Archived Content

Veterinary Drugs Directorate

Health Products and Food Branch
Health Canada

STRATEGIC PLAN

April 25, 2005

April 2005 - March 2008

TABLE OF CONTENTS

INTRODUCTION . . . . . Page 2 of 17

ORGANIZATIONAL PROFILE AND HISTORY . . . . . Page 2 of 17

Health Canada's Mandate . . . . . Page 2 of 17

Health Products and Food Branch's Mandate . . . . . Page 2 of 17

Veterinary Drugs Directorate's Mandate . . . . . Page 3 of 17

VISION . . . . . Page 3 of 17

GUIDING PRINCIPLES . . . . . Page 3 of 17

CORE ACTIVITIES . . . . . Page 3 of 17

STRATEGIC DIRECTION FOR 2005-2008 . . . . . Page 5 of 17

Strategic Goal 1 - Evaluate, monitor and address the risks associated with the safety, efficacy and quality of veterinary drugs . . . . . Page 6 of 17

Strategic Goal 2 - Maintain and continuously improve a modern policy and regulatory framework for veterinary drugs . . . . . Page 9 of 17

Strategic Goal 3 - Strive to be a flexible organization that has the capacity to fulfill its mandate and priorities in a changing environment . . . . . Page 11 of 17

Strategic Goal 4 - Foster sound decision making and greater collaboration through public involvement, stakeholder outreach and international cooperation . . . . . Page 13 of 17

APPENDIX 1 . . . . . Page 17 of 17

INTRODUCTION

The Veterinary Drugs Directorate (VDD) is a proactive public health organization that looks towards the future to anticipate potential opportunities and challenges, and develops viable plans to ensure that resources are used as efficiently and effectively as possible. The VDD Strategic Plan acts as a compass to guide the Directorate in delivering on its mandate by focusing on Strategic Goals, Core Activities, Objectives and Strategies.

This document outlines the strategic direction of VDD for the fiscal years 2005-2008.[1] The Strategic Plan is updated annually, taking into account progress made on specific issues, as well as the factors and influences that may affect program delivery in the short and long term future. Factors and influences taken into account in developing this plan included: public and animal health issues, changes in government and governmental priorities, the Speech from the Throne, stakeholder priorities, and the recent report of the External Advisory Committee on Smart Regulation (EACSR) entitled *Smart Regulation - A Regulatory Strategy for Canada*[2]. Regular updates to the VDD Strategic Plan ensure that the Directorate continues to be aligned with the broader objectives of the Government of Canada, the Department, the Health Products and Food Branch (HPFB) and stakeholder priorities.

The Veterinary Drugs Directorate Strategic Plan for 2005-2008 was approved by the VDD Management Committee on April 25, 2005.

ORGANIZATIONAL PROFILE AND HISTORY

VDD was established in October 2001. It is one of several Directorates in HPFB that reports to the Assistant Deputy Minister of this Branch. The mandate of VDD flows from the mandate of HPFB, and ultimately is an extension of the mandate of Health Canada (HC).

Health Canada's Mandate

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

HEALTH PRODUCTS AND FOOD BRANCH'S MANDATE

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.

[1] As a Government of Canada organization, the fiscal year for the Veterinary Drugs Directorate extends from April 1 to March 31.

[2] http://www.pco-bcp.gc.ca/smartreg-regint/en/index.html, April 25, 2005.

Veterinary Drugs Directorate's Mandate

To protect human and animal health and the safety of Canada's food supply, VDD evaluates and monitors the safety, quality and effectiveness, sets standards, and promotes the prudent use of veterinary drugs administered to food-producing and companion animals.

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 VDD towards its vision, and in keeping with the principles of the Health Products and Food Branch,[3] VDD has adopted the following Guiding Principles:

- Effectiveness
- Efficiency
- Transparency
- Accountability
- Cooperation

Consideration of the five guiding principles above will be applied to all decisions and actions taken by VDD. This will foster sound decision making, and make certain that the best interests of Canadians are met in delivering on VDD's mandate.

CORE ACTIVITIES

VDD delivers on its mandate through a range of Core Activities (CAs). Core activities represent the foundation of the work done by the Directorate, and each serves an important role in protecting human and animal health, as well as satisfying the needs of Canadians. These core activities are not mutually exclusive in practice but interconnect throughout VDD's daily operations. They are separated to highlight VDD's major functional activities and illustrate the scope and breadth of the Directorate's work. The core activities are outlined in detail below.

CA 1 - Pre-Market Activities and Standard Setting

[3] Health Canada, Health Products and Food Branch, *Serving Canadians - Now and Into the Future*, (Ottawa: Health Canada Publication, 2004), p. 8.

- Review of Drug Submissions from Industry, including:
  - New Drug Submissions (NDS)
  - Supplemental New Drug Submissions (SNDS)
  - Abbreviated New Drug Submissions (ABNDS)
  - Supplemental Abbreviated New Drug Submissions (SABNDS)
  - Drug Identification Number Applications (DIN)
  - Investigational New Drug Submissions (IND)
  - Experimental Studies Certificates (ESC)
  - Emergency Drug Release (EDR)
  - Protocol Review (PR)
  - Notifiable Changes (NC)
- Establishment of Maximum Residue Limits (MRLs) and Administrative Maximum Residue Limits (AMRLs) for veterinary drugs in foods
- Process support activities, which are initiatives designed to improve the submission review process, including: electronic review of submissions and external charging

CA 2 - Post-Market Activities

- Pharmacovigilance, including:
  - Receiving and evaluating Adverse Drug Reaction (ADR) reports from drug sponsors, manufacturers, health care practitioners, animal owners and producers;
  - Requesting and evaluating Periodic Summary Update Reports (PSURs), which take into account national and international safety data from drug sponsors on targeted classes of drugs; and
  - Ongoing monitoring of the accuracy of label information based on post-market conditions of use.
- Enforcement and Compliance Related Activities, including:
  - Development of Health Risk Assessments (HRAs);
  - Identifying and participating in risk mitigating measures; and
  - Determining compliance with the *Food & Drugs Act and Regulations.*

CA 3 - Research and Surveillance

- Research and surveillance supported by VDD to improve public health, the safety of Canada's food supply and support sound policy and regulatory development. This core activity involves continuous improvement of drug residue detection methodologies, as well as monitoring food safety and the prevalence of antimicrobial resistance (AMR) in Canada.

CA 4 - Policy and Regulatory Development

- Development and implementation of all policies, regulations, guidance documents, guidelines and standard operating procedures (SOPs) to support all of VDD’s core activities.

CA 5 - Issues Management

- Development of issues management strategies, briefing notes and QP notes to advise senior departmental officials, as well as to provide advice to staff and partners on issues related to veterinary drugs. This core activity includes risk communication and management of emerging and urgent issues.

CA 6 - Management of Human and Financial Resources

- Financial and human resources management (e.g., resource allocation, staff training and development, succession planning etc.) including office administration
- Planning and reporting (e.g., strategic planning, performance measurement, Directorate quarterly reports, annual reports, etc.)

CA 7 - Public Involvement and Outreach

- Consultation with stakeholders and the public on issues related to veterinary drugs.
- Outreach activities (e.g., quarterly *Communiqué to Stakeholders*, fact sheets, educational material, presentations at conferences/seminars and other outreach tools as required) with key partners including academia and professional organizations.
- Provision of balanced and objective information to the public to facilitate sound decision making on veterinary drug issues, as well as to involve them in VDD's policy development and decision making process.

CA 8 - International Cooperation and Harmonization

- Further development of relationships with the US Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM), Australian Pesticides and Veterinary Medicines Authority (APVMA) and other foreign jurisdictions.
- Fulfil role as an observer in the Veterinary International Cooperation on Harmonization of Technical Requirements (VICH).
- Participate in FAO/WHO Codex Alimentarius Commission activities, particularly those related to veterinary drugs.

STRATEGIC DIRECTION FOR 2005-2008

Any organization needs an established strategic direction to ensure that it continually works towards delivering on its mandate, but it must not be so prescriptive as to limit the organizations ability to adapt to a changing environment. For this reason, VDD has established a set of four strategic goals that represent the overarching goals and key result areas of the Directorate. The strategic goals focus the work of the Directorate towards balanced positive outcomes for the organization and stakeholders that are each supported by particular core activities, objectives and strategies that outline how the desired results will be achieved. An illustration of how the strategic goals and core activities contribute to the overall mandate of the organization is included in Appendix 1.

VDD's Strategic Goals:

1. Evaluate, monitor and address the risks associated with the safety, efficacy and quality of veterinary drugs.

2. Maintain and continuously improve a modern policy and regulatory framework for veterinary drugs.

3. Strive to be a flexible organization that has the capacity to fulfill its mandate and

priorities in a changing environment.

4. Foster sound decision making and greater collaboration through public involvement, stakeholder outreach and international cooperation.

Strategic Goal 1 - Evaluate, monitor and address the risks associated with the safety, efficacy and quality of veterinary drugs

Under the Canadian *Food and Drugs Act and Regulations* (*F&DA*), manufacturers who wish to sell veterinary drugs in Canada must receive approval from Health Canada's Veterinary Drugs Directorate. Manufacturers must make a submission to have the veterinary health product evaluated on the basis of safety, efficacy and quality. If the submission is approved, the product and its usage are monitored for safety through a number of post-market programs, including VDD's Pharmacovigilance Program, HPFB Inspectorate's GMP Inspection and Investigation Programs, the Canadian Food Inspection Agency's (CFIA) Monitoring and Compliance Program (for residues in food) and the Canadian Integrated Program for Antimicrobial Resistance (CIPARS). Diligence in pre-market evaluation and post-market surveillance help to identify potential risks, allowing VDD to implement risk-management strategies and make informed regulatory decisions that ultimately protect the safety of Canada's food supply as well as animal and public health.

Research and surveillance activities are also critical to addressing potential risks associated with the safety, efficacy and quality of veterinary drugs and to support sound policy and regulatory development. VDD funds research initiatives related to veterinary drugs that are undertaken by HPFB's Food Directorate. VDD also provides funding to the Public Health Agency of Canada (PHAC) to support the CIPARS program, which provides an ongoing, permanent, national surveillance system to monitor AMR trends among selected enteric organisms from humans, animals and animal-derived food sources across Canada. Together, these activities serve the ultimate goal of improving public health and the safety of Canada's food supply.

Impact on Canadians

Timely evaluation of the safety, efficacy and quality of veterinary drugs contributes to Canadian public health by increasing the availability of approved drugs that when used in food-producing animals pose no undue risk to human health. Timely evaluation will result in higher quality and more affordable food products, enable innovation, facilitate international trade, and contribute to building a 21st century Canadian economy.

Diligence in post-market surveillance will result in the timely identification of potential health risks related to veterinary drugs, as well as timely access to accurate safety information for Canadians.

Ongoing research and surveillance activities funded by VDD will improve public health and the safety of Canada's food supply by ensuring that the levels of veterinary drug residues present in foods do not pose an unacceptable risk to the health of Canadians. Monitoring of AMR trends provides valuable information to support sound policy and regulatory development which ultimately contributes to public health.

VDD's Strategic Goal 1 is supported by the following core activities, with their respective corresponding objectives and strategies:

CA 1 - Pre-Market Activities and Standard Setting

Objective 1.1 Review submissions in a timely and efficient manner without compromising VDD's commitment to safe, effective and quality veterinary drugs.

Strategy 1.1.1 Strive toward the elimination of VDD's backlog for the following types of submissions: NDS, SNDS, ABNDS and SABNDS.

Strategy 1.1.2 Strive to meet and maintain VDD's service standards for submission types that do not have a backlog, once service standards are established (refer to strategy 1.4.1).

Objective 1.2 Increase VDD's capacity by augmenting expertise and knowledge in emerging science areas.

Strategy 1.2.1 Continue to implement HC's Learning & Development Policy to provide employees with opportunities to improve their knowledge as well as their ability to work in teams and in partnerships. This strategy is linked to strategy 6.1.1 but focuses specifically on offering VDD staff regular opportunities for training, seminars and conferences to continuously upgrade their scientific skill sets.

Objective 1.3 Develop and implement policies and procedures which will facilitate the submission review process. Clear, explicit and documented policies, guidance documents and SOPs will allow for effective and efficient actions by all employees and greater understanding and compliance by external stakeholders. Once implemented, policies and guidelines will improve efficiency and effectiveness in the review divisions, for example, by improving the quality of incoming files and facilitating the screening and review of submissions based on objective standards.

Strategy 1.3.1 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, and the corresponding objective, link closely with the core activity of policy and regulatory development, but focuses on development of documents to facilitate the submission review process. This strategy also links to the core activity of public involvement and outreach, since it requires VDD to collaborate and consult with partners and stakeholders.)

Strategy 1.3.2 Apply enabling tools to facilitate review of submissions and improve timeliness (e.g., electronic submission reviews).

Objective 1.4 Develop, implement and monitor performance indicators for submission reviews.

Strategy 1.4.1 Establish standards for submission review.

Objective 1.5 Explore options for cooperative submission review arrangements with other jurisdictions in support of the long-term goal of joint review.

Strategy 1.5.1 Develop an implementation plan for cooperative submission review arrangements with the US FDA's CVM pursuant to the Memorandum of Understanding on information sharing signed between HPFB and the US FDA.

Strategy 1.5.2 Identify and analyse options for cooperative submission review arrangements with other similar jurisdictions having well established, internationally recognized conformity assessment procedures already in place.

CA 2 - Post-Market Activities

Objective 2.1 Strengthen post-market risk assessment, management and communication to facilitate access to accurate and up-to-date safety information for health professionals and consumers.

Strategy 2.1.1 Leverage resources and maximize the benefits from national and international cooperation related to post-market surveillance.

Strategy 2.1.2 Ongoing data collection and assessment of national and international post-market safety data, as well as Adverse Drug Reaction (ADR) reports.

Strategy 2.1.3 Enhance outreach and communication for post-market activities through the distribution of warnings and advisories, Web site postings, and information sharing with stakeholders and the public.

Objective 2.2 Enhance the drug review process by providing easy access to timely and accurate safety information from national and international sources.

Strategy 2.2.1 Ensure pre-market reviewers have easy access to safety assessments, which take into account national and international post-market safety data.

CA 3 - Research and Surveillance

Objective 3.1 Support research and surveillance that contributes to improving public health, the safety of Canada’s food supply, and which supports sound policy and regulatory development.

Strategy 3.1.1 Sponsor, support and undertake research and surveillance in collaboration with partners within and external to the public service.

Strategic Goal 2 - Maintain and continuously improve a modern policy and regulatory framework for veterinary drugs

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 important health and safety issues. 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 Regulations[4] 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 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 into the *Food and Drugs Act and Regulations*. VDD's commitment to transparency is highlighted by the posting of all AMRL proposals on the Directorate Web site.

When developing new policies, regulations and guidelines, VDD makes every effort to review and adopt international approaches where possible, in order to improve international harmonization and minimize the impact of regulatory differences.

In the 2004 Speech from the Throne, the Federal Government reaffirmed its commitment to proceed with renewing Canada's health protection legislation.[5] VDD will use this opportunity to ensure that new statutes and regulations pertaining to veterinary drugs are clearly drafted and allow for regulatory approaches that strongly support the Government of Canada's public health objectives.

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 mitigation. Policies that are explicit and transparent contribute to the health and safety of Canadians by ensuring that regulatory and risk-management decisions are made appropriately and consistently.

VDD also undertakes frequent policy and regulatory gap analyses to focus the efforts of the Directorate on priority issues. These gap analyses take into consideration the varied needs of stakeholders and the public to ensure resources are directed toward issues with the greatest impact on public health.

[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] Speech from the Throne, (Ottawa, 2004) p. 8.

VDD's Strategic Goal 2 is supported by the following core activity, with the corresponding objectives and strategies:

CA 4 - Policy and Regulatory Development

Objective 4.1 Develop and implement policies, regulations, guidance documents, guidelines and SOPs within the context of Health Canada's existing legislative and regulatory framework in order to support all of VDD's core activities[6].

Strategy 4.1.1 Continue to support an ongoing cycle of policy and regulatory gap analysis in order to focus the efforts of VDD on priority issues.

Strategy 4.1.2 Coordinate and develop policies, regulations, guidance documents, guidelines and SOPs across VDD to ensure consistency, and align those being developed with other directorates, branches, departments and international jurisdictions where possible. (This strategy also links to the core activity of Public Involvement and Outreach, since it requires VDD to collaborate and consult with stakeholders.)

Strategy 4.1.3 Ensure that any policy, regulation, guidance document, guideline and SOP is developed using a Smart Regulations approach to encourage the use of modern regulatory techniques.

Objective 4.2 Actively participate in Health Protection Legislative Renewal in order to examine the legislative basis of existing policies and regulations and assess and promote possible changes in the context of Health Canada's proposed legislative framework.

Strategy 4.2.1 Review current policies and regulations and identify any existing constraints.

Strategy 4.2.2 Undertake a gap analysis in consultation with partners and stakeholders.

Strategy 4.2.3 Develop and implement policy and regulatory development priorities for Legislative Renewal.

Strategy 4.2.4 Establish an ongoing program of evaluation and modernization of policies and regulations to ensure that VDD's regulatory framework evolves with social needs and scientific advances.

Objective 4.3 Develop a framework for performance measurement of policies and regulations.

---

[6] 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.

Strategy 4.3.1	Ensure that all significant policies and regulations are accompanied by a performance measurement plan.

Strategic Goal 3 - Strive to be a flexible organization that has the capacity to fulfill its mandate and priorities in a changing environment

Through the obligations to protect human and animal health, as well as the safety of Canada's food supply with respect to veterinary drug residues, VDD's mandate embodies a level of complexity that exists in few other organizations. This complexity is compounded by rapid scientific discovery, technological advances, as well as changing governmental and stakeholder priorities. VDD must therefore be a flexible organization, that has the capacity to fulfill its mandate and priorities in a changing environment.

To support this flexibility, VDD 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. VDD also maintains the in-house capacity to manage emerging and urgent issues, in order to supply the Directorate and stakeholders with risk management and outreach strategies.

The ability to deliver on one's mandate in a changing environment is also affected by how financial resources are managed. VDD is committed to effectiveness, efficiency, transparency, accountability and cooperation 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 outlined below will ensure that VDD operations are streamlined and accountable, resulting in maximum benefits for the resources expended. VDD will be more responsive to the changing needs of Canadians, and will be better positioned to deliver on its mandate and priorities in a changing environment.

VDD's Strategic Goal 3 is supported by the following core activities, with their corresponding objectives and strategies:

CA 5 - Issues Management

Objective 5.1 Address emerging and urgent issues in a timely manner, in order to ensure that risk management and communications approaches are developed and implemented for the benefit of Canadians.

Strategy 5.1.1 Enhance transparency and the timely response to emerging and urgent issues by building positive relationships with stakeholders, and by garnering their support and cooperation.

Strategy 5.1.2 Ensure VDD has the internal capacity to satisfy issues management requirements.

CA 6 - Management of Human and Financial Resources

Objective 6.1 Maintain an organization that embraces good science and best management practices through teamwork based on leadership and mutual respect. (VDD is comprised of a 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.)

Strategy 6.1.1 Continue to implement the HC Learning and Development Policy, in order to provide employees with opportunities to improve their knowledge as well as their ability to work in teams and in partnerships.

Strategy 6.1.2 Continue to implement the Performance Discussion Process (PDP) Framework (i.e., related to employee appraisal) to assess the quality of VDD's work, in order to accomplish the goals of the organization and adapt to new requirements in terms of time management and scientific advancement.

Strategy 6.1.3 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.

Strategy 6.1.4 Continuously improve internal communication mechanisms to share information within VDD in an efficient and effective manner.

Objective 6.2 Ensure sound financial management.

Strategy 6.2.1 Ensure the development and use of Directorate/Divisional work plans and resource allocation tools.

Strategy 6.2.2 Maintain a modern financial management system.

Objective 6.3 Develop and implement an accountability framework suitable for VDD.

Strategy 6.3.1 Develop and implement program performance indicators to assess the quality of VDD's work and achievement of fiscal goals/objectives, and to adapt to new requirements and priorities.

Objective 6.4 Strive to integrate modern comptrollership practices as key elements of VDD's management improvement agenda.

Strategy 6.4.1 Strive to ensure that management practices within VDD manifest the four principles of modern comptrollership, which include: developing and using integrated financial and non-financial

performance information, making decisions based on sound risk management, undertaking program delivery with appropriate internal controls and making decisions grounded in the values and ethics of the Federal Public Service.

Strategic Goal 4 - Foster sound decision making and greater collaboration through public involvement, stakeholder outreach and international cooperation

Since its establishment as a Directorate in 2001, VDD has worked 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 established a series of programs and activities to ensure that stakeholders are adequately consulted throughout the 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 its decision making in accordance with HC's Decision Making Framework.

VDD recognizes the importance of establishing linkages with Federal, Provincial and Territorial Governments, and ensuring their involvement early in the decision making process. VDD consults regularly with provinces and territories on various issues through specialized consultations (e.g., on antimicrobial resistance), the F/P/T Committee on Food Safety Policy and Agri-Food Inspection, as well as through the Canadian Food Inspection System Implementation Group.

International cooperation and harmonization is important for public health reasons (e.g., ensuring quality of imported and domestic food and veterinary health products through high standards) and for business (e.g., ensuring a level playing field in the global marketplace). Sharing scientific knowledge, identifying best practices and improving collaboration with foreign countries facilitates access to information, which allows for timely response to public health concerns in relation to veterinary drugs.

To enhance harmonization with other jurisdictions, VDD is an 'observer' in the *Veterinary International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medical Products* (VICH)[7]. Involvement in the VICH harmonization process allows VDD to participate on behalf of the Government of Canada as an observer in the VICH Steering Committee, as well as a number of technical working groups. Working together with partners such as CFIA (also representing the Government of Canada on specific VICH working groups) and the Canadian Animal Health Institute (CAHI, representing Canadian veterinary drug manufacturers as an observer on the VICH Steering Committee and specific working groups), enables Canada to have guidelines for data requirements that are harmonized with other countries.

VDD also participates in representing the Government of Canada on the *Codex Committee on Residues of Veterinary Drugs in Food* (CCRVDF). CCRVDF works to develop international

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

standards pertaining to residues of veterinary drugs in foods, most importantly MRLs.

VDD encourages active and strategic involvement where possible in international regulatory co-operation. This is exemplified through VDD's efforts to establish a Memorandum of Understanding with the Australian Pesticides and Veterinary Medicines Authority (APVMA) in order to increase international cooperation and information sharing between the two organizations.

Impact on Canadians
VDD's commitment to public involvement and stakeholder outreach will ensure that stakeholders are adequately consulted in the Directorate's decision making process, and play a more direct role in policy and program development. Increased public involvement and outreach will also support VDD's effort to meet the varied needs of stakeholders, and will contribute to enhanced public trust and confidence in the Canadian food system.

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 ensures 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.

VDD's Strategic Goal 4 is supported by the following core activities, with their corresponding objectives and strategies:

CA 7 - Public Involvement and Outreach

Objective 7.1 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.

Strategy 7.1.1 Ensure that public involvement and outreach activities commence as early as possible and continue throughout the decision making process.

Strategy 7.1.2 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.

Objective 7.2 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.

Strategy 7.2.1 Participate in and make presentations at national, provincial and professional events.

Strategy 7.2.2 Develop educational materials about VDD and veterinary drugs

issues related to public health.

Strategy 7.2.3 Maintain and update the VDD Web site as an effective tool to provide a single window of access to information on veterinary drug issues, increase transparency and inform the public and stakeholders of emerging health issues.

Objective 7.3 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.

Strategy 7.3.1 Consult with VDD stakeholders on proposed policies, guidelines and amendments to the *Food and Drug Regulations,* such as the establishment of MRLs.

Strategy 7.3.2 Utilize a variety of consultation methods (e.g., meetings, working groups, Web consultations) in order to obtain feedback from stakeholders and the public.

Strategy 7.3.3 Consult with VDD's Stakeholder Committee on programs and priorities, as well as establish and maintain advisory/expert committees on important issues such as AMR and Extra Label Drug Use (ELDU).

Objective 7.4 Partner with internal and external stakeholders on decision making regarding national and cross-jurisdictional issues by seeking their advice and innovative solutions.

Strategy 7.4.1 Maintain partnerships with other government departments, agencies, branches and directorates to jointly address ongoing and emerging public health issues.

Strategy 7.4.2 Partner with key external stakeholder groups on specific issues as appropriate.

Objective 7.5 VDD to improve the efficiency and effectiveness of public involvement activities.

Strategy 7.5.1 Regularly assess VDD's achievable level of participation in national events and public involvement activities, taking into account VDD's priorities, capacity, financial resources and progress made to date.

Strategy 7.5.2 Develop and implement an internal system that will track key participants, the resource requirements, expected outcomes and performance indicators, to be used to evaluate each participation.

CA 8 - International Cooperation and Harmonization

Objective 8.1 VDD to actively participate in international activities to achieve its primary strategic goals, including increased international cooperation for harmonization of the technical requirements for registration of veterinary drugs and standards.

Strategy 8.1.1	Regularly assess VDD's achievable level of participation in international initiatives, taking into account VDD's priorities, capacity, financial resources and progress made to date.
Strategy 8.1.2	Participate in the development and implementation of a framework for international regulatory cooperation, and implement an internal system that will track key participants, the resource requirements, expected outcomes and performance indicators, to be used to evaluate each participation.
Strategy 8.1.3	Enhance VDD's bilateral relationship with the US FDA's CVM and other jurisdictions to build mutual trust and confidence in each other's regulatory processes.
Strategy 8.1.4	Develop and implement a Memorandum of Understanding with the Australian Pesticides and Veterinary Medicines Authority (APVMA) to strengthen cooperation on shared issues, and identify options for collaboration with other similar jurisdictions.

APPENDIX 1
How Strategic Goals and Core Activities Contribute to the Mandate of the Veterinary Drugs Directorate

The diagram below illustrates the interrelationship between VDD's mandate, strategic goals and core activities. The mandate of the Directorate is the target upon which all goals, activities, objectives and strategies are aimed. VDD's mandate is supported by a balanced collection of strategic goals, which are in turn each supported by their respective core activities. The circular nature of the diagram highlights the interconnection of the mandate, strategic goals and core activities, which are not mutually exclusive in practice but interact throughout VDD's daily operations.