the government of Canada on the *Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF)*. CCRVDF works to develop international standards pertaining to residues of veterinary drugs in foods, such as maximum residue limits.

Impact on Canadians

International cooperation will increase the level of harmonization between VDD and equivalent organizations in other jurisdictions. VDD's participation in global standard-setting initiatives ensures that Canada's views and priorities are taken into consideration when harmonizing technical requirements internationally. Participation in such international activities also contributes to the federal government's goal of ensuring Canada's role in the world as one of pride and influence in order to advance Canadian values and promote Canada's independent voice abroad.

Strategic Objectives:

- 3.1 VDD to actively participate in international activities to achieve its key business objectives.

Strategies:

⁶ Launched in 1996, VICH is a trilateral (EU-Japan-USA) program aimed at harmonizing technical requirements for veterinary product registration.

- 3.1.1 Reassess our achievable level of participation in international initiatives, taking into account our capacity, financial resources and progress made to date.
- 3.1.2 Implement an internal system that will track key participants, the resource requirements, expected outcomes and performance indicators, to be used to evaluate each participation.
- 3.1.3 Enhance our bilateral relationship with the United States Food and Drug Administration Center for Veterinary Medicine and other jurisdictions.

PUBLIC INVOLVEMENT AND OUTREACH

Since its establishment as a Directorate in 2001, VDD has worked intensively to develop linkages that contribute to enhanced partnerships and continuous exchange of information with stakeholders. With public health issues becoming increasingly more complex and the public requesting a more direct role in policy and program development, VDD has set up a series of programs and activities to ensure that stakeholders are adequately consulted throughout our decision making process.

VDD's Stakeholder Committee, established in September 2002, is comprised of representatives from a broad spectrum of interests including other federal government partners (e.g., CFIA), other levels of government (e.g., provincial/territorial), industry, veterinarians, academia, producers, consumers, animal welfare and environmental groups. The Stakeholder Committee meets regularly, allowing VDD to involve stakeholders in our decision making in accordance with Health Canada's Decision Making Framework.

VDD recognizes the importance of establishing linkages with federal, provincial and territorial governments. VDD consults regularly with provinces and territories on various issues through special consultations (e.g. on AMR), the F/P/T Committee on Food Safety Policy and Agri-Food Inspection Committee, as well as through the Canadian Food Inspection System Implementation Group.

Impact on Canadians

Maintaining an open, transparent, leading-edge and proactive organization will support VDD in its efforts to satisfy the varied needs of our stakeholders, and will contribute to enhanced public trust and confidence in the Canadian food system.

Strategic Objectives:

- 4.1 Maintain an open, transparent, leading-edge and proactive organization by ensuring that effective outreach and public involvement mechanisms are in place, which will enable its stakeholders/partners and the public to understand and contribute to VDD's programs, priorities, capacity and performance.

Strategies:

- 4.1.1 Ensure proper instrument choice for public involvement mechanisms by following the criteria and methodologies outlined in VDD's and Health Canada's Public Involvement policies.

- 4.2 Provide the public with balanced and objective information to educate and inform them on veterinary drug issues and obtain their feedback related to policy development and decision making.

Strategies:

- 4.2.1 Participate in and make presentations at national, provincial and professional events.
- 4.2.2 Develop educational materials about VDD and veterinary drugs issues related to public health.
- 4.2.3 Conduct Web consultations to obtain feedback from the public and stakeholders.
- 4.2.4 Maintain and update the VDD Web site as an effective tool to increase transparency and inform the public and stakeholders of emerging health issues.
- 4.3 Consult directly with the public throughout VDD's priority setting, decision making, policy and regulatory development process to ensure that issues and concerns are understood and addressed accordingly.

Strategies:

- 4.3.1 Consult with VDD's Stakeholder Committee on programs and priorities, as well as set up and maintain steering and advisory expert committees on important issues such as AMR and ELDU.
- 4.3.2 Consult with VDD stakeholders on proposed amendments to the *Food and Drug Regulations*, such as the establishment of Maximum Residue Limits.
- 4.3.3 Develop public involvement plans to consult appropriately with the public and stakeholders on VDD policy development such as AMR, Unapproved Drugs, Natural Health Products, etc.
- 4.4 Partner with internal and external stakeholders on decision making regarding national and cross-jurisdictional issues by seeking and receiving advice and innovative solutions.

Strategies:

- 4.4.1 Maintain partnerships with other government departments, agencies, branches and directorates to jointly address ongoing and emerging public health issues.
- 4.4.2 Partner with key external stakeholder groups on specific issues as appropriate.
- 4.5 VDD to improve the efficiency and effectiveness of public involvement activities.

Strategies:

- 4.5.1 Reassess our achievable level of participation in national events and public involvement activities, taking into account our capacity, financial resources and progress made to date.
- 4.5.2 Implement an internal system that will track key participants, the resource requirements, expected outcomes and performance indicators, to be used to evaluate each participation.

**EFFECTIVE AND RESPONSIBLE MANAGEMENT OF HUMAN
AND FINANCIAL RESOURCES**

The Veterinary Drugs Directorate's dual mandate to ensure the safety of food from animals treated with veterinary drugs, and to ensure that veterinary drugs sold in Canada are safe and effective for animals, embodies a level of complexity that exists in few other organizations. As a result, VDD's staff must possess the requisite level of competencies, skills and abilities. VDD recognizes the value these skills and competencies add to the organization, and is committed to lifelong learning for its management and staff.

The guiding principles of the Veterinary Drugs Directorate are particularly relevant to the effective and responsible management of financial resources. VDD is committed to transparency, accountability, financial responsibility and ethical conduct with regard to fiscal management. This is exemplified in VDD's use of work plans and resource allocation tools to ensure accountability and make the best use of available resources.

Impact on Canadians

The strategies above will ensure that VDD operations are streamlined and accountable, resulting in maximum benefits for the resources expended. They will result in a professional and flexible organization, that has the capacity to fulfil its mandate and priorities in a changing environment.

Strategic Objectives:

- 5.1 Maintain an organization that embraces good science and best management practices through teamwork based on leadership and mutual respect.

This organization is comprised of a sufficient number of highly qualified, competent and motivated employees who acknowledge their roles and responsibilities and serve as ambassadors of the Directorate. Conditions conducive to a respectful, healthy and vibrant workplace are critical in achieving this objective.

Strategies:

- 5.1.1 Implement the Learning and Development Framework and the Orientation Package to provide employees with opportunities to improve their knowledge as well as their ability to work in teams and in partnerships. This includes offering regular scientific seminar opportunities for VDD staff.

- 5.1.2 Apply the Performance Discussion Process (PDP) Framework (e.g. related to employee appraisal) to assess the quality of our work, in order to continuously accomplish the goals of the organization and adapt to new requirements in terms of time management and scientific advancement.
- 5.1.3 Develop succession and staffing plans. These will allow VDD to better match the knowledge and expertise of candidates with the Directorate's requirements for scientific and managerial knowledge and competency.
- 5.1.4 Continuously improve internal communication mechanisms so that they strategically address the quality and the quantity of information.
- 5.2 Ensure sound financial management.
 - 5.2.1 Ensure the development and use of Divisional/Directorate work plans and resource allocation tools.
 - 5.2.2 Implement a modern financial management system.
- 5.3 Develop/Adapt and implement an accountability framework suitable for VDD.
 - 5.3.1 Develop and implement program performance indicators to assess the quality of our work and achievement of fiscal goals/objectives, and to adapt to new requirements and priorities.
 - 5.3.2 Build a Quality Management System which encompasses Values and Ethics. (Included in CA 8)
 - 5.3.3 Ensure the use of modern comptrollership practices.