Health Canada Santé Canada

Canada's Access to Medicines Regime (CAMR)

Implementation - Focused Evaluation of Health Canada's Responsibilities

Final Report

Approved by

Departmental Executive Committee on
Finance, Evaluation and Accountability (DEC-FEA)
Health Canada

April 28, 2008

Canada

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Management Response and Action Plan

This action plan has been developed by the Canada's Access to Medicines Regime (CAMR) participating organizations (i.e., Therapeutic Products Directorate (TPD), Biologic and Genetic Therapies Directorate (BGTD), Marked Health Products Directorate (MHPD and the Health Products and Food Branch Inspectorate (HPFBI)) in response to the recommendations made in the Implementation - Focused Evaluation of the CAMR.

Recommendations	Response	Key Activities	Responsibility	Time Frame
1. Health Canada should implement its Performance Measurement System for CAMR.	Management concurs. Information about the number of submissions associated with CAMR will continue to be gathered.	The funding for the Regime is sunsetting at the end of fiscal year 2008-09. HC will continue to participate in the Regime and will collect information related to its CAMR activities.	Director, Bureau of Policy, Science and International Programs, TPD, Health Products and Food Branch (HPFB)	January 2008
2. Health Canada should continue to monitor developments in international jurisdictions that have developed legislation or policies related to the WTO Decision to learn from their experiences.	Management concurs. Monitoring of other jurisdictions will be done by the Interdepartmental Working Group so that the monitoring is in line with the responsibilities of the respective policy departments.	Health Canada is a member of the Interdepartmental Working Group led by Industry Canada. As such, Health Canada will continue to participate in monitoring international activities related to the Regime.	Director, Bureau of Policy, Science and International Programs, TPD, HPFB Industry Canada (lead)	January 2008

Recommendations	Response	Key Activities	Responsibility	Time Frame
3. Health Canada should revisit allocations of funding to Directorates involved in CAMR, and in particular, increase funding allocated to post-market surveillance and communication and outreach.	Management concurs. Health Canada will revisit allocations of funding to Directorates involved in CAMR, and in particular, increase funding allocated to post-market surveillance and communication and outreach.	Funding was provided in Dec 2004 in the amount of $15M for five years to implement CAMR. The funding for the Regime is sunsetting 2008-2009. HC will continue to participate in the Regime. As a result, Branch Operational Planning will address how to resource HC's activities under CAMR. The Operational Planning exercise is led by PPIAD.	Director, Policy Planning and International Affairs Directorate (PPIAD), HPFB with affected Directorates	January 2008
4. Health Canada should continue to clarify and amend, as needed, its guidance documents and lines of accountability.	Management concurs.	Health Canada will continue to clarify and amend, as needed, its guidance documents and lines of accountability.	Director, Bureau of Policy, Science and International Programs, TPD, HPFB	January 2008

Implementation-Focused Evaluation of Health Canada's Responsibilities under Canada's Access to Medicines Regime (CAMR)

Final Report

By:
Universalia

December, 2007

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Purpose and Methodology of the Evaluation

In May 2007, Health Canada commenced an implementation-focused evaluation of its responsibilities under CAMR, the purpose of which is to provide senior management in Health Products and Food Branch (HPFB) with timely information on how well CAMR has been implemented. This will enable mid-course corrections to be taken, if required, increasing the likelihood of achieving expected outcomes that countries and manufacturers participate in the regime, and that products developed meet Canadian standards and regulatory requirements and are distinguishable from patented products. The requirement to conduct an evaluation arose from Health Canada's Treasury Board (TB) Submission to access CAMR funds. The scope is on Health Canada's activities associated with implementing CAMR during the period of FY 2004-05 to FY 2006-07.

Data for this evaluation was obtained from document review; interviews with key informants, partners and external stakeholders; and from a case scenario exercise. These data were summarized within the framework of the evaluation matrix, triangulated and assessed to produce findings and recommendations for this evaluation.

History and Description of CAMR

The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) sets out the minimal norms and standards to which WTO Members must adhere to protect intellectual property rights, including patent protection for pharmaceutical products. Because TRIPS placed restrictions on countries' abilities to grant compulsory licenses, the 2001 Doha Declaration on the TRIPS Agreement and Public Health recognized that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector faced difficulties making effective use of compulsory licensing under the TRIPS Agreement, since they would be unable to import products under compulsory license from other WTO members. In August 2003, negotiations among WTO members resulted in a decision to waive two provisions of TRIPS that prevented the export of certain generic products to developing countries. This decision allows WTO member countries with pharmaceutical manufacturing capacity to issue compulsory licenses for the manufacture and export of generic versions of patented pharmaceutical products to developing countries that face public health problems, such as HIV/AIDS, tuberculosis, malaria and other epidemics, and that lack the capacity to manufacture the products themselves.

In September 2003, Canada became the first WTO member to announce its intention to implement the WTO Decision. On May 14, 2004, the Jean Chrétien Pledge to Africa, an Act providing the legislative framework for CAMR, received royal assent. One year later, on May 14, 2005, following the passage of the regulations necessary to round out this legislative framework, CAMR came into force.

CAMR is an interdepartmental initiative involving Health Canada, Industry Canada (IC), the Canadian Intellectual Property Office (CIPO), the Canadian International Development Agency (CIDA) and the Department of Foreign Affairs and International Trade (FAITC).

The main objective of Health Canada's role in CAMR is to ensure products developed under CAMR meet Canadian standards and regulatory requirements, and are distinguishable from patented products. Health Canada's responsibilities under this Regime involve the review of products for safety against Canadian standards and distinguishability; the pre-export inspection program; the notification to the Commissioner of Patents if a product is, or is not in compliance with the requirements of the Food and Drugs Act and its Regulations under the Regime; and any policy, legal and program support work associated with the Regime.

Evaluation Findings

The evaluation resulted in the following findings.

Finding 1: A lack of uptake of the WTO Decision in other countries means that little can be learned from international models. A review conducted of other jurisdictions has revealed a lack of uptake of the WTO Decision internationally, meaning that it is not yet possible for Health Canada to learn from the experiences of others

Finding 2: HC's responsibilities under the Regime are clearly aligned with the Department's role, capacities and expertise. Its alignment with the priorities and strategic outcomes of the Department and of the GoC could be better reflected.

Finding 3: While Health Canada's responsibilities under CAMR were designed to meet the needs of external stakeholders as much as possible, there is disagreement among external stakeholders on what the Department's role in the Regime should be. This renders impossible the design of a system to meet all needs.

Finding 4: The planning and design process for Health Canada's responsibilities under CAMR was appropriate. It was conducted according to established standards and in a consultative manner, ensuring the input of key stakeholders.

Finding 5: The activities that HC has undertaken to implement the Regime have changed over time, in recognition of changing realities.

Finding 6: The logic model for Health Canada's responsibilities under CAMR is appropriate, but there is some room for improvement, namely the addition of Health Canada's activities regarding the Inter-Departmental Working Group, and the elimination of the "Health Canada" immediate outcomes.

Finding 7: In most cases, resource allocations are appropriate for Health Canada's responsibilities under CAMR, despite difficulties in assessing appropriate allocations. However, a greater amount is needed for post-market surveillance.

Finding 8: HC's roles and responsibilities under CAMR are appropriate. Internally it was not always clear to all who had the overall responsibility for decision-making within Health Canada for larger issues beyond the responsibilities of individual directorates (such as statutory review and the future direction of CAMR).

Finding 9: Health Canada has implemented its responsibilities as needed, and according to the design in the logic model, except where limited by external factors, such as lack of uptake. Appropriate outputs have been produced in a timely manner when needed.

Finding 10: Outputs not completed to date are due to factors outside of Health Canada, such as lack of uptake of the Regime. Health Canada has effectively adapted its implementation to changes in context.

Finding 11: Due to limited uptake of the Regime to date, a complete assessment of effectiveness is not possible. However, there are some early indications of outcome achievement, including the participation of external stakeholders (manufacturers and countries) in the Regime.

Finding 12: Funds that Health Canada has received for CAMR have largely been spent as planned, despite difficulties in tracking spending for CAMR.

Evaluation Recommendations

The recommendations of this evaluation are the following:

Recommendation 1: Health Canada should implement its Performance Measurement System for CAMR.

Recommendation 2: Health Canada should continue to monitor developments in international jurisdictions that have developed legislation or policies related to the WTO Decision to learn from their experiences.

Recommendation 3: Health Canada should revisit allocations of funding to Directorates involved in CAMR and, in particular, increase funding allocated to post-market surveillance and communication and outreach.

Recommendation 4: Health Canada should continue to clarify and amend, as needed, its guidance documents and lines of accountability.

Acronyms

AR	Adverse Reaction
BGTD	Biologics and Genetic Therapies Directorate
CAMR	Canada's Access to Medicines Regime
CBSA	Canada Border Services Agency
CIDA	Canadian International Development Agency
CIPO	Canadian Intellectual Property Office
DPMED	Departmental Performance Measurement and Evaluation Directorate
EBP	Employee Benefit Plan
EU	European Union
FAITC	Foreign Affairs and International Trade Canada
FTE	Full-Time Equivalent
GMP	Good Manufacturing Practices
HPFB	Health Products and Food Branch
HPFBI	Health Products and Food Branch Inspectorate
IC	Industry Canada
IDWG	Inter-Departmental Working Group
IRS	Inspection Report System
MHPD	Marketed Health Products Directorate
NGO	Non-Governmental Organization
PEACO	Program Evaluation and Audit Coordination Office
PMAF	Performance Measurement and Accountability Framework
PMF	Performance Measurement Framework
PQP	Pre-Qualification Programme
SOP	Standard Operating Procedure
TB	Treasury Board
TPD	Therapeutic Products Directorate
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization
YSD	Social Development Policies, Canadian International Development Agency

1. Introduction

1.1 Organization of the Report

This introductory section describes the purpose, objectives, methodology, scope and limitations of the evaluation. This report is organized as follows:

- Section 2 provides a history and description of Canada's Access to Medicines Regime (CAMR), with a specific focus on Health Canada's responsibilities. It provides a history of CAMR, Health Canada's objectives and specific responsibilities within CAMR as well as CAMR's stakeholders and its current status.
- Section 3 provides the findings of the evaluation. It provides a description and assessment of the context of Canadian and international experiences with the World Trade Organization (WTO) Decision; the rationale for Health Canada's responsibilities under CAMR; the planning, design, delivery and implementation of the Regime; and, finally, the effectiveness and efficiency of the Regime to date.
- Section 4 presents the conclusions, recommendations and lessons learned through the evaluation.

1.2 Purpose and Objectives of Evaluation

The purpose of this implementation-focused evaluation is to provide senior management in Health Products and Food Branch (HPFB) with timely information on how well CAMR has been implemented. This will enable mid-course corrections to be taken, if required, increasing the likelihood of achieving expected outcomes that countries and manufacturers participate in the regime, and that products developed meet Canadian standards and regulatory requirements and are distinguishable from patented products. The requirement to conduct an evaluation arose from Health Canada's Treasury Board (TB) Submission to access CAMR funds.

The clients of this evaluation are Health Canada's Director of Performance Measurement and Evaluation Directorate (DPMED), HPFB's Program Evaluation and Audit Coordination Office (PEACO) and, more broadly, the Evaluation Advisory Committee, consisting of PEACO and the Directorates of HPFB involved in CAMR.

The original scope of this implementation-focused evaluation was on Health Canada's activities associated with implementing CAMR during the period of FY 2004-05 to FY 2006-07. However, for various reasons the data collection period was extended and additional data was collected up until September 2007.

An implementation evaluation is defined as systematic data collection about the extent and form of program implementation and an analysis of that data to guide decisions about program implementation.

The main objectives of the implementation evaluation are:

- To assess Health Canada's implementation of its responsibilities under the Regime by:
    - Assessing its rationale;
    - Validating its design;
    - Providing information useful for steering implementation as it proceeds;
    - Providing feedback on achievement of short-term outcomes to date; and
- To assess how the funds have been spent to date and identify any gaps, lapses and/or re-allocation of funding.

The evaluation was conducted from June to October 2007.

1.3 Methodology and Scope

The design for this evaluation is based on the evaluation workplan contained in the Performance Management Accountability Framework (PMAF), which was developed by the Evaluation Advisory Group. The evaluation workplan was further refined in consultations between Universalia and the Evaluation Advisory Group, including the Program Evaluation and Audit Coordination Office.

1.3.1 Evaluation Methodology

The table in Appendix I shows the evaluation framework used for the implementation evaluation of CAMR.

Data Sources

Data was obtained from the following sources (corresponding with the "data collection" columns in the evaluation framework):

Documents: A review of documents, both internal and external to Health Canada, was undertaken. A list of documents reviewed is found in Appendix V.

Key Informant, Partner and External Stakeholder Interviewees: A total of 19 interviews were carried out with Health Canada staff involved in the Regime (hereinafter named "key informants"), other external individuals within partner departments (called "partner interviewees" in this report), and stakeholders from external organizations who are knowledgeable of Health Canada's activities in the area (called "external stakeholder interviewees"). Interviews were conducted on a one-to-one basis, with the exception of one

group interview of four people, for the Marketed Health Products Directorate (MHPD), and one interview of an external stakeholder conducted via e-mail. Individual interviews were approximately one hour in duration and the group interview lasted two hours. Each of the interviews was conducted by two people: at least one member of the Evaluation Team and an assistant, either from Universalia or from Health Canada's Program Evaluation and Audit Coordination Office. Appendix IV shows the list of organizations represented in interviews for this evaluation, while Appendix VI provides the interview protocols. Interviewees were assured that their responses to the questions would be kept confidential. As a result, individual responses have been aggregated or kept anonymous in the report.

Case Scenario Exercise: Since the activities associated with Post-Market Surveillance and Compliance/Enforcement have not yet occurred, a case scenario exercise approach was applied to these two activities. The exercise included an informal discussion with program staff knowledgeable about the Post-Market Surveillance and Compliance/Enforcement activities, and a "walk-through" of the process and procedures put in place. Information on the effectiveness and functionality of the infrastructures for these two activities was gathered in this fashion.

While it was planned to obtain information from the CAMR Performance Measurement System, no data has been collected due to limited uptake of the Regime to date.

Data Analysis

Data from the document review, interviews and case scenario exercise were summarized within the framework of the evaluation matrix (see Appendix I), and then triangulated. Responses to each question were analyzed through an inductive process to develop the findings and recommendations for this evaluation. The achievement of outcomes to date was assessed based on comparing available baseline measures to actual measures in 2007 (See Exhibit 3.6, pg. 27). Finally, evaluation findings were reviewed, analyzed and interpreted to distil the strengths and weaknesses of the implementation of CAMR.

1.3.2 Scope

Exhibit 1.1 below shows the limitations in scope placed on this evaluation as well as the reasons for these limitations.

Exhibit 1.1 Evaluation scope

SCOPE	REASON FOR LIMITATION IN SCOPE
The evaluation covers the period from Treasury Board approval for funding (December 2004) to the period of data collection for the evaluation (September 2007).	Activity prior to December 2004 was primarily restricted to the development of the legislative framework, which is the subject of the Industry Canada statutory review and not of primary interest to the evaluation's main users: Health Canada's CAMR program managers.
Only Health Canada responsibilities under CAMR have been assessed.	The purpose of the evaluation was to help inform Health Canada's program managers, since only Health Canada was recipient of funding from Treasury Board for CAMR. Furthermore, the requirement to conduct an evaluation arose from Health Canada's TB submission to access those funds. Treasury Board did not direct any other department to conduct an evaluation. It was also intended that this evaluation does not duplicate efforts of the statutory review of the government-wide Regime undertaken by Industry Canada.

1.4 Limitations

Exhibit 1.2 below describes the key limitations to this evaluation and the evaluation team's response to these limitations.

Exhibit 1.2 Limitations

LIMITATION	RESPONSE
A limited number of external stakeholders and partners has been interviewed for this evaluation (two external stakeholders and three stakeholders from partner departments have been interviewed, versus 14 key informants). There is a possibility that external stakeholder views may not be adequately reflected in this evaluation	This limitation to the interview data has been addressed by obtaining additional data from the document review. The following documentary evidence has been collected reflecting external stakeholders' views on CAMR: ▪ Comments received from organizations and individuals on the consultation paper, as part of the Industry Canada statutory review; ▪ Evidence from the Parliamentary Standing Committee on Industry, Science and Technology; and, ▪ Reports and other briefing material from these stakeholders. See Appendix V for an outline of other documents reviewed as part of this evaluation.
A lack of uptake to date experienced by the Regime renders an evaluation of its implementation problematic. To date, some but not all established procedures, activities and policies have been put to use.	The activities not yet exercised within Health Canada's responsibilities under CAMR (post-market surveillance and pre-export inspection) were addressed in an informal discussion intended to provide a "walk-through" of the implementation of these processes (see Case Scenario Exercise, Section 1.3.1). During the data collection period, the Regime saw more activity as a result of Rwanda's notification of its intent to request products under the WTO Decision, and the subsequent granting of a compulsory license to Apotex. Further data collection was undertaken at this point to examine the success of the implementation of the Regime under these new developments.
A review of best practices internationally has proven impossible due to the lack of activity internationally. A review conducted as part of this evaluation, intended to examine the implementation of the regimes of other countries, was unable to meet its objective since no other country had successfully granted a compulsory licence.	Instead of examining practices in other jurisdiction, this review focused only on the differences in legislative and regulatory frameworks among the participating countries and regions.

2. History and Description of CAMR

2.1 TRIPS and the August 2003 WTO Decision[1]

The World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was negotiated in the 1986-94 Uruguay Round and came into effect on 1 January 1995. Prior to TRIPS, the extent of protection and enforcement of intellectual property rights varied widely around the world. As intellectual property became more important in international trade, these differences became a source of tension among some trading partners. The WTO and its members believed that the development of internationally-agreed trade rules for intellectual property rights could help improve trade and international relations and simplify dispute resolutions. The Uruguay Round addressed these issues with the TRIPS Agreement, an attempt to narrow the gaps in the way these rights are protected around the world and to bring them under common international rules.

TRIPS sets out the minimal norms and standards to which WTO Members must adhere to protect intellectual property rights, including patent protection for pharmaceutical products.[2] While developed countries were granted a transition period of one year (until January 1996) to apply the provisions of TRIPS, other countries (developing countries, least-developed countries and transition economies) were given varying periods of four to 20 years in order to apply these provisions.

One of the areas covered by TRIPS is compulsory licensing, the granting of licenses by a government for the use of a patent without the authorization of the patent owner. Prior to TRIPS, the WTO did not place restrictions on its members' legislations regarding granting of compulsory licenses for products for export. However, in order to be compliant with TRIPS's provisions, WTO members were required to ensure their respective legislations prohibited compulsory licensed products to be exported. While Article 31 of TRIPS allows for compulsory licensing under certain conditions, Article 31(f) stipulates that the compulsory licence of the patented invention be predominantly for the supply of the domestic market.

The 2001 Doha Declaration on the TRIPS Agreement and Public Health recognized that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector faced difficulties making effective use of compulsory licensing under the TRIPS Agreement, since they would be unable to import products under compulsory license from WTO members (except from those whose transition periods were still in effect, as described above). The Council for TRIPS was thus instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

In August 2003, negotiations among WTO members resulted in a decision to waive two provisions of TRIPS that prevented the export of certain generic products to developing countries faced with public health problems. This decision (hereinafter referred to as the WTO Decision) allows WTO member countries with pharmaceutical manufacturing capacity to issue compulsory licenses for the manufacture and export of generic versions of patented pharmaceutical products to developing countries that face public health problems, such as HIV/AIDS, tuberculosis, malaria and other epidemics, and that lack the capacity to manufacture the products themselves. The key points of this Decision, describing the minimum conditions to grant a compulsory license, are shown in the sidebar on the next page. According to the Decision, countries may include other provisions as they see fit.

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[1] Adapted from Canada's Access to Medicines Regime – Consultation Paper, November 2006. http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.html and WTO TRIPS Gateway, http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

[2] For the purposes of this report, the term "pharmaceutical products" refers to both pharmaceutical and biologic drugs as well as medical devices.

On December 6, 2005, WTO Members approved an amendment to the TRIPS Agreement to make permanent the August 2003 Decision. Members originally had until December 2007 to accept this change, upon which the amendment would be formally built into the TRIPS Agreement. On October 23, 2007 the TRIPS Council which consists of all WTO members, agreed to extend the deadline to December 31, 2009.

Key Points of the August 2003 WTO Decision[3]

A country may allow exports of patented products to eligible countries if the following conditions are met:

The importing country notifies the WTO with the name and quantities of the product, confirms it has insufficient manufacturing capacity, and confirms it has or intends to grant a compulsory license, if applicable.

Only the amount necessary to meet the importing country's needs are to be exported.

Products are clearly identified through specific labelling or marking. Products should be distinguished through special packaging and/or colouring/shaping of the products.

The licensee creates a web site with a description of the products to be exported.

The exporting country notifies WTO of the grant of a license.

Adequate remuneration is given to the patent holder.

Members ensure the availability of legal means to prevent diversion and re-importation.

2.2 Canada's Access to Medicines Regime

2.2.1 History of the Regime

In September 2003, Canada became the first WTO member to announce its intention to implement the WTO Decision. On May 14, 2004, the Jean Chrétien Pledge to Africa, an Act providing the legislative framework for CAMR, received royal assent. This framework consists of amendments to the *Patent Act*, authorizing the Commissioner of Patents to grant compulsory licenses allowing the manufacture and export of lower-cost versions of patented pharmaceutical products, and to the *Food and Drugs Act*, authorizing Health Canada to review these products for safety, efficacy and quality. One year later, on May 14, 2005, following the passage of the regulations necessary to round out this legislative framework, CAMR came into force.

[3] Source: WTO General Council, September 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

CAMR is an interdepartmental initiative involving Health Canada, Industry Canada (IC), the Canadian Intellectual Property Office (CIPO), the Canadian International Development Agency (CIDA) and the Department of Foreign Affairs and International Trade (FAITC). A total of $15 million[4] was allocated to Health Canada over five years (from fiscal year 2004-05 to 2008-09) to ensure that submissions under this humanitarian initiative would be reviewed on a priority basis while ensuring that there would be no negative impact on Canadians' access to generic medicines. The funds were allocated in the following fiscal years:

	2004-05	2005-06	2006-07	2007-08	2008-09
Vote 1	1,392,197	2,643,736	3,095,538	2,728,585	2,005,856
Accommodation Costs	107,803	218,965	266,071	239,420	174,925
Frozen Allotment		637,299	638,391	531,995	319,219
Total Allocation	**1,500,000**	**3,500,000**	**4,000,000**	**3,500,000**	**2,500,000**

No funds were allocated to other departments or agencies under CAMR.

2.2.2 Objectives of Health Canada's role in CAMR

The main objective of Health Canada's role in CAMR is to ensure products developed under CAMR meet Canadian standards and regulatory requirements, and are distinguishable from patented products.

CAMR is intended to reach the least-developed and developing countries that have insufficient or no manufacturing capacity in the pharmaceutical sector. Affordable medicines for public health problems, such as HIV/AIDS, malaria and tuberculosis, are targeted. By implementing the Health Canada component of CAMR, the products exported to these countries will be manufactured and evaluated in accordance with Canadian standards. Furthermore, the required distinguishing features of the exported product may be verified at the time of the Health Canada regulatory review.

2.2.3 Health Canada's Responsibilities under CAMR

In order to fulfill its objectives and help meet overall goals for the Regime, the specific responsibilities of Health Canada under CAMR include Policy, Legal and Regime Support; Product Evaluation; Post-Market Surveillance; Compliance and Enforcement; and Communication and Outreach.

Policy, Legal and Regime Support activities develop the foundation for Health Canada's involvement in the Regime. They include development of the regulatory framework, guidance documents, standard operating procedures (SOPs), fee remittance mechanisms, and tracking systems such as the Drug Submission Tracking System and Inspection Reporting System.

Product Evaluation primarily involves the review by Health Canada of product submissions by manufacturers wishing to participate in the Regime. These reviews ensure the products meet Canadian standards for quality and safety, and are distinguishable from domestic products to help prevent diversion and re-importation. Other activities in this category include notifying the Commissioner of Patents of the results of this review, conducting submission meetings with external stakeholders, and undertaking remission of fees to the manufacturer, in recognition of the humanitarian nature of this Regime.

Post-Market Surveillance activities address the need for ongoing communication of potential risks after the product has been approved for manufacture. Health Canada's responsibilities include development of a system to collect adverse reaction reports relating to CAMR and development of a policy and processes to communicate this risk information. Information on adverse reactions will be collected, both domestically and internationally, and made available to manufacturers and appropriate health officials.

[4] This amount includes $1,007,184 in accommodation costs and $2,126,904 in "frozen" costs for use if and when actual workload exceeded the base funded workload.

Compliance and Enforcement activities help ensure products manufactured for this Regime meet the same standards and regulatory requirements as those products destined for the Canadian market. Pre-export inspections, as part of anti-diversion measures, will be conducted to confirm the existence of distinguishing characteristics on the products, their immediate containers, if applicable, and their labels as well as the quantity to be exported as per the authorization. All regulatory requirements that a manufacturer must meet for drug products destined for the Canadian market also apply to CAMR products, in addition to Part C Division 7 of the *Food and Drug Regulations*. Therefore, inspections regarding establishment licensing and good manufacturing practices (GMP) will continue to take place for manufacturers of these products. Health Canada will undertake enforcement actions in cases of non-compliance.

Communication and Outreach activities help ensure external stakeholders are aware of and informed about CAMR. Health Canada's activities in this area include provision of information to the public, industry and other stakeholders; development of information products; collaboration with external stakeholders and partners; formation of effective linkages with international partners to support CAMR; and, establishment of an Advisory Committee on CAMR. While some of these activities are responsibilities of Health Canada as per the Treasury Board Submission,[5] the importance of outreach activities was not fully realized until after this Submission was drafted, thus many communication and outreach activities were not included in the Submission. Nonetheless, communication and outreach for CAMR overall is not the official responsibility of Health Canada.

Health Canada's responsibilities under CAMR are managed by four directorates within HPFB:

- **Therapeutic Products Directorate** (TPD) plays a lead role in CAMR overall and in submission reviews for therapeutic products;
- **Biologics and Genetic Therapies Directorate** (BGTD) undertakes submission reviews for biologics such as vaccines;
- **Marketed Health Products Directorate** (MHPD) adapts systems for post-market surveillance related to the collection of adverse reaction reports and dissemination of risk communications; and
- **Health Products and Food Branch Inspectorate** (HPFBI) conducts pre-export inspections and other compliance and enforcement activities.

2.2.4 CAMR Stakeholders and Beneficiaries

CAMR involves both external stakeholders, with which it interacts directly, and intended beneficiaries. Its external stakeholders include manufacturers, the public and non-governmental organizations (NGOs). The key intended beneficiaries of CAMR are developing and least-developed countries. It is expected that they will benefit from CAMR through improved access to high-quality, less expensive products.

2.3 Current Status of CAMR

On September 19, 2007, the Commissioner of Patents granted to the generic drug company Apotex, Inc. an authorization to manufacture a pharmaceutical product used in the treatment of HIV/AIDS for export to Rwanda. This represents the first such authorization since the coming into force of CAMR in 2004 as well as the first such authorization under the WTO Decision in any country.

Because of this lower-than-expected uptake on the part of generic manufacturers and eligible countries, the departments involved in CAMR have recognized the need to increase international awareness of the Regime and build relationships with eligible countries. For its part, Health Canada's activities under CAMR have been evolving to meet this emerging need and place greater focus on outreach.

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[5] Activities related to communication and outreach specifically mentioned in the Treasury Board Submission include collaborating with partners, consulting with external stakeholders, and providing guidance and other assistance to industry.

In April and May 2007, the Parliamentary Standing Committee on Industry, Science and Technology conducted a study of CAMR at the government-wide level, inviting input from the Canadian Government, NGOs, the pharmaceutical industry and others. One key area of interest in this study was an examination of the reasons for a lack of uptake by eligible countries and the changes needed to change the status quo. This study resulted in a letter from the Committee Chair to the Minister of Industry advising of 16 major issues and requesting that these issues be addressed in Industry Canada's statutory review.
The statutory review of the Regime, led by Industry Canada, sought external stakeholders' views on the various components of the Regime, with a specific view to informing decisions on what changes are required at the legislative level. This review was completed in May 2007 and a report is expected to be tabled by the Minister of Industry in both Houses of Parliament in Fall 2007

3. Evaluation Findings

The findings of the evaluation are presented in this section. A summary of all findings can be found in Appendix II. A description and assessment is provided of the context of Canadian and international experiences with the WTO Decision; the rationale for Health Canada's responsibilities under CAMR; the planning, design, delivery and implementation; and, finally, the effectiveness and efficiency of the Regime to date.

3.1 Context of Canadian and International Experiences

Finding 1: A lack of uptake of the WTO Decision in other countries means that little can be learned from international models

A review conducted of other jurisdictions has revealed a lack of uptake of the WTO Decision internationally, meaning that it is not yet possible for Health Canada to learn from the experiences of others.

It needs to be emphasized that CAMR, which implements the 2003 WTO Decision, deals with the export of patent protected drugs and medical devices. At the time of the WTO negotiations, developed countries could only supply the brand versions, or generic versions for which a patent owner (the brand) had issued a voluntarily licence. There has never been a restriction on the export of generic copies of products no longer under patent protection nor the export of the patented products themselves. While the focus of the WTO Decision has been to increase the accessibility of medicines to treat HIV/AIDS, malaria and tuberculosis, for which the most effective medicines are still under patent protection, the eventual application of the Decision may go beyond those diseases depending on the public health urgencies that emerge in coming years.

After the August 2003 WTO Decision, countries and regions were able to amend their respective legislations and regulations to allow generic versions of patented products to be manufactured for export to eligible countries. Four years later, however, no pharmaceutical products have yet been exported under the WTO Decision from any country (although a compulsory license has recently been granted by Canada for one product). Until each country experiences uptake of the WTO Decision (i.e., products are exported under the TRIPS waiver), and in the absence of any evidence for the rationale behind the designs of each international model, it is not possible at the current time to assess the relative advantages and disadvantages of each model.

Outside Canada, responses to the WTO Decision currently exist in the European Union (EU), Norway, Switzerland, Korea, China and India. The Netherlands has in place policy rules to implement the WTO decision, which will be superseded by EU legislation. A review of international literature for the purposes of this evaluation attempted to identify practices from other jurisdictions that could provide information in terms of lessons learned to improve the delivery of CAMR. Unfortunately, due to lack of uptake internationally, no such practices could be identified. Appendix VII contains a table highlighting the key differences between countries and, for the WTO Decision itself, in areas corresponding to Health Canada's responsibilities under CAMR.

While the interpretations of each jurisdiction adhere to the WTO Decision, this Decision leaves room for adaptation in each country and, therefore, Canada's Regime provides a different structure from those of other jurisdictions. As discussed in the following sub-section, the design of Canada's Regime is the result of a consultative process that sought to achieve a balance among the interests of stakeholders involved. There are three primary differences between CAMR and international experiences relating to health, according to our literature review, namely:

- **List of eligible products:** Canada is the only country with a list of products that are eligible for compulsory license. Schedule 1 to the *Patent Act* lists the products eligible for compulsory licensing under CAMR. Other countries do not require that products be eligible in this manner.[6]
- **Health and safety review:** Canada is the only country that requires a health and safety review by the domestic regulatory authority. CAMR requires that all pharmaceutical products intended for export be reviewed by Health Canada in accordance with the standards prescribed by the *Food and Drugs Act* and its regulations. This is intended to provide eligible importing countries with an assurance that products exported under CAMR are of the same safety, efficacy and quality as those available to Canadians. Other countries and regions, such as the EU, have a voluntary review system in place. Others place this responsibility on the importing country.
- **Post-market surveillance:** None of the other jurisdictions examined made reference to post-market surveillance activities. Health Canada has adapted its domestic risk communication system to CAMR, collecting and disseminating information on adverse reactions. There is no reference in any other jurisdiction of this type of activity as part of their application of the WTO Decision.

Due to the lack of uptake in other jurisdictions, this evaluation compares CAMR activities primarily against equivalent activities of Health Canada outside of CAMR. Most of Health Canada's activities under CAMR are identical to activities the Department undertakes outside of CAMR. For this reason, Canada has been the basis for comparison where possible throughout this report (e.g., submission reviews were compared to targets for non-CAMR submission reviews).

Other countries have had experience exporting generic versions of patented products to other countries. However, since these have been undertaken outside of the provisions of TRIPS, it would not be useful to learn from these experiences since Canada, a signatory to TRIPS, must abide by its provisions. These experiences are therefore considered outside the scope of the evaluation. Certain countries were allowed special "transition periods" in which to enact legislation that is compliant with TRIPS. India, for example, was granted such a transition period but now has legislation that conforms to TRIPS (including the August 2003 Decision on compulsory licensing).

3.2 Rationale

This section examines the rationale of Health Canada's responsibilities under CAMR. Since the scope of this evaluation is limited to Health Canada's responsibilities (as per Section 1.3), the relevance of the Regime overall is not assessed. This is in part the subject of an Industry Canada-led statutory review of the Regime. In this evaluation, we examine two areas related to the rationale behind Health Canada's responsibilities under CAMR: (i) the extent to which these responsibilities, as designed, align with Departmental and Government-wide goals and priorities; and, (ii) the extent to which they meet the needs of external stakeholders.

[6] The Schedule 1 list of products is amended and updated by Order-in-Council advised by a committee established by the Ministers of Health and Industry. Since this is not a responsibility of Health Canada, it is considered to be out of the scope of this evaluation.

Finding 2: Health Canada's responsibilities under the Regime are clearly aligned with the Department's role, capacities and expertise. Its alignment with the priorities and strategic outcomes of the Department and of the GoC could be better reflected.

All key informants who answered this question (26% of interviewees) stated that the Regime is fully aligned with Departmental objectives, although they generally did not specify which priorities or how they aligned. Partner interviewees share in general (67%) this view. However, an examination of Health Canada's priorities and strategic outcomes shows that it is not clear how well they align with CAMR. While the portion of CAMR that is the responsibility of Health Canada is appropriate to the Department in terms of its role and capacities, the alignment of these responsibilities to Department and Government-wide priorities is not completely clear under the current statement of such priorities.

Health Canada's responsibilities under CAMR are aligned with Health Canada's role as a regulator and with its technical capacities and areas of expertise, since many of Health Canada's responsibilities under CAMR are in essence identical to activities the Department conducts outside of CAMR. For example, the health and safety review of a submission for a generic product follows the same process whether the product is intended for the domestic market or for export under CAMR. On the other hand, those aspects that are *unique* to CAMR, and which are conducted by Health Canada, are those that require the technical expertise of this Department. For example, Health Canada has helped in communication and outreach activities in part by developing information materials on the health and safety reviews.

Although Health Canada's responsibilities under CAMR are in line with the Department's capacities and role, further clarification is needed to align CAMR with Departmental priorities and strategic outcomes. Health Canada's corporate priorities, as shown in the sidebar, and its strategic outcomes are focused on the health of Canadians.[8] Health Canada's mission and vision also maintain this exclusive focus on benefits to Canadians. Any health benefits to CAMR, on the other hand, will be to intended beneficiaries in developing and least-developed countries.

Health Canada's corporate priorities[7]

Contributing to the improvement of the health of Canadians.

Reducing the risks to the health of the people of Canada.

Working with others to strengthen the efficiency and effectiveness of the publicly-funded health care and health system.

Strengthening accountability to Parliament and the public.

Despite this focus on Canadians in its Department-wide goals, Health Canada is increasingly engaged in activities with an international focus. Engagement in international health issues is one of the Department's operating principles. Outside of CAMR, Health Canada is an active participant in a number of different international and regional discussions and initiatives. This increased significance of international issues may need to be more clearly communicated in the Department's corporate priorities and strategic outcomes in order to recognize and clearly demonstrate the relevance of its internationally-focused programs.

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7 Health Canada, Report on Plans and Priorities, 2007-2008. http://www.tbs-sct.gc.ca/rpp/0708/HLTH-SANT/hlth-sant01_e.asp#1_4_6

8 While the departmental strategic outcomes do not specify reach, they are expected to contribute to the Government-wide outcome of "healthy Canadians".

Finding 3: While Health Canada's responsibilities under CAMR were designed to meet the needs of external stakeholders as much as possible, there is disagreement among external stakeholders on what the Department's role in the Regime should be.

Despite the consultative process used to design Health Canada's responsibilities under CAMR (as discussed in Finding 4), fundamental disagreements among stakeholders about what a Regime to implement the WTO Decision should look like renders impossible the design of a system to meet all needs.[9]

An example of this disagreement can be observed in the results of requests for recommendations to changes to CAMR from Industry Canada's statutory review of the Regime in April and May 2007. A consultation paper[10] was prepared on CAMR for this review, which requested comments from external stakeholders on their views about CAMR and what aspects they would recommend changing. It specifically asked about two areas within Health Canada's jurisdiction: product evaluation and anti-diversion measures. These CAMR activities are described in Section 2.2.

Product evaluation is not required by the WTO Decision, and while the Decision does require anti-diversion measures be established, participating countries are able to define their own modalities for doing so. For this reason there has been some debate around these two areas among external stakeholders.

Exhibit 3.1 below shows the responses from external stakeholders to each of these two areas: For each, the "Yes" column indicates the stakeholder recommended changing or eliminating the requirement, and the "No / No comment" column means the stakeholder either recommended not changing it or made no recommendations on the matter.

Exhibit 3.1 External stakeholder recommendations for Statutory Review consultation paper

Type of organization	Change product evaluation?		Change anti-diversion measures?		Total
	Yes	No / No comment	Yes	No / No comment	
Innovative pharmaceutical company / association	0	14	1	13	**14**
Generic pharmaceutical company / association	0	2	2	0	**2**
NGO	6	1	2	5	**7**
Other	2	3	0	5	**5**
Total	**8**	**20**	**5**	**23**	**28**

As shown in Exhibit 3.1, the majority of respondents appear to favour the Regime as it currently exists. However, outside of the first group – innovative pharmaceutical companies and associations – there is a diversity of opinions for each of the two questions.

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[9] Because the purpose of this evaluation is to help Health Canada's senior management assess implementation of the Regime and make mid-course corrections if necessary, it should be noted that Finding 3 does not lend itself to recommendations, all of which are directed at senior management, the evaluation users. Legislated aspects of CAMR, such as those discussed in this Finding, are outside the scope of senior management responsibility and are the subject of a statutory review conducted by Industry Canada. The intent of Finding 3 is to illustrate that a diversity of views on CAMR exists among external stakeholders, requiring careful consultation on the part of Health Canada during design of the Regime. The extent of consultations in the design phase of the Regime is discussed in sub-section 3.3.

[10] Canada's Access to Medicines Regime – Consultation Paper, November 2006. http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.html

Those who recommend changes to Product Evaluation (most NGOs and some in the "other" category, a total of 29% of respondents) most commonly cited duplication of the World Health Organization's (WHO) Pre-Qualification Programme (PQP) as the reason. The PQP, created by the WHO in 2001, aims to increase access to priority medicinal products that meet unified standards of acceptable quality, safety and efficacy, currently focusing on those used for HIV/AIDS, malaria, tuberculosis and reproductive health.[11] Some respondents proposed eliminating Health Canada's review requirement, while others recommended making it optional for those products already on the PQP list. Those who recommended not changing this review requirement stated that it is not, in fact, a duplication of the PQP, since products reviewed by Health Canada are accepted onto the WHO's list. Furthermore, many felt that importing countries should be entitled to the same level of safe and reliable medicine that Canadian citizens rely on.

Critics of anti-diversion measures (18% of respondents) felt they were too onerous, went beyond the provisions of the WTO Decision and acted as disincentives to participation. Supporters of these measures felt that the measures were important in order to help ensure that the products reach intended beneficiaries.

This diversity of opinion is upheld by the external stakeholder interviews undertaken for this evaluation. In addition to product evaluation and anti-diversion measures, evaluation interviewees discussed CAMR's communication and outreach. Post-market surveillance was not raised as an issue by the external stakeholder interviewees in this evaluation or by the statutory review consultation paper.

Product evaluation: External stakeholder interviewees were divided on the rationale for Health Canada to conduct product evaluations. One stated "The review is essentially a duplication of the work of the WHO Prequalification [Programme][12] and it is also a double-standard since non-CAMR drugs for 'export only' are not required to meet these same standards." However, a Canadian manufacturer disagrees: "The requirement for review of the pharmaceutical product by Health Canada is not a deterrent to manufacturers. Health Canada enjoys a reputation for rigorous regulatory review. This allows WHO the confidence to understand the product has been subjected to well-defined regulatory requirements for safety, efficacy and quality. As such, it allows WHO to accept the review for inclusion of the product on the Prequalification list. This does not put an unnecessary drain on WHO resources and allows for timely inclusion on the [Prequalification Programme]. It also benefits the manufacturer as the product would be eligible for approval within Canada once the patent expires."[13]

Anti-diversion measures: External stakeholders interviewed for this evaluation agree that anti-diversion measures in CAMR are too onerous. According to one, "anti-diversion measures such as specific labelling and marketing that generic companies must comply with are onerous and are further disincentives to their participation in the process." Another, however, stated that while CAMR's anti-diversion measures are effective against diversion and re-importation, the requirement for each company to maintain a website is onerous.

Communication and outreach: Many of those who provided comments for the statutory review, and key informants, partner stakeholders and external stakeholders interviewed for this evaluation, upheld the need for greater communication and outreach for CAMR, validating the increased focus this has taken in Health Canada since the beginning of implementation.

Given a lack of agreement among external stakeholders about the structure of CAMR, it was not possible to meet all needs. However, by following the consultative approach to Regime design described in the following section, Health Canada has developed a model that balances the needs of various stakeholders.

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11 World Health Organization Prequalification Programme web site: http://mednet3.who.int/prequal/

12 For more on the WHO Prequalification Programme, see Finding 10.

13 Letter from Apotex to Health Canada, January 23 2007. http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_apotex_18_e.pdf

3.3 Planning and Design

This sub-section assesses the planning and design of Health Canada's responsibilities under CAMR, including the following: planning and design process; logic model; budgeted resource allocations; and, roles and responsibilities.

3.3.1 Planning and Design Process

Finding 4: The planning and design process for Health Canada's responsibilities under CAMR was appropriate.

The planning and design process for Health Canada's responsibilities under CAMR involved several stages, as shown in Exhibit 3.2. This sub-section focuses primarily on the last three stages in this exhibit – development of the regulatory framework, the PMAF, and policies, guidelines and SOPs. Planning and design that took place prior to these (including the development of legislation, the Memorandum to Cabinet and the Treasury Board Submission) are out of the scope of this evaluation, which examines activities taking place from 2004 to 2007, during the time of Treasury Board funding. Since the development of policies, guidance and SOPs are included within the Health Canada CAMR logic model, this stage is also discussed in Section 3.4 on Implementation.

Exhibit 3.2 History of the planning and design of Health Canada's responsibilities under CAMR

STAGE	DESCRIPTION	TIME PERIOD
Legislation and Memorandum to Cabinet (MC)	Amendments to the Food and Drugs Act and the Patent Act	September 2003 to May 2004
Treasury Board Submission	Request access to funding provided in the MC to support Health Canada's responsibilities under the Regime	October to November 2004
Regulatory framework	Amendments created to Food and Drug Regulations and Medical Devices Regulations.	December 2003 to May 2005
Performance Measurement and Accountability Framework (PMAF)	Regime planning framework clarifying program theory and establishing a Performance Measurement Framework and Evaluation Strategy.	Originally developed from Summer 2005 to March 2006 and updated on a periodic basis, most recently in March 2007.
Policies, guidelines and standard operating procedures	Development of policies, guidance and SOPs on product evaluation, post-market surveillance, pre-export inspection, and inter-directorate coordination.	June 2005 to present

The appropriateness and success of the processes undertaken to develop the above frameworks are discussed in this finding. Overall, the design of the Regime was conducted according to established standards and in a consultative manner, ensuring the input of key stakeholders. One area for improvement to the design is in the establishment of performance targets, as discussed in Finding 9.

Regulatory development followed a consultative process. Comments received from innovative and generic pharmaceutical companies and associations, NGOs, and others during legislative development were taken into account for development of the regulatory framework. In July and August 2004, Health Canada undertook further consultations and workshops with these groups for the development of the regulations. The resulting draft regulations were published in the Canada Gazette Part I in

> "Had Health Canada not had the expertise and dedicated individuals they have, the already difficult process would have been a disaster."
>
> *Partner interviewee*

October 2004, after which it was left open for comment for 75 days. Minor modifications were made to one provision on pre-export notification. Final regulations were published in the Canada Gazette Part II in June 2005.

The development of the PMAF involved a series of internal workshops and other communications. The framework established the program theory through a logic model and provided a Performance Measurement Framework (PMF) as well as evaluation strategy.

The development of policies, guidelines and SOPs was undertaken by individual directorates in consultation with other stakeholders both internal and external to Health Canada. Guidelines and standard practices are still being clarified and amended as Health Canada continues to implement new areas of the Regime.

Overall, most consulted individuals (86% of those involved in the planning phase) commented positively on the planning and design process: While the initial planning for CAMR was carried out under immense time pressure, Health Canada and the other departments involved managed to develop high quality products, according to interviewees from all interview groups (key informants, partner interviewees and external stakeholder interviewees). The start-up phase was repeatedly described as a work-intensive period that was only successful due to the dedication of all staff involved.

It was positively noted that Health Canada conducted stakeholder consultations from very early in the process onwards. All external stakeholders reported positively on Health Canada's consultation processes during this phase.

Positive comments were addressed to the level of coordination among the different departments and bureaus involved: "Communication between Health Canada bureaus and among different government agencies was good. Industry Canada, CIDA and DFAIT were very engaged."

Finding 5: The activities that HC has undertaken to implement the Regime have changed over time, in recognition of changing realities.

The design of the Health Canada's responsibilities under the Regime has evolved in the course of time, as demonstrated by the description of this design in two separate documents: the Treasury Board Submission and the logic model contained in the PMAF. As described in the finding above, there were several stages of design for Health Canada's responsibilities under CAMR. This finding compares the original design encapsulated in the Treasury Board Submission of December 2004 to the design described by the logic model (see Appendix VIII), developed in March 2006, during the implementation of the Regime.

A comparison of these two documents shows three key differences in design:

- **Communication and outreach:** The TB Submission describes some but not all communication and outreach activities undertaken by Health Canada as per the later logic model. Specifically, development of information products and performing outreach to eligible countries and manufacturers are Health Canada activities as per the logic model not mandated by the TB Submission. While communication and outreach for CAMR is not the responsibility of Health Canada, the Department has recognized the need for its involvement in outreach and has collaborated with its partner departments in this area.
- **Fee remission process:** While the TB Submission stated in the description of the Regime that fees for the submission review would be remitted to the manufacturer due to the humanitarian nature of the Regime, the process to be put in place to remit fees was not described, nor were any parts of this process mentioned in the description of Health Canada's activity under CAMR. The logic model establishes the need for such a mechanism to be developed and implemented as part of HC's activities under the Regime.
- **Post-market surveillance:** The logic model clarifies that the post-market surveillance activities described in the TB Submission focus exclusively on collection and communication of risk information, aligning Health Canada's post-market surveillance activities under CAMR to the system in place domestically.

Each of these changes has come about in recognition of a need. The need for communication and outreach was recognized by both internal and external stakeholders. The issues described in the latter two bullets above arose out of a need to clarify the wording of the TB Submission during implementation of the Regime. In each case, the changes were brought about in a consultative manner.

As described in Finding 9, the Regime has been implemented largely according to the design expressed in the logic model, with the exception of some activities yet to be implemented due to lack of uptake of the Regime.

3.3.2 Logic Model

Finding 6: The logic model for Health Canada's responsibilities under CAMR is appropriate, but there is some room for improvement.

The logic model (see Appendix VIII) for Health Canada's responsibilities under CAMR was developed in March 2006 as part of the PMAF. It describes the program theory of the Regime – how inputs and activities lead to intended outputs and immediate and intermediate outcomes.

Key informants were asked to comment on the logic model, for two purposes: to ensure the articulated program theory aligns with key informants' implicit conceptions, and to discuss their impressions of the design process, including the development of the logic model. While personnel perceive it to accurately reflect Health Canada's responsibilities and actual work, the logic model appears to be little used or understood among the Regime's personnel. It was developed as a requirement, but it is not perceived to be as useful as, for example, more detailed SOPs and guidance materials developed for the Regime.

As explained below, an analysis of the vertical logic of this model found that, while overall it is appropriate to the Regime, activities around the Inter-Departmental Working Group (IDWG) should be added to it. Furthermore, the goal of CAMR overall may need adjustment to show explicitly the rationale for Health Canada activities under the Regime.

In order to analyse the logic and the assumptions underlying the logic model, it was necessary first to understand how the elements were connected, since in the original logic model linkages are not specified from one level to the next. Exhibit 3.3 below shows the evaluation team's estimation of these linkages. In the interest of space, individual activities and outputs are not shown in this exhibit, only the activity/output categories. The goal of CAMR[14] is included at the bottom of this exhibit, in order to assess the extent to which the intended results of Health Canada's responsibilities link with the overall goal of the Regime. Furthermore, the immediate outcomes for Health Canada ("fully operational CAMR", and "efficient and effective systems and processes") are not shown in this exhibit. These outcomes are similar to the outputs of the Regime. It may help to simplify and clarify the logic model to remove this set of immediate outcomes.

Each linking arrow in this chart is numbered, from one to eight: these numbers correspond to the numbers in the table in Exhibit 3.4, which provides the evaluation team's assessment and analysis of the assumptions of each of these linkages.

[14] From the CAMR web site: http://camr-rcam.hc-sc.gc.ca/index_e.html

Exhibit 3.3 Health Canada's responsibilities under CAMR logic model showing evaluation team's estimation of logical linkages

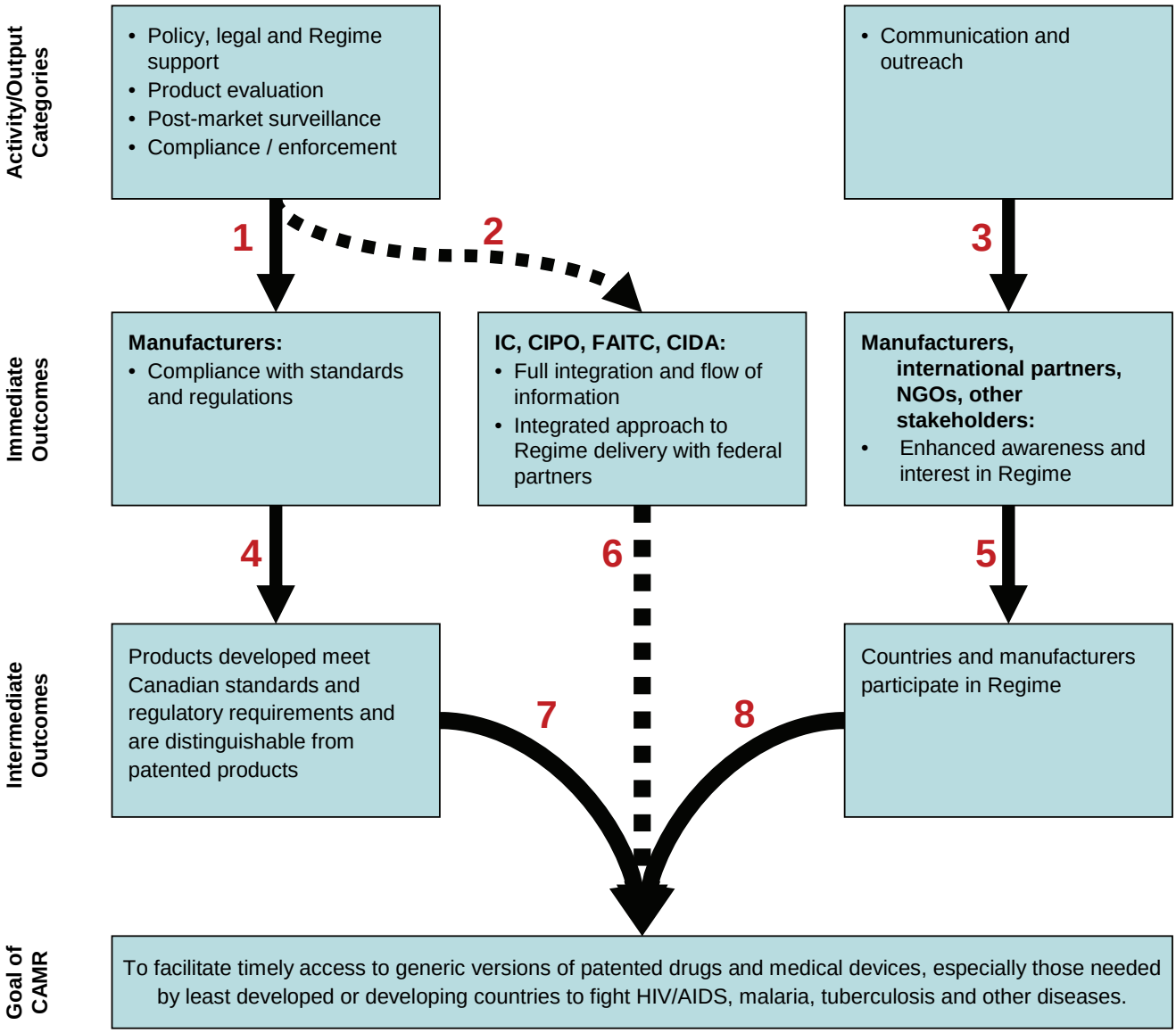

Exhibit 3.4 Evaluation team's analysis of assumptions in the logic model for Health Canada's responsibilities under CAMR

NUMBER[15]	ASSUMPTIONS	ANALYSIS OF LOGICAL LINKAGES
Output to Immediate Outcomes		
1	Manufacturers and countries participate in the Regime. Manufacturers abide by standards and regulations.	It was in recognition of this assumption that the communication and outreach component of CAMR was created. Given the presence of communication and outreach activities, assumptions are judged to be plausible.
2	Federal partners support initiative and are clear on their roles and responsibilities There is effective cross-departmental management of the Regime	It is unclear which activity/output areas lead to integration of federal partners. Health Canada's work on the IDWG should be included in one of the activity/output areas. The activities for the IDWG may be included in the "Regime management and monitoring system" within Policy, Legal and Regime Support.
3	Regime's stakeholders lack knowledge of technical aspects of the Regime Knowledge of the Regime will lead to greater interest in participating	Assumptions are judged to be plausible.
Immediate Outcomes to Intermediate Outcomes		
4	Products will be developed (e.g., countries obtain compulsory license)	Assumption is judged to be plausible (as per 1 above).
5	Awareness and interest lead to participation	Assumption is judged to be plausible.
Outcomes to Goal Achievement		
6	Federal partners are effective in their respective responsibilities.	Assumption is judged to be plausible.
7	Developing products that meet Canadian standards and regulatory requirements will facilitate access to these products in eligible countries.	The assumption is not plausible - It is clear from the fact that Health Canada is undertaking a regulatory role that there are other goals of CAMR than what is described in Exhibit 3.3. Canada does not merely want to facilitate access to generic versions of patented products; it also wants to ensure these products are of high quality and do not pose a risk for diversion and/or re-importation.
8	Countries and manufacturers comply with Canadian requirements. All federal departments are effective in their respective responsibilities.	Assumptions are judged to be plausible.

As shown in Exhibit 3.4, the implicit assumptions within the logic model appear to be mostly reasonable, with the exception of the following:

- Linkage #2: The IDWG deals with the broad policy issues related to CAMR and allows Health Canada's role under CAMR to be coordinated with the other departments' responsibilities. To that extent, Health Canada's activities and output draw from the interdepartmental coordination and management of CAMR.

[15] The numbers in this column correspond to the numbers in Exhibit 3.3.

- Linkage #7: Although CAMR's goal, as expressed in the logic model, does not explicitly mention the Health Canada role vis-a-vis the safety, efficacy and quality of exported products, there can be no doubt that this was Parliament's intent when it incorporated these responsibilities into the Food and Drugs Act.

A number of additional suggestions for adjustments to the logic model arose from key informant interviews. One key informant felt that activities around updating the Schedule 1 list of drugs should be included, while others felt that this goes beyond the scope of Health Canada's responsibilities. Since making amendments to the Schedule 1 list of eligible products is updated by Order-in-Council, advised by a committee established by the Ministers of Health and Industry, and not the responsibility of Health Canada, it is considered to be out of the scope of this evaluation. Another key informant believed that the Canadian Border Services Agency's (CBSA) role should be clarified, in the event that diverted drugs are discovered at the border. Further, one key informant felt that the term "manufacturer" should be elaborated to clarify that a Canadian manufacturer can be one that either fabricates or packages/labels its product in Canada.[16]

3.3.3 Budgeted Resource Allocations

Finding 7: In most cases, resource allocations are appropriate for Health Canada's responsibilities under CAMR, despite difficulties in assessing appropriate allocations. However, a greater amount is needed for post-market surveillance.

Based on a comparison of actual vs. planned spending to date[17] and on self-reported needs collected from key informant interviews, resource allocations were appropriate for most aspects of Health Canada's responsibilities under CAMR with the exception of post-market surveillance. However, for the Regime as a whole, there is no clear mechanism to determine appropriate minimum amounts to maintain capacity and appropriate amounts when applications are submitted. Minimum capacity would entail some amount of resources allocated to FTEs in each directorate to ensure CAMR applications receive priority and do not use resources intended for domestic products.

The allocations for MHPD were deemed to be insufficient to undertake the post-market surveillance activities for which it is responsible, based on self-reported interview responses. The Directorate was assigned 0.8 Full-Time Equivalents (FTEs) for these activities, as defined in the logic model:

- System to collect adverse reaction reports relating to CAMR;
- Policy for risk communication; and
- Processes for communicating relevant risk information to manufacturers and appropriate health officials.

MHPD is currently spending more than the budgeted amounts in order to fulfill its obligations under CAMR. The development of a guidance document on risk communication alone has consumed more than the allocated FTEs in the necessary consultations with various stakeholders, both internal and external to the Regime.

3.3.4 Roles and Responsibilities within Health Canada

Finding 8: HC's roles and responsibilities under CAMR are appropriate. Internally it was not always clear to all who had the overall responsibility for decision-making within Health Canada for larger issues beyond the responsibilities of individual directorates (such as statutory review and the future direction of CAMR).

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[16] A manufacturer in Canada is one that performs any of the five following activities: fabricate, package/label, test, import or distribute.

[17] See Exhibits 3.7 to 3.9 for planned vs. actual spending for the fiscal years to date.

Health Canada's roles and responsibilities under CAMR have been designed in accordance with the capacities, expertise and existing responsibilities of the participating directorates.

> "We do for CAMR what we do anyway, and what we know how to do. It's not much different."
>
> "Roles and responsibilities assigned to the HPFB Inspectorate are appropriate: This is what we do. Canada's inspectors are regarded as among the best in the world – we have the knowledge and capacities to do this work well."
>
> *Key informants*

All consulted bureaus/directorates stated that they found the division of roles and responsibilities within Health Canada appropriate and effective, as it was based on the already existing responsibilities, capacities and areas of expertise of the different units. TPD, for example, regularly conducts product evaluation on generic product submissions for the domestic market. These reviews, in general, involve the same process as those conducted for CAMR. The responsibilities of other directorates are also not substantially different from non-CAMR responsibilities. However, there has been some lack of clarity around the leadership of CAMR within Health Canada. Not all key informants were clear on which directorate or bureau has lead responsibility for CAMR overall. Such a lack of clarity on Regime leadership can have negative consequences in the future, if and when decisions need to be made affecting more than one Directorate.

3.4 Delivery and Implementation

This sub-section examines the extent to which Health Canada's responsibilities under CAMR have been implemented as planned. It provides an assessment of the extent of implementation of the Regime to date and a discussion of the factors that have inhibited certain of the planned activities.

Finding 9: Health Canada has implemented its responsibilities as needed.

Health Canada has implemented its responsibilities under CAMR according to the design in the logic model, except where limited by external factors, such as lack of uptake, as described in the next finding. Because of these factors, not all activities shown in the logic model have been undertaken to date. Exhibit 3.5 presents the portion of the PMF for Health Canada's responsibilities under CAMR related to outputs (a complete version of the PMF can be found in Appendix IX). It shows, for each output, the associated indicators, baseline measures and measures of that indicator as of September 2007. A more comprehensive description of achievements to date is provided below this table. Please refer to Section 3.6 for information on financial expenditures.

Since targets have not been set for any of these indicators (apart from existing targets not specific to CAMR[18]), and in the absence of some other comparison, the table does not provide an assessment of the extent to which performance has matched expectations for this period. For this reason, exhibit 3.5 is best regarded not as an assessment of performance, but rather as an overview of which services have been required to date under the Regime.

[18] There are targets set in terms of number of days for submission reviews within TPD: 150 days for generic submission reviews, and 300 days for clinical reviews. These are not specific to CAMR reviews.

Exhibit 3.5 Output achievement to date: HC's responsibilities under CAMR

LOGIC MODEL ELEMENT	INDICATOR	BASELINE MEASURE	MEASURE – 2007
Outputs			
Policy, Legal & Regime Support	Regulatory framework in place	Existing regulatory framework; CAMR-specific modifications needed	CAMR-specific modifications made to the regulatory framework.
	# & type of new policies, guidance documents and SOPs against planned	Existing policies, guidance documents or SOPs; CAMR-specific modifications needed	The following guidance documents and SOPs have been developed for the various components of CAMR within Health Canada: **Overall CAMR:** guidance, SOPs and process maps on overall CAMR process **Product Evaluation:** SOPs on review process **Post-market surveillance:** Draft guidance on risk communication and reporting adverse reactions to marketed health products **Compliance and enforcement:** Inspection strategy, pre-export inspection SOP and notification guide **Communications and outreach:** Outreach strategy
	Modifications to current tracking systems (content, scope, etc. against planned)	Existing tracking systems	Data not available
Product Evaluation	Submission review meets stated targets	No CAMR submissions received	Three bioequivalence reviews and one clinical review have been conducted. All have been within the review performance targets (150 days for generic submission reviews, 300 days for clinical reviews)
	# and type of decisions made on product submissions	No CAMR decisions	Product submissions placed on patent hold
	# of and total $ amount of fee remissions	No fee remissions	No fee remissions
Post-Market Surveillance	Type of enhancements made to policy & processes for risk communication and adverse reaction (AR) reporting	Existing domestic policies and processes	Draft guidance developed on risk communication and adverse reaction reporting

LOGIC MODEL ELEMENT	INDICATOR	BASELINE MEASURE	MEASURE – 2007
	Number of AR reports received from manufacturers under CAMR	No existing reports	None
	# of risk communications issued related to CAMR products	No risk communications issued related to CAMR products	None
Compliance / Enforcement	# of inspections, assessments, and compliance verifications	No inspections, assessments, or verifications	None
	# and type of enforcement actions taken on pre-export inspections in relation to total # of inspections	No enforcement actions	None
	# of C.07.011 notices to the Minister	No C.07.011 notices	No C.07.011 notices
Communication and Outreach	Description of information and information products	No information or info products	Information products have been created and made available, including CD-ROM, web site, and online user's guide. See Finding 9 – "Communication and Outreach"
	Examples of collaboration and linkages with partners	Description of existing relationships	Health Canada has collaborated with partners and formed linkages internally, across partner departments and internationally as required. See Finding 9 – "Creating Linkages"

Achievement of outputs to date has been appropriate, in that all outputs required have been produced when needed. Those not produced, such as adverse reaction reports and inspections, have been due to lack of need for these services. Interviewees both inside and outside of Health Canada have consistently stated that the Health Canada bureaus and directorates involved in CAMR have performed well in delivering the necessary services, and have done so on a priority basis. 92% of interviewees who responded to the question stated that Health Canada has implemented its roles and responsibilities under CAMR as planned and according to their design. Many of those who did not answer the question stated that it is too early to comment because of the lack of licenses granted. Partner and external stakeholder interviewees also commented positively on the Department's implementation to date of the Regime.

> "My overall experience with Health Canada has been extremely positive. All individuals involved at Health Canada are extremely professional, cognizant of their and CAMR's mandate, and take their work seriously."
>
> *Partner interviewee*
>
> "I can't say enough about Health Canada's staff, their commitment and passion for the process, and their ability to support us."
>
> *External stakeholder interviewee*

Below we describe the extent of implementation for each category of outputs of the Regime.

Policy, Legal and Regime Support

As shown in exhibit 3.5, the outputs for "Policy, Legal and Regime Support" have been largely implemented to date. The regulatory framework for all aspects of CAMR was finalized in June 2005. Guidance documents and SOPs have been developed for all aspects of the Regime, which are undergoing further minor adjustments as implementation progresses.

In the course of this evaluation, Rwanda became the first country to provide a notification of its intent to import under the terms of the WTO Decision, with a request to import the triple-combination HIV/AIDS therapy manufactured by Apotex. On September 4 2007, Apotex applied to the Commissioner of Patents for a compulsory licence, and on September 7, 2007 Health Canada's Office of Patented Medicine notified the Commissioner that the requested product met the requirements of the Food and Drugs Act. On September 19, 2007 the Commissioner of Patents issued the compulsory license to Apotex.

A series of meetings arising out of the successful Apotex application has clarified the steps in the application process, and identified areas where guidance materials need minor adjustments. External stakeholders interviewed expressed satisfaction with this process to date, and expressed a high opinion of the hard work and dedication of those in Health Canada responsible for CAMR.

A performance measurement system has not formally been developed for the Regime.

Product Evaluation

Two bioequivalent study reviews and one clinical review have been conducted as part of Health Canada's product evaluation activities for CAMR. These reviews were all conducted within the performance targets set for them, and external stakeholders spoke positively of Health Canada's ability to bring resources to bear at key decision points and to communicate "clear and unequivocal" recommendations to the applicant manufacturer.

As a result of the successful application by Apotex for a compulsory license, Health Canada undertook a series of consultations to ensure that all directorates understood their responsibilities, and that the design for cross-directorate communication was appropriate. While these consultations confirmed the appropriateness of the design overall (in terms of guidance materials and SOPs developed to date), some areas for improvement were identified. One of these was a letter sent to Apotex after notification was sent to the Commissioner of Patents, listing the immediate next steps in its interactions with Health Canada related to the compulsory license. The utility of this letter was recognized and it was made part of SOPs for future compulsory license applications. Other areas of improvement primarily involved cross-linking guidance materials to ensure appropriate "triggers" were built into the process to signal the need for involvement of individual directorates.

Post-Market Surveillance

As shown in exhibit 3.5, the guidance document for risk communication[19] under CAMR has been developed in draft form and has been circulated within HPFB for comments. The document is under review and will soon be sent out to external stakeholders for comments.[20] The guidance document for industry on Reporting Adverse Reactions to Marketed Health Products is being adapted to address aspects of foreign adverse reaction reports for health products exported under CAMR and will be going for a second round of external consultations. Risk communication has posed difficulties for Health Canada due to the challenges around communicating risk internationally. Health Canada recognizes the need to have effective risk communication processes in place, and is currently building on domestic mechanisms as well as foreign partnerships to establish the necessary links.

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[19] Risk communication refers to the communication of risks arising from adverse effects of health products authorized for export under CAMR.

[20] Subsequent to the time of data collection for this evaluation, the Risk Communication Guidance Document for CAMR was posted on the Health Canada web site for external stakeholder consultation (November 22, 2007).

Compliance and Enforcement

The Inspectorate has used its CAMR resources for coordination and planning activities, but also for inspections in the regions: Some funds were used to carry out current GMP inspections of generic drug manufacturers to ensure that potential manufacturers using CAMR comply with GMP standards, so as not to delay the process should they decide to submit a compulsory license application.

HPFBI is preparing for a pre-export inspection of Apotex, which may occur soon. Consultations across directorates have clarified processes for ensuring HPFBI's information requirements are met prior to conducting this inspection.

Communication and Outreach

While Health Canada is not the department primarily responsible for CAMR communication and outreach activities, it has recognized a need among partner departments for technical expertise in aspects of the Regime related to health, and has responded with information packages and other assistance in order to help raise awareness of CAMR among potential participants.

> "Health Canada has done a lot of work on outreach [domestically and internationally]. Health Canada has done a good job – it has done its work to its maximum."
>
> *Key informant*
>
> "Health Canada has put great information packages together, with help from other departments. It took the lead in that."
>
> *Partner interviewee*

Health Canada has led the development of a website for CAMR and outreach materials including a CD-ROM and an online user's guide. The materials produced by Health Canada have been positively commented on by partner interviewees as being of high quality.

Health Canada has also engaged in workshops and conferences and in some "practical outreach": providing support to firms and countries as required to clarify the steps involved in participating in the Regime. According to some key informants more outreach could have been done towards the Global Fund, the Gates Foundation or other international actors.

The individuals within Health Canada engaged in communications and outreach are highly regarded. Health Canada, and in particular a number of individuals, have been mentioned repeatedly as having been key for successful outreach to various stakeholders in Canada and internationally. Their personal commitment, expertise and diplomatic skills were acknowledged.

While many of Health Canada's activities under CAMR were identical or similar to its domestic regulatory activities, the implementation of CAMR required linkages to be created among participating directorates, among partner departments and agencies, and internationally (in particular the WHO), to ensure information is shared and that the "triggers" for involvement of each stakeholder are clear to all. According to key informants, Health Canada has been successful in establishing these linkages. However, several of those interviewed were unclear about the lines of responsibility within CAMR. It was unclear to some which department had the lead on the overall Regime, while internally it was not clear to all who had the overall responsibility for decision-making within Health Canada for larger issues beyond the responsibilities of individual directorates (such as statutory review and the future direction of CAMR).

In terms of international linkages, key informants outside of TPD, while aware that the Directorate was interacting with the WHO and others on CAMR, were generally unaware of the specifics. Within TPD, all key informants felt that there were "good, effective linkages" with international organizations and with the WHO in particular. Other than for the WHO, international relationships are generally the responsibility of FAITC or other departments.

Most respondents agreed that Health Canada formed effective linkages across CAMR partners. This view was shared by those within the partnering departments: "They have always been very respectful and conscious of other departments' mandates, and have done a good job in briefing others, and consulting with others. They never take an important decision without consulting others." Some key informants and

partner stakeholders, however, noted differences in purposes, interests, and cultures of the partner departments affecting the success of these relationships, while agreeing that working relationships among the departments are generally good.

Several key informants felt that there are no major difficulties since all directorates directly involved are in the same branch. However, others expressed a desire to better understand CAMR's "big picture", and stated that there is room for improvement regarding communication across directorates. Since the entire process has not yet been operationalized, not all key informants were clear on the triggers in the process that alerted other directorates of the receipt of an application and the issuance of a compulsory license so that the various directorates can take appropriate action.

Finding 10: Outputs not completed to date are due to factors outside of Health Canada, such as lack of uptake of the Regime. Health Canada has effectively adapted its implementation to changes in context.

As noted in Exhibit 3.5 above, not all outputs have been achieved to date, such as fee remissions, adverse reaction reports and pre-export inspections. This is due primarily to the lack of uptake of the Regime – up until July 2007 no countries had declared interest in participating under the WTO Decision. It is important to note that this lack of uptake is experienced internationally and is not unique to Canada. The reason for this lack of demand is not agreed upon by all. This is examined by the statutory review of CAMR by Industry Canada.

According to key informants, other outside influences that have affected which activities of the Regime have been undertaken include:

- Changes in government leadership which led to some CAMR activities being stalled for several months.
- The sensitivity of the topic and the difficulty in determining the optimal balance between improving access to needed medicines in the developing world, while respecting international trade obligations and maintaining the integrity of the domestic patent system.

Health Canada has been effective in adapting its implementation to external factors. One such change arose over the issue of WHO's PQP. Some external stakeholders believe that this Programme duplicates the efforts of Health Canada under CAMR. However, Health Canada officials have ensured Health Canada's reviews are accepted under this Programme. Health Canada had to adapt its procedures surrounding the issuance of Certificates of Pharmaceutical Products in order to allow drug products manufactured for CAMR to be listed on the WHO's PQP list without rendering the product eligible for marketing in Canada. Certificates of Pharmaceutical Products granted to a generic product normally allow for its sale in Canada. However, in this instance, the Certificate was needed for the product to be included in the list of eligible products maintained by the WHO, and the product was not intended for sale domestically. According to at least one external stakeholder interviewee, this problem was "sorted out in a number of days", due to the priority that Health Canada has placed on it.

Challenges also arose around distinguishability features (required under the WTO Decision). According to key informants and external stakeholder interviewees, there have been some concerns among generic manufacturers that requirements for distinguishability can affect the quality and cost of drugs. Health Canada has been working with generic manufacturers and others to ensure minimal cost to participating companies while upholding the intent of the WTO Decision.

Another challenge arose after Rwanda notified of its intent to import under the WTO Decision. Due to Rwanda's competitive bidding requirements for procurement, Apotex needed to ensure its price would be competitive. It therefore identified less expensive sources for certain raw materials than what was originally approved by Health Canada. According to both key informants and external stakeholder interviewees, Health Canada moved quickly to review and approve the new material sourcing.

3.5 Effectiveness

The effectiveness of a program or regime can be defined as the extent to which it achieves its intended results. In this section, we discuss Health Canada's performance in achieving the intended outcomes of CAMR, as defined in the logic model (see Appendix VIII). The indicators in the Performance Measurement Framework (PMF) for Health Canada's responsibilities under CAMR measure achievement of these results.

Finding 11: Due to limited uptake of the Regime to date, a complete assessment of effectiveness is not possible. However, there are some early indications of outcome achievement.

It is not possible to claim that CAMR has been effective to date in achieving its goal of facilitated access to generic products, since access to products has not been facilitated in any measurable way. In terms of Health Canada's responsibilities under CAMR, some progress towards achievement of outcomes can be seen in the participation of external stakeholders (manufacturers and countries) in the Regime.

Exhibit 3.6 shows the progress made in intended outcomes, as measured by the outcome indicators of the PMF (a complete version of the PMF can be found in Appendix IX). As discussed in Finding 6, however, not all of the outcomes and indicators shown here are appropriate for the Regime at the outcome level, as several refer to issues of implementation.

Exhibit 3.6 Outcome achievement to date: HC's responsibilities under CAMR

LOGIC MODEL ELEMENT	INDICATOR	BASELINE MEASURE	MEASURE – 2007
Immediate Outcomes			
Fully operational CAMR (Health Canada)	Infrastructure in place (employees, processes, tracking systems, guidance documents, regulatory framework, SOPs, fee remittance)	No infrastructure in place	Infrastructure mostly in place. See Finding 9.
Efficient and effective systems and processes (Health Canada)	Staff fully trained on new systems and CAMR processes	Staff not trained, no new systems or processes	Meetings have taken place to ensure consensus and clarity on systems and processes for CAMR within Health Canada. While there have been some areas requiring clarification (see Finding 9), in general the personnel involved were clear on their respective responsibilities. Formal training of all Health Canada GMP inspectors occurred in April 2006 in order to prepare the inspectors for upcoming pre-export inspections under CAMR.
Full integration and flow of information (IC, CIPO)	Level of satisfaction among manufacturers	N/A	The one manufacturer available for interview indicated satisfaction with integration and flow of information across departments.

Logic Model Element	Indicator	Baseline Measure	Measure – 2007
Integrated approach to outreach with federal partners (IC, CIPO, FAC, ITC, CIDA, CBSA)	Evidence of collaboration	N/A	Communication strategy developed for CAMR. Health Canada has conducted outreach and has supported the outreach activities of partner departments. See Finding 9.
Enhanced awareness of and interest in Regime (Manufacturers)	# of inquiries and pre-submission meetings	No requests for inquiries and pre-submission meetings received	Data not available
	Level of awareness and interest	N/A	The one manufacturer available for interview for this evaluation has declared interest and is actively participating in the Regime.
Compliance with regulations (Manufacturers)	% of compliant pre-export inspections	No pre-export inspections	None
Enhanced awareness of and interest in Regime (International Partners, NGOs, Public, Other Stakeholders)	Level of awareness and interest	N/A	Data not available
	# of web site hits	No web hits	14,607 page views from May to August 2007
Intermediate Outcomes			
Countries and manufacturers participate in Regime	# of countries participating	No countries participating	One country participating
	# of manufacturers participating	No manufacturers participating	One manufacturer participating (one other manufacturer has submitted products for review)
Products meet Canadian standards and regulatory requirements and are distinguishable from patented products	# of notifications to Commissioner of Patents	No CAMR notifications issued	One notification to Commissioner of Patents

3.6 Efficiency

This section examines the *efficiency* of Health Canada's responsibilities under CAMR; specifically, the degree to which money for the Regime has been spent as planned.

Finding 12: Funds that Health Canada has received for CAMR have largely been spent as planned.

Despite difficulties in tracking spending for CAMR, it appears that funds have largely been spent as planned. Tracking expenditures for CAMR is a challenge for Health Canada due to the nature of the Department's financial system. The system does not easily allow for coding of activities of personnel who work on more than one file.

Exhibits 3.7 to 3.9 below show the planned versus actual expenditures for Health Canada's responsibilities under CAMR for the fiscal years 2004-05 to 2006-07. The differences shown are a result of the following:

- TPD undertook communication and outreach activities that were not in the original budget. This has resulted in money that was originally allocated to Program, Legal and Regime Support moved to Communication and Outreach.
- Less money was spent on Policy, Legal and Regime Support than was planned as the planned amount included a frozen allotment that was not needed in the policy area.
- Some funding was lapsed due to delays in staffing.
- A spending freeze occurred in fiscal year 2005-06.
- Some costs, such as the cost of contracted legal services, were less costly than anticipated.

Exhibit 3.7 Planned vs. Actual Spending, FTEs, Salary and Operating – Fiscal Year 2004-05

Program Activity	FY 2004-05											
	FTEs			Salary (incl. EBP & Accom)			Operating			Total - Salary and Operating		
	Planned	Actual	Diff.	Planned	Actual	Diff.	Planned	Actual	Diff.	Planned	Actual	Diff.
Policy, Legal and Administration (plus Variable Costs)												
TPD	5.50	2.78	-2.72	450,036	250,959	-199,077	250,539	193,585	-56,954	700,575	444,544	-256,031
BGTD	0.80	0.80	0.00	53,408	60,351	6,943	33,829	33,829	0	87,237	94,180	6,943
Subtotal	**6.30**	**3.58**	**-2.72**	**503,444**	**311,310**	**-192,134**	**284,368**	**227,414**	**-56,954**	**787,812**	**538,724**	**-249,088**
Pharmaceutical and Biologics Review												
TPD	2.00	2.10	0.10	256,284	268,392	12,108	48,391	45,000	1,609	299,675	313,392	13,717
BGTD	0.00	0.00	0.00	0	0	0	0	0	0	0	0	0
Subtotal	**6.30**	**2.10**	**0.10**	**256,284**	**268,392**	**12,108**	**48,391**	**45,000**	1,609	299,675	**313,392**	**13,717**
Compliance and Enforcement												
Inspectorate	0.80	0.80	0.00	80,040	90,445	10,405	13,788	13,788	0	93,828	104,233	10,405
Subtotal	**0.80**	**0.80**	**0.00**	80,040	90,445	10,405	**13,788**	**13,788**	**0**	93,828	**104,233**	10,405
Post-Market Surveillance												
MHPD	0.00	0.00	0.00	0	0	0	24,175	24,175	0	24,175	24,175	0
Subtotal	**0.00**	**0.00**	**0.00**	**0**	**0**	**0**	**24,175**	**24,175**	**0**	**24,175**	**24,175**	**0**
Communication and Outreach												
TPD	0.00	1.86	1.86	0	187,641	187,641	0	194,340	194,340	0	381,981	381,981
Subtotal	**0.00**	**1.86**	**1.86**	**0**	**187,641**	**187,641**	**0**	**194,340**	**194,340**	**0**	**381,981**	**381,981**
Departmental Costs			**0**			**0**	**186,707**	**186,707**	**0**	**186,707**	**186,707**	**0**
PWGSC Accom			**0**			**0**	**107,803**	**107,803**	**0**	**107,803**	**107,803**	**0**
Frozen Allotment			**0**			**0**			**0**	**0**	**0**	**0**
Subtotal	**0.00**	**0.00**	**0.00**	**0**	**0**	**0**	**294,510**	**294,510**	**0**	**294,510**	**294,510**	**0**
Total	**9.10**	**8.34**	**-0.76**	**839,768**	**857,788**	**18,020**	**660,232**	**799,227**	**138,995**	**1,500,000**	**1,657,015**	**157,015**

Exhibit 3.8 Planned vs. Actual Spending, FTEs, Salary and Operating – Fiscal Year 2005-06

Program Activity	FY 2005-06											
	FTEs			Salary (incl. EBP & Accom)			Operating			Total - Salary and Operating		
	Planned	Actual	Diff.	Planned	Actual	Diff.	Planned	Actual	Diff.	Planned	Actual	Diff.
Policy, Legal and Administration (plus Variable Costs)												
TPD	7.80	2.37	-5.43	651,120	378,812	-272,308	337,413	118,536	-218,877	988,533	497,348	-491,185
BGTD	3.10	3.10	0.00	218,838	249,775	30,937	510,086	510,086	0	728,924	759,861	30,937
Subtotal	**10.90**	**5.47**	**-5.43**	**869,958**	**628,587**	**-241,371**	**847,499**	**628,622**	**-218,877**	**1,717,457**	**1,257,209**	**-460,248**
Pharmaceutical and Biologics Review												
TPD	4.30	4.10	-0.20	542,400	685,865	143,465	52,785	37,800	-14,985	595,185	723,665	128,480
BGTD	0.30	0.30	0.00	23,052	23,052	0	11,959	11,959	0	35,011	35,011	0
Subtotal	**4.60**	**4.40**	**-0.20**	**565,452**	**708,917**	**143,465**	**64,744**	**49,759**	**-14,985**	**630,196**	**758,676**	**128,480**
Compliance and Enforcement												
Inspectorate	2.50	3.13	0.63	215,640	419,953	204,313	248,310	50,200	-198,110	463,950	470,153	6,203
Subtotal	**2.50**	**3.13**	**0.63**	215,640	**419,953**	204,313	**248,310**	**50,200**	**-198,110**	463,950	**470,153**	6,203
Post-Market Surveillance												
MHPD	0.80	0.80	0.00	70,800	80,004	9,204	16,293	0	-16,293	87,093	80,004	-7,089
Subtotal	**0.80**	**0.80**	**0.00**	70,800	**80,004**	9,204	**16,293**	**0**	**-16,293**	87,093	**80,004**	-7,089
Communication and Outreach												
TPD	0.00	0.72	0.72	0	284,001	284,001	0		0	0	284,001	284,001
Subtotal	**0.00**	**0.72**	**0.72**	**0**	**284,001**	**284,001**	**0**	**0**	**0**	**0**	**284,001**	**284,001**
Departmental Costs				**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Evaluation PPIAD						**0**	**20,000**	**20,000**	**0**	**20,000**	**20,000**	**0**
PWGSC Accom						**0**	**166,264**	**166,264**	**0**	**166,264**	**166,264**	**0**
Frozen Allotment						**0**	**415,040**	**0**	**-415,040**	**415,040**	**0**	**-415,040**
Subtotal	**0.00**	**0.00**	**0.00**	**0**	**0**	**0**	**601,304**	**186,264**	**-415,040**	**601,304**	**186,264**	**-415,040**
Total	**18.80**	**14.52**	**-4.28**	**1,721,850**	**2,121,462**	**399,612**	**1,778,150**	**914,845**	**-863,305**	**3,500,000**	**3,036,307**	**-463,693**

Exhibit 3.9 Planned vs. Actual Spending, FTEs, Salary and Operating – Fiscal Year 2006-07

PROGRAM ACTIVITY	FY 2006-07											
	FTES			SALARY (INCL. EBP & ACCOM)			OPERATING			TOTAL - SALARY AND OPERATING		
	PLANNED	ACTUAL	DIFF.	PLANNED	ACTUAL	DIFF.	PLANNED	ACTUAL	DIFF.	PLANNED	ACTUAL	DIFF.
Policy, Legal and Administration (plus Variable Costs)												
TPD	7.80	3.37	-4.43	231,241	243,571	12,330	233,158	86,836	-136,322	454,399	330,407	-123,992
BGTD	2.00	2.00	0.00	446,050	160,000	-286.050	632,100	0	-632,100	1,078,150	160,000	-918,150
Subtotal	**9.80**	**5.37**	**-4.43**	**677,291**	**403,571**	**-273,720**	**855,258**	**86,836**	**-768,422**	**1,532,549**	**490,407**	**-1,042,142**
Pharmaceutical and Biologics Review												
TPD	4.30	3.55	-0.75	548,759	302,935	-245,824	4,342	2,341	-2,001	553,101	305,276	-247,825
BGTD	0.50	0.50	0.0	56,000	56,000	0	15,000		-15,000	71,000	56,000	-15,000
Subtotal	**4.80**	**4.05**	**-0.75**	**604,759**	**358,935**	**-245,824**	**19,342**	**2,341**	**-17,001**	**624,101**	**361,276**	**-262,825**
Compliance and Enforcement												
Inspectorate	2.50	3.13	0.63	365,280	419,953	54,673	248,310	50,200	-198,110	613,590	470,153	-143,437
Subtotal	**2.50**	**3.13**	**0.63**	365,280	**419,953**	54,673	**248,310**	**50,200**	**-198,110**	613,590	**470,153**	-143,437
Post-Market Surveillance												
MHPD	0.80	0.80	0.00	70,800	65,769	-5,031	15,300	44,073	28,773	86,100	109,842	23,742
Subtotal	**0.80**	**0.80**	**0.00**	70,800	**65,769**	-5,031	15,300	**44,073**	28,773	86,100	**109,842**	23,742
Communication and Outreach												
TPD	0.00	0.00	0.00	0	0	0	0		0	0	0	0
Subtotal	**0.00**	**0.00**	**0.00**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Departmental Costs							**433,308**	**433,308**	**0**	**433,308**	**433,308**	**0**
Evaluation PPIAD							**0**	**0**	**0**	**0**	**0**	**0**
PWGSC Accom							**214,462**	**214,462**	**0**	**214,462**	**214,462**	**0**
Frozen Allotment							**495.890**	**0**	**-495.890**	**495.890**	**0**	**-495.890**
Subtotal	**0.00**	**0.00**	**0.00**	**0**	**0**	**0**	**1,143,660**	**647,770**	**-495.890**	**1,143,660**	**647,7700**	**-495.890**
Total	**17.90**	**13.35**	**-4.55**	**1,718,130**	**1,248,228**	**-469,902**	**2,281,870**	**831,220**	**-1,450,650**	**4,000,000**	**2,079,448**	**-1,920,552**

4. Conclusion and Recommendations

This section presents the conclusion and recommendations arising from the evaluation. A summary list of all recommendations can be found in Appendix III.

4.1 Conclusion

Overall, there is a near-consensus that Health Canada has implemented its responsibilities well under this Regime and according to design. The fact that up until recently no authorization had been granted is due to factors outside of Health Canada's areas of responsibility and therefore out of the scope of this evaluation. The majority view among those interviewed, both inside and outside Health Canada, is that the Department has fulfilled its obligations and met the needs of its partners and external stakeholders.

There is some room for improvement, as described in the recommendations below. However, for the most part Health Canada has been effective in identifying needed areas for improvement and adjusting its implementation accordingly.

Some findings have not resulted in recommendations (i.e., Findings 2 to 5 and 10 to 12). This is because the findings were positive and no significant changes were required, or because the findings were more descriptive in nature, providing context to later findings (e.g., Finding 3 – see footnote 9).

4.2 Recommendations

Recommendation 1: Health Canada should implement its Performance Measurement System for CAMR

Relates to findings: 6 – Logic model; and 9 – Implementation

As mentioned in Finding 9, Health Canada has developed a PMF for its responsibilities but has not yet implemented the system. Due to limited uptake of the Regime, there has been no performance data generated for some activity areas, but performance measurement should have been ongoing in those areas where there has been activity (i.e., in the "Policy, Legal & Regime Support", "Product Evaluation" and "Communication and Outreach" areas). Health Canada should begin to track the data on its indicators. It may wish to begin with the data collected for this evaluation, as shown in Exhibits 3.5 and 3.6 above.

Health Canada may also wish to revisit the design of its logic model and PMF, as per the suggestions in Finding 6. For example, the two immediate outcomes related specifically to Health Canada ("fully operational CAMR" and "efficient and effective systems and processes") may be omitted as a duplication of outputs, and the number of indicators may be reduced.

Recommendation 2: Health Canada should continue to monitor developments in international jurisdictions that have developed legislation or policies related to the WTO Decision to learn from their experiences.

Relates to findings: 1 – Context

Due to a lack of uptake of the WTO Decision internationally, it is not yet possible for Health Canada to learn from the experiences of others. Canada's Regime provides a different structure from those of other jurisdictions in many respects, including the Schedule 1 list of eligible products, the health and safety review, and post-market surveillance. If and when other countries grant compulsory licenses under the WTO Decision, Health Canada may wish to monitor the experiences of these other jurisdictions to learn the relative advantages and disadvantages of each model. Lessons may also be derived from these experiences to improve standard operating procedures in Canada.

Recommendation 3: Health Canada should revisit allocations of funding to Directorates involved in CAMR and, in particular, increase funding allocated to post-market surveillance and communication and outreach.

Relates to findings: 7 – Resource allocations

While Finding 7 notes that resource allocations for Health Canada's responsibilities under CAMR were appropriate for the most part, the amount allocated to MHPD for its post-market surveillance activities was insufficient. Furthermore, the allocations established in the Treasury Board Submission do not take account of the need for communication and outreach activities. As a result, funding for communication and outreach has had to come from other areas (such as Regime Support). Health Canada should review allocations for future fiscal years and adjust as necessary. This review should attempt to develop a mechanism for establishing appropriate allocations for the Regime.

Recommendation 4: Health Canada should continue to clarify and amend, as needed, its guidance documents and lines of accountability.

Relates to findings: 8 – Roles and responsibilities; 9 – Implementation

Health Canada continues to be effective in developing and amending its SOPs and guidance materials as it learns from experience in implementing CAMR. However, there are still areas where further refinement and clarification would be desirable, primarily in areas of inter-Directorate responsibilities. Guidance materials developed by the Directorates may need to be compared to each other to ensure they are cross-linked. This will most likely evolve over time through the experience of practice.

As noted in Finding 8, there was some lack of clarity among Health Canada personnel about which Directorate has lead responsibility for the Regime within the Department. The Regime's internal structure, including lines of accountability, needs to be clarified or communicated to those involved internally.

Appendix I Evaluation Framework

Issue	Questions	Data Collection					Description of Methodology
		Case Scenario Exercise	PM System	Document Review	Key Informant Interviews	Stakeholder Interviews	
Rationale	Does this Program overlap with any similar programs? (At either the federal or provincial levels) Do the objectives of Health Canada's responsibilities under the Regime align with Departmental and Government priorities and the needs of stakeholders and beneficiaries?			✓	✓	✓	Research and analysis on Canadian programs. Interviews with key informants and select stakeholders.
Planning & Design	Are the design of CAMR activities and outputs plausibly linked to the attainment of outcomes as outlined in the logic model? How appropriate is the logic model in terms of its vertical and horizontal logic? What are the assumptions of these logical linkages?			✓	✓		Review of logic model and other documentation. Interviews with Program personnel within HC.
	To what extent is the infrastructure for CAMR fully operational? (e.g., policies, procedures, etc.) How appropriate are the budgeted resource allocations to the program design? How appropriate are the roles and responsibilities within Health Canada for CAMR?		✓	✓	✓		Analysis of relevant indicators from the PM System. Review of documents describing implemented policies and procedures, including SOPs, guidance documents, etc., compared against planned, as described in TB Submission. Interviews with key HC Program personnel.
	How has the communication and outreach program been designed to contribute to the attainment of outcomes?			✓	✓	✓	Review of documented decisions regarding communication and outreach activities. Interviews with HC personnel involved and relevant partners. Since communication and outreach is an interdepartmental responsibility, an interdepartmental perspective will be reflected in answering this question.

Issue	Questions	Data Collection					Description of Methodology
		Case Scenario Exercise	PM System	Document Review	Key Informant Interviews	Stakeholder Interviews	
Delivery / Implementation	Is CAMR being implemented as planned and according to its design? If not, what are the differences and challenges encountered? (e.g. intended positive and unintended negative impacts) Were roles and responsibilities fulfilled (including operational activities, management, monitoring and evaluation, and reporting)?	✓	✓	✓	✓	✓	Information collected from PM System. Review of project reports and other documentation, compared against planned, as described in the TB Submission, etc. Interviews with key informants and stakeholders.
	To what extent are expected activities and outputs (as outlined in the logic model) being achieved? What are the reasons for variances?		✓	✓	✓	✓	Information collected from PM System and from other CAMR tracking systems. Review of key documents including project reports, etc. Interviews with key informants and stakeholders.
	Are there any best practices from other jurisdictions that could provide information in terms of lessons learned to improve the delivery of CAMR?			✓	✓	✓	Best practice research and analysis, corroborated by interviewees from other jurisdictions if available.
	Are there effective linkages with internal and international partners to support CAMR?		✓	✓	✓	✓	Information collected from PM System. Review of communication products developed and other documentation. Interviews with key informants.
	To what extent have there been environmental factors that have impacted on the implementation of CAMR? How has CAMR responded to these?			✓	✓	✓	Interviews with key informants and stakeholders. Comparison of anticipated environmental factors with those factors that have actually had an impact.
	Did the communication and outreach strategies that were used in promoting CAMR actually achieve their intended purposes?				✓	✓	Interviews with Key Informants and stakeholders.
	Are there any suggestions on how to improve the communication and outreach strategies that could contribute to the attainment of the outcomes of CAMR?				✓	✓	Interviews with Key Informants and stakeholders.

Issue	Questions	Data Collection					Description of Methodology
		Case Scenario Exercise	PM System	Document Review	Key Informant Interviews	Stakeholder Interviews	
Effectiveness	To what extent does CAMR have efficient and effective processes? How is this revealed?		✓	✓	✓	✓	Analysis of degree to which regulated performance targets have been met. Analysis of impact of CAMR Regime on core HPFB activities.
	To what extent has CAMR succeeded in developing an integrated approach to Regime delivery with federal partners?				✓	✓	Interviews with federal partners involved operationally in the Regime (CIPO, IC, CBSA) to identify evidence of collaboration.
	What is the level of participation by countries, manufacturers and other stakeholders in CAMR?		✓	✓	✓	✓	Level of satisfaction and participation as defined in PM Strategy. Interviews with key informants and stakeholders.
	To what extent are manufacturers and products in compliance with standards and regulations?		✓	✓	✓		Count of notices to CIPO. Key informant interviews.
Efficiency	Are the funds being spent as planned? Are there any gaps, lapses or re-allocation of funding?			✓	✓		Review of documentation, information from financial systems, and interviews with key informants.
Recommendations and Lessons Learned	How could the implementation of CAMR be improved? What are the lessons learned?	✓	✓	✓	✓	✓	

Appendix II List of Findings

Finding 1: A lack of uptake of the WTO Decision in other countries means that little can be learned from international models

Finding 2: Health Canada's responsibilities under the Regime are clearly aligned with the Department's role, capacities and expertise. Its alignment with the priorities and strategic outcomes of the Department and of the GoC could be better reflected.

Finding 3: While Health Canada's responsibilities under CAMR were designed to meet the needs of external stakeholders as much as possible, there is disagreement among external stakeholders on what the Department's role in the Regime should be.

Finding 4: The planning and design process for Health Canada's responsibilities under CAMR was appropriate.

Finding 5: The activities that HC has undertaken to implement the Regime have changed over time, in recognition of changing realities.

Finding 6: The logic model for Health Canada's responsibilities under CAMR is appropriate, but there is some room for improvement.

Finding 7: In most cases, resource allocations are appropriate for Health Canada's responsibilities under CAMR, despite difficulties in assessing appropriate allocations. However, a greater amount is needed for post-market surveillance.

Finding 8: HC's roles and responsibilities under CAMR are appropriate. Internally it was not always clear to all who had the overall responsibility for decision-making within Health Canada for larger issues beyond the responsibilities of individual directorates (such as statutory review and the future direction of CAMR).

Finding 9: Health Canada has implemented its responsibilities as needed.

Finding 10: Outputs not completed to date are due to factors outside of Health Canada, such as lack of uptake of the Regime. Health Canada has effectively adapted its implementation to changes in context.

Finding 11: Due to limited uptake of the Regime to date, a complete assessment of effectiveness is not possible. However, there are some early indications of outcome achievement.

Finding 12: Funds that Health Canada has received for CAMR have largely been spent as planned.

Appendix III List of Recommendations

Recommendation 1: Health Canada should implement its Performance Measurement System for CAMR

Recommendation 2: Health Canada should continue to monitor developments in international jurisdictions that have developed legislation or policies related to the WTO Decision to learn from their experiences.

Recommendation 3: Health Canada should revisit allocations of funding to Directorates involved in CAMR and, in particular, increase funding allocated to post-market surveillance and communication and outreach.

Recommendation 4: Health Canada should continue to clarify and amend, as needed, its guidance documents and lines of accountability.

Appendix IV List of Interviewees

The following organizations were interviewed for this evaluation. All interviews were in-person, individual interviews except for the interview with Médecins Sans Frontières, which was conducted via e-mail, and the four interviewees from Marketed Health Products, Health Canada, who were interviewed together in a group.

Health Canada

- Six interviewees from Therapeutic Products Directorate, HPFB
- Two interviewees from Biologics and Genetic Therapies Directorate, HPFB
- Four interviewees (interviewed together) from Marketed Health Products Directorate, HPFB
- Two interviewees from Health Products and Food Branch Inspectorate, HPFB

Government of Canada CAMR Partners

- One interviewee from Industry Canada
- One interviewee formerly of Foreign Affairs and International Trade
- One interviewee from Canadian International Development Agency

External Stakeholders

- One organization-wide response from Médecins Sans Frontières
- One interviewee from Apotex

Appendix V Document List

The table below lists the documents reviewed for this evaluation. The columns marked "Report Section" indicate which sections of the evaluation report each document or set of documents was used for.

Document	Report Section					
	2.1 Context	2.2 Rationale	2.3 Planning and Design	2.4 Delivery and Implementation	2.5 Effectiveness	2.6 Efficiency
Legislation, regulations, policies and other documentation on the responses to the WTO Decision in other jurisdictions[21]	✓					
Treasury Board Submission on the Access to Medicines Program, December 2004		✓	✓			
Canada's Access to Medicines Regime (CAMR) Performance Measurement and Accountability Framework, Health Canada, March 2007		✓	✓	✓	✓	✓
Canada's Access to Medicines Regime Web Log Analysis Custom Date Range Report, NetIQ Corporation, September 2007				✓	✓	
Stakeholder comments on CAMR consultation paper (comments from 28 organizations)		✓	✓	✓		
Oxfam Briefing Paper 95: Patents versus Patients, November 2006		✓	✓			
Evidence from Standing Committee on Industry, Science and Technology, 39th Parliament, 1st Session, April 16, 18 and 23 2007		✓	✓	✓	✓	
Industry Canada Draft Statutory Review of CAMR, October 2007		✓				
SOPs, guidance, strategies and process maps for Health Canada's responsibilities under CAMR			✓	✓		

[21] See Implementation-Focused Evaluation of Canada's Access to Medicines Regime (CAMR), First Technical Report: Survey of Experiences in Other Jurisdictions, Appendix I.

Appendix VI Interview Questions

Key Informant Interviews (Health Canada)

Background: Health Canada received Treasury Board funding for the implementation of its responsibilities under Canada's Access to Medicines Regime (CAMR). It is required to carry out an evaluation to account for the appropriate use of these resources.

Purpose of this evaluation: To provide senior management in Health Canada with timely information on how well Health Canada's responsibilities under CAMR have been implemented to date. This will enable mid-course corrections to be taken, if required, increasing the likelihood of achieving the ultimate outcomes.

Objectives of this interview: To obtain your feedback on the effectiveness of implementation of Health Canada's responsibilities under the Regime.

Please be assured that your responses to these questions will be kept strictly confidential. Individual responses will be aggregated or kept anonymous in all reports for this evaluation.

Background

- What are the overall responsibilities of your Directorate/Bureau under CAMR?
- When did you begin working on CAMR and what are your responsibilities?

Rationale

- Do you think that the objectives of Health Canada's responsibilities under the Regime align with the overall objectives of CAMR, and with the needs of CAMR beneficiaries (developing countries) and stakeholders (e.g. manufacturers, NGOs,)?
- Are you aware of any similar programs at federal or provincial levels that may overlap with Health Canada's responsibilities under CAMR?

Planning and Design

- Have you been involved in the planning and design processes of specifying Health Canada's role in CAMR (including development of TB Submission, logic model and PMAF, or other strategic level planning/design processes)? If yes, what, in your opinion, were strengths and weaknesses of these processes?
- Do you feel that the design of Health Canada's responsibilities under CAMR, as outlined in the logic model, is appropriate? What factors may impede the achievement of expected outcomes?
- In your view, how appropriate are the roles and responsibilities assigned to your Directorate/Bureau under CAMR given existing capacities and areas of expertise?

Delivery and Effectiveness

- What specific activities/processes related to the implementation of CAMR has your Directorate/Bureau carried out to date? What went well/ what were challenges? Can be further elaborated into targeted questions to specific individuals, e.g.:
    - Development of Regulatory Regime (all interviewees): Were you directly involved in the development of the regulatory regime (e.g. policies, regulations, procedures)? If so, in your experience, how well did the process go? Were there any surprises or unintended results? Were appropriate stakeholders involved? What are the strengths and weaknesses of the resulting infrastructure developed?

- Drug Submission process (select interviewees: In your experience, how effective and efficient is the current process for drug submissions? What has worked well and what are areas for improvement? Were there any surprises or unintended results? What challenges have been experienced?
- Communication and Outreach (select interviewees): What do you see as the role of Health Canada for outreach for CAMR? Do you feel that Health Canada is fulfilling this role? What went well and what have been the challenges or limitations in Health Canada's outreach activities to date? Were there any surprises or unintended results?

- What external influences or events have had an impact on the implementation of Health Canada's responsibilities under CAMR? How has Health Canada responded to these?
- In your view, has Health Canada formed effective linkages with international health partners (e.g. WHO, drug regulatory authorities) to support the implementation of its responsibilities under CAMR?
- To members of the Inter-Departmental Working Group: What is the role of the Inter-Departmental Working Group? To what extent do you think the federal departments involved in CAMR have developed an integrated approach to the delivery of the Regime? To communication and outreach activities? To what extent has there been full integration and flow of information among departments?
- Have the funds for your Directorate/Bureau been spent as planned? What is the reason for any variations?
- What, in your opinion, can Health Canada do to further improve the implementation of its responsibilities under CAMR? Are you aware of any processes implemented by other drug regulating authorities in other countries that could help to inform Health Canada's implementation of its responsibilities under CAMR?

Key Informant Interviews (Government Partners)

Background: Health Canada has received Treasury Board funding for the implementation of its responsibilities under Canada's Access to Medicines Regime (CAMR). It is required to carry out an evaluation to account for the appropriate use of these resources.

Canada's Access to Medicines Regime aims to allow the world's developing and least-developed countries to import high-quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens. Health Canada's responsibilities under CAMR are the following:

- Undertaking regulatory review of drug submissions to verify that the product meets requirements for safety, efficacy and quality;
- Ensuring the product is distinguishable from the patented version available in Canada; and
- Performing pre-export inspections to ensure distinguishing features are in place and the quantities to be exported are accounted for.

Purpose of this evaluation: To provide senior management in Health Canada with timely information on how well Health Canada's responsibilities under CAMR has been implemented to date. This will enable mid-course corrections to be taken, if required, increasing the likelihood of achieving the ultimate outcomes.

- **Objectives of this interview:** To obtain your feedback on the effectiveness of implementation of Health Canada's responsibilities under the Regime.

Please be assured that your responses to these questions will be kept strictly confidential. Individual responses will be aggregated or kept anonymous in all reports for this evaluation.

Background

- What are your department's roles responsibilities under CAMR? What are your personal roles and responsibilities?
- How does your department work with Health Canada on CAMR?

Rationale

- Do you think that the objectives of Health Canada's responsibilities under CAMR align with the overall objectives of the Regime? Are the objectives of Health Canada's responsibilities under CAMR complementary to those of your Department?
- Are you aware of any similar programs at federal or provincial levels that may overlap with Health Canada's responsibilities under CAMR?

Delivery and Effectiveness

- To your knowledge, what has Health Canada done to date to put an operational infrastructure for its responsibilities under CAMR into place? (E.g., development of regulations, policies, procedures). What do you consider to be strengths and weaknesses of the CAMR infrastructure put into place by Health Canada? (What works well/ what are challenges?)
- Have you had experience with Health Canada's drug submission process in practice? If yes, how effective and efficient is it in your opinion? What has worked well and what are areas for improvement? What challenges have been experienced?
- What, if any, unintended impacts has the implementation of Health Canada's responsibilities under CAMR had, either positive or negative?

- What contextual factors or events have impacted on the implementation of Health Canada's responsibilities under CAMR? How has Health Canada responded to these?
- What are the role and responsibilities of the Inter-Departmental Working Group? In your view, have the federal departments involved in CAMR successfully developed and implemented an integrated approach to delivery of the Regime? To what extent has there been full integration and flow of information among departments?
- How have communication and outreach activities for CAMR been coordinated among the participating departments? Are you aware of any communication and outreach activities carried out by Health Canada? If yes, how informative and appropriate do you think have they been?
- Are you aware of whether Health Canada has formed effective linkages with international partners (e.g. WHO, drug regulatory authorities)? If so, in your view, has Health Canada formed effective linkages with these partners to support the implementation of its responsibilities under CAMR?
- What, in your opinion, can Health Canada do to further improve the implementation of its responsibilities under CAMR? Are you aware of any processes implemented by the drug regulatory authorities of other countries that could help to inform Health Canada's implementation of its responsibilities under CAMR?

Stakeholder Interviews

Background: Health Canada has received Treasury Board funding for the implementation of its responsibilities under Canada's Access to Medicines Regime (CAMR). It is required to carry out an evaluation to account for the appropriate use of these resources.

Health Canada's responsibilities under CAMR are the following:

- Undertaking regulatory review of drug submissions to verify that the product meets requirements for safety, efficacy and quality;
- Ensuring the product is distinguishable from the patented version available in Canada; and
- Performing pre-export inspections to ensure distinguishing features are in place and the quantities to be exported are accounted for.

Purpose of this evaluation: To provide senior management in Health Canada with timely information on how well Health Canada's responsibilities under CAMR has been implemented to date. This will enable mid-course corrections to be taken, if required, increasing the likelihood of achieving the ultimate outcomes.

Objectives of this interview: To obtain your feedback on the effectiveness of implementation of Health Canada's responsibilities under the Regime.

Please be assured that your responses to these questions will be kept strictly confidential. Individual responses will be aggregated or kept anonymous in all reports for this evaluation.

Background

- Please briefly describe the nature of your organization and your current role in it.
- Please outline your organization's involvement in CAMR to date.

Development of the Regulatory Regime

- Were you consulted during the development of the regulatory regime for Health Canada's responsibilities under CAMR? If yes, how and on what? Did the consultative process work well? What could have been improved? What worked well?
- What have been your practical experiences with the regulations and processes put into place by Health Canada under CAMR? What worked well? What were challenges?
- How effective do you feel the resulting processes and regulations are? Have there been any unexpected results from these processes and regulations?

Drug Submissions / Review

- What was the extent of your experience with Health Canada's drug submission and review process for CAMR?
- Based on your experience, to what extent did the process for drug submission review work well? To what extent did you experience challenges?
- Were there any impediments to this process? Were there any unexpected results?

Communication and Outreach

- Are you aware of any activities or strategies Health Canada put into place for communication & outreach under CAMR? If yes, were you consulted along the way? How useful did you find them?
- Are you aware of whether Health Canada has formed effective linkages with international partners (e.g. WHO, drug regulatory authorities)? If so, in your view, has Health Canada formed effective linkages with these partners to support the implementation of its responsibilities under CAMR?
- What external factors or events do you think have had an impact on the implementation of Health Canada's communication and outreach activities? How has Health Canada responded to them?
- In your experience, have there been any surprises or unintended effects of Health Canada's communication and outreach activities for CAMR? If so, what were they?

Future

- What can Health Canada do to further improve the implementation of its responsibilities under CAMR?
- Are you aware of any processes implemented by other drug regulating authorities in other countries that could help to inform Health Canada's implementation of its responsibilities under CAMR?

Appendix VII Key Differences among International Jurisdictions in the Application of the WTO Decision[22]

	WTO DECISION	CANADA	EU	SWITZERLAND	NORWAY	INDIA	CHINA	KOREA	NETHERLANDS
Implementing Instrument	N/A	Patent Act , s.21.01-21.2	Regulation 816/2006	Draft Amendment to Federal Law on Patents for Inventions	Amendments to Act of 15/12/1967 No.9 relating to patents by Act of 19/12/2003 no. 127/Patent Regulations of 20 December 1996 No. 1162 amended by Royal Decree of 14/05/2004	The Patents (Amendments) Act , 2005 No. 15 of 2005	State Intellectual Property Order #37	Korean Patent Act	Policy Rules for the issuance of a compulsory license under s. 57 of the Patents Act 1995
Date in Effect	August 30, 2003	May 14, 2005 (Royal Assent May 14, 2004)	June 29, 2006	Draft amendment dated November 23, 2005, not enacted.	June 1, 2004 : Regulations Dec. 2003: Patent Act	January 1, 2005	January 1, 2006	December 1, 2005	December 23, 2004
Health and Safety Review	Not required	S. 21.04 (3) (b) of the Patent Act and C.07.004 of the Food and Drug Regulations provide for a mandatory	Art. 18 provides for a voluntary review: Where the application for a compulsory license concerns a	Art.5 (1) Law on Therapeutic Products: Licensee must obtain authorization for the	Not required.	Not required.	Not required.	Not required.	Not required.

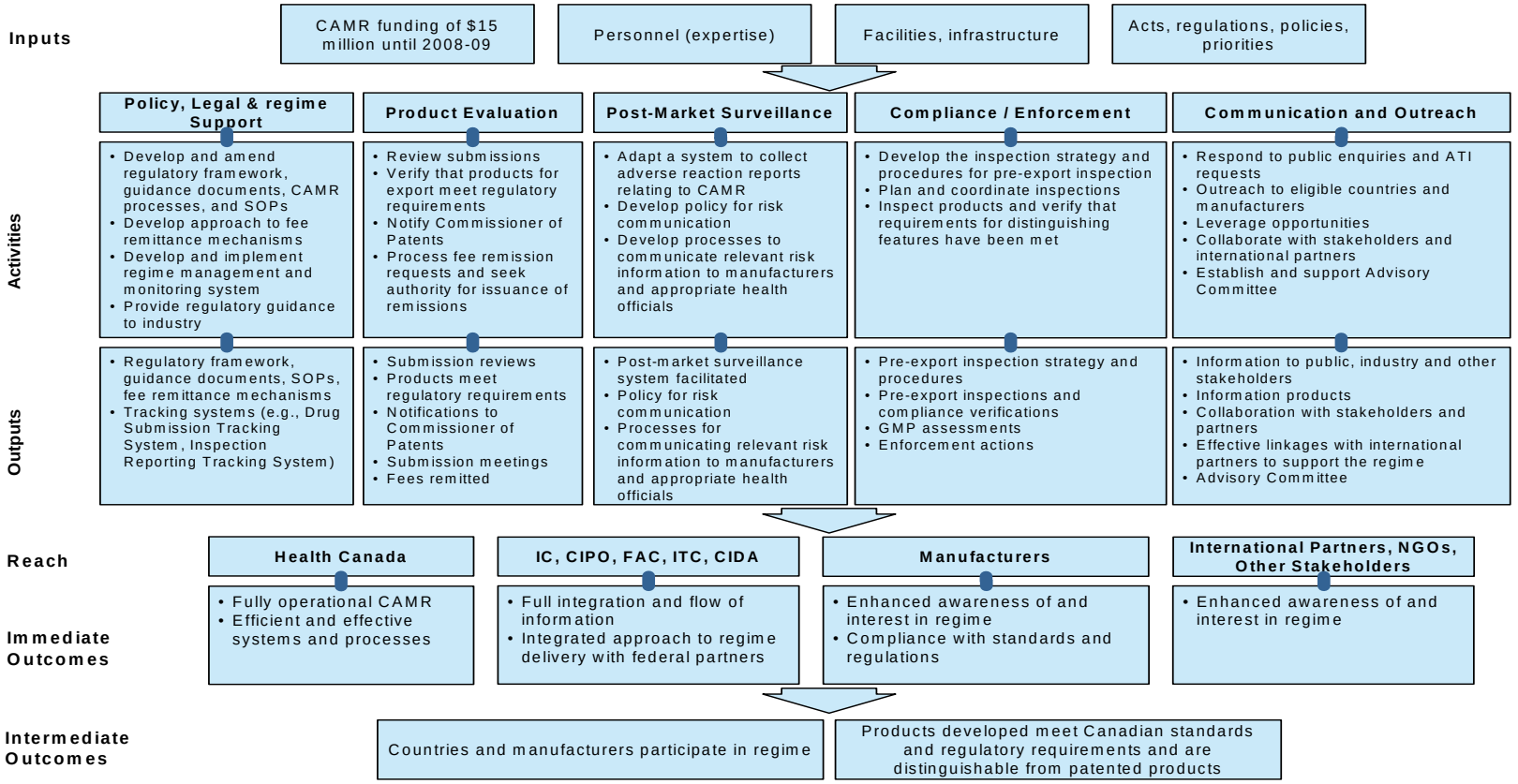
[22] Adapted from CAMR Consultation Paper, Annex B.

	WTO DECISION	CANADA	EU	SWITZERLAND	NORWAY	INDIA	CHINA	KOREA	NETHERLANDS
		review by Health Canada to ensure exports are of the same safety, efficacy and quality as drugs approved for sale in Canada.	medicinal product, the applicant may avail himself of the scientific option procedure or any similar procedures under national law.	production of the licensed products to ensure their high quality from the Swiss Institute of Therapeutical Products. Art. 7 Law on Therapeutic Products: licensee must guarantee that the products will be produced in conformity with standards of Good Laboratory Practice.					
Anti-Diversion Measures	Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their	S.21.06: requires the licensee to establish a website disclosing the name of the licensed product, its distinguishing characteristics, identity of the importing country and amount to be	Art. 10(5) : All products must be identifiable as being produced under the Regulation and be distinguished from the patentee's product through packaging and/or colour/shaping. Preamble, par.	Art. 40 d.4: Product must be distinguished from patented version by means of packaging, colouring, shape provided no major impact on price.	S. 108 (1) 1 Regulation s: Product must be distinguished from patented version by means of packaging. S. 108 (1) 2 Regulations : Product must bear a label indicating it was produced	Not specified.	Not specified.	Art. 110(2)(iii) : Product must have packaging or labelling to distinguish it from patented version and website on which appears the matters set by the adjudication must be established.	Art. 3(4): The manufacturer must take measures with regards to packaging, colouring, and/or shaping provided the measures are feasible and there is no impact on price. Art. 3: Prior to

	WTO DECISION	CANADA	EU	SWITZERLAND	NORWAY	INDIA	CHINA	KOREA	NETHERLANDS
	markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.	manufacturer and sold for export. S.21.07: export notice provided by the licensee to the patent holder, the importing country and the purchaser. Food and Drug Regulations C.07.008: Exported products must bear the mark "XCL" (for solid dosage forms), be a colour that is significantly different from the version sold in Canada and include certain information on all labelling to distinguish them from the patented versions available on the Canadian market. C.07.009 : Products are issued an export tracking number by Health Canada which	11 : To avoid overproduction and diversion, authorities should take into consideration existing licenses for the same product and countries. Art. 10(6) : The licensee must establish a website prior to export.		for export. S. 109 Regulations: The licensee must establish a website listing the name and quantity of the product and identify the importing country. The Court may stipulate more detailed requirements.				export, the licensee must post, on either its own website or the WTO webpage, the anti-diversionary measures it has taken and the quantity of the pharmaceutical product being shipped.

	WTO DECISION	CANADA	EU	SWITZERLAND	NORWAY	INDIA	CHINA	KOREA	NETHERLANDS
		must be printed on the product label.							
Post-Market Surveillance	Not required	Health Canada's responsibilities for post-market surveillance under CAMR are the following: system to collect adverse reaction reports relating to CAMR; policy for risk communications; and processes to communicate relevant risk information to manufacturers and appropriate health officials.	Not required	Not required	Not required	Not required	Not required	Not required	Not required

Appendix VIII Logic Model – Health Canada's Responsibilities under CAMR



Appendix IX CAMR Performance Measurement Framework

Logic Model Element	Indicator	Baseline Measure	Data Source	Collection Method	Responsibility for Collection	Timing and Frequency
Outputs						
Policy, Legal & Regime Support	Regulatory framework in place	Existing regulatory framework; CAMR-specific modifications needed	Canada Gazette	Document review	TPD, BGTD	2006
	# & type of new policies, guidance documents and SOPs against planned	Existing policies, guidance documents or SOPs; CAMR-specific modifications needed	Project reporting	Document review	All Directorates	As required
	Modifications to current tracking systems (content, scope, etc. against planned)	Existing tracking systems	Project reporting	Document review	All Directorates	2006
Product Evaluation	Submission review meets stated targets	No CAMR submissions received	Drug Submission Tracking System	Information system report	TPD, BGTD	Annual
	# and type of decisions made on product submissions	No CAMR decisions	Drug Submission Tracking System	Information system report	TPD, BGTD	Annual
	# of and total $ amount of fee remissions	No fee remissions	Administrative data	Document review	TPD	Annual
Post-Market Surveillance	Type of enhancements made to policy & processes for risk communication and adverse reaction (AR) reporting	Existing domestic policies and processes	Administrative data	Document review	MHPD	Annual

Logic Model Element	Indicator	Baseline Measure	Data Source	Collection Method	Responsibility for Collection	Timing and Frequency
	Number of AR reports received from manufacturers under CAMR	No existing reports	AR reports	Document review	MHPD	On-going
	# of risk communications issued related to CAMR products	No risk communications issued related to CAMR products	Administrative Data	Document review	MHPD	Annual
Compliance / Enforcement	# of inspections, assessments, and compliance verifications	No inspections, assessments, or verifications	Inspection Reporting System	Information system report	HPFB Inspectorate	Annual
	# and type of enforcement actions taken on pre-export inspections in relation to total # of inspections	No enforcement actions	Inspection Reporting System	Information system report	HPFB Inspectorate	Annual
	# of C.07.007 notices to Commissioner of Patents	No C.07.007 notices	Administrative data	Document review	HPFB Inspectorate	Annual
Communication and Outreach	Description of information and information products - perhaps examples could be provided here (videos, web site information)	No information or info products	Administrative data	Document review	TPD	Annual
	Examples of collaboration and linkages with partners	Description of existing relationships	Project reporting	Document review	All Directorates	Annual
Immediate Outcomes						
Fully operational CAMR (Health Canada)	Infrastructure in place (employees, processes, tracking systems, guidance documents, regulatory framework, SOPs, fee remittance)	No infrastructure in place	Project reporting	Document review	All Directorates	Annual
			Interview data	Interviews with key informants	Evaluator	Implementation Evaluation / Parliamentary Review

Logic Model Element	Indicator	Baseline Measure	Data Source	Collection Method	Responsibility for Collection	Timing and Frequency
Efficient and effective systems and processes (Health Canada)	Staff fully trained on new systems and CAMR processes	Staff not trained, no new systems or processes	Project reporting	Document review,	All Directorates	Annual
Full integration and flow of information (IC, CIPO)	Level of satisfaction among manufacturers	N/A	Interview data	Interviews with federal partners (IC, CIPO, ITC, CIDA)	Evaluator	Implementation Evaluation / Parliamentary Review
Integrated approach to outreach with federal partners (IC, CIPO, FAC, ITC, CIDA, CBSA)	Evidence of collaboration	N/A	Interview data	Interviews with federal partners	Evaluator	Implementation Evaluation / Parliamentary Review
Enhanced awareness of and interest in Regime (Manufacturers)	# of inquiries and pre-submission meetings	No requests for inquiries and pre-submission meetings received	Administrative data?	Document review	TPD, BGTD	Annual
	Level of awareness and interest	N/A	Interview data	Interviews with manufacturers (stakeholder)	Evaluator	Implementation Evaluation / Parliamentary Review
Compliance with regulations (Manufacturers)	% of compliant pre-export inspections	No pre-export inspections	Inspection Reporting System	Information system report	HPFB Inspectorate	Annual
Enhanced awareness of and interest in Regime (International	Level of awareness and interest	N/A	Administrative data	Document review	TPD	Implementation Evaluation / Parliamentary Review

Logic Model Element	Indicator	Baseline Measure	Data Source	Collection Method	Responsibility for Collection	Timing and Frequency
Partners, NGOs, Public, Other Stakeholders)			Interview Data	Interview with stakeholders (International Partners, NGOs)	Evaluator	Implementation Evaluation / Parliamentary Review
	# of web site hits	No web hits	Web reports	Document review	TPD	Annual
Intermediate Outcomes						
Countries and manufacturers participate in Regime	# of countries participating	No countries participating	FAC web site	Document review	TPD- Science and International Programs Division	Parliamentary Review
	# of manufacturers participating	No manufacturers participating	Administrative data	Document review	TPD, BGTD	Parliamentary Review
Products meet Canadian standards and regulatory requirements and are distinguishable from patented products	# of notifications to Commissioner of Patents	No CAMR notifications issued	Administrative data	Document review	TPD	Parliamentary Review