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Report of the  
**Auditor General  
of Canada**  
to the House of Commons

**MARCH**

**Chapter 2**  
Health Canada—  
Regulation of Medical Devices



Office of the Auditor General of Canada

*The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.*

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Office of the Auditor General of Canada  
240 Sparks Street, Stop 10-1  
Ottawa, Ontario  
K1A 0G6

Telephone: (613) 952-0213, ext. 5000, or 1-888-761-5953  
Fax: (613) 954-0696  
E-mail: [distribution@oag-bvg.gc.ca](mailto:distribution@oag-bvg.gc.ca)

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Chapter

# 2

Health Canada

Regulation of Medical Devices

*All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.*

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# Health Canada

## Regulation of Medical Devices

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### Main Points

**2.1** While Health Canada has made progress in important aspects of managing risks related to medical devices before they are made available for sale, it needs to better manage risk after they are available for sale. As a result of the gaps in its Medical Devices Program, Health Canada does not have a comprehensive program to protect the health and safety of Canadians from risks related to medical devices, even though it committed to such a program over a decade ago. Its failure to deliver such a program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk—risk of both injury and liability.

**2.2** The current Medical Devices Program manages risks before products are made available for sale, through quality systems requirements and pre-market activities.

**2.3** However, to better manage risks after products are available for sale, Health Canada needs to have a more proactive inspection program at the post-market phase to verify that industry is complying with the Medical Devices Regulations, and it needs a better approach to managing risks related to the sale of unlicensed medical devices. An improved post-market surveillance system is also required to provide timely, accurate, and complete information about adverse events once devices are in use. And once safety concerns are identified, there must be better communication in a timely manner with those who need to know.

**2.4** Health Canada is taking only limited action to address the risks posed by the reuse of single-use devices. As one of the entities responsible for protecting the health and safety of Canadians, it must take action immediately.

### Background and other observations

**2.5** Equal and timely access to quality health care is a priority for Canadians. This includes timely access to medical devices, which play an important role in all stages of the delivery of quality health care. Medical devices such as blood test kits, diagnostic imaging equipment, and heart valves are used to diagnose, treat, mitigate, and prevent diseases and medical conditions.

**2.6** The Medical Device Review Committee was established in 1991 to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. A 1992 report of the Committee was used to prepare the Development Plan for an Improved

Medical Devices Regulatory Program. This Plan and the consultation with stakeholders that followed formed the basis of a new Medical Devices Program that began with the introduction of new Medical Devices Regulations in 1998. Since then, Health Canada has introduced some new activities and made improvements to some existing activities, but significant gaps and weaknesses remain.

**2.7** Our audit examined how Health Canada manages the risks and benefits related to medical devices at each stage of the product life cycle of a licensed device. Because Health Canada responded to the Medical Devices Review Committee's report and made efforts to implement changes, we used the Department's response as the standard against which we measured the Medical Devices Program. We also examined how the achievements and challenges facing this Program were measured and reported to Parliament.

**2.8** Health Canada is aware of the gaps and weaknesses in the Program, but has made limited efforts to address them. Limited financial and human resources and limited progress in advancing international regulatory co-operation prevent Health Canada from addressing these gaps and weaknesses. This in turn, prevents it from delivering the Medical Devices Program as designed.

**2.9** Our findings indicate that the current Program is not sustainable. As such, Health Canada must make a choice: It must provide adequate resources to deliver the Program as designed or redesign the Program and the Regulations to allow for health and safety risks to be managed in a way that requires fewer resources.

**2.10** Health Canada needs to act to ensure that Canadians have timely access to all available medical devices. It also needs to play a more active role in the conduct of investigational testing.

**2.11** Finally, Health Canada needs to improve its evaluation, measurement, and reporting of the results of its Medical Devices Program. This is especially important given the challenges that the Program faces and the questions about continuing with the current Program or redesigning it.

**The Department has responded.** Health Canada's responses to our recommendations are included in this chapter. The Department has responded positively to our recommendations and has agreed to take corrective action. In some instances, the action is already under way.



## Introduction

### The importance of medical devices in quality health care

**Health care professionals**—Professionals who provide health care services, including doctors, surgeons, nurses, dentists, dental assistants, and psychologists.

**Therapeutic products**—Health products that are used to diagnose or treat illness, including medical devices (such as blood test kits, diagnostic imaging equipment, heart valves), over-the-counter drugs (such as ASA, allergy medication), prescription drugs (such as asthma medication, blood pressure medication), natural health products (such as echinacea, vitamin supplements), biologic and genetic therapies (such as blood, vaccines), and organs and tissues (such as hearts and lungs for transplant).

**2.12** Equal and timely access to quality health care is a priority for Canadians. This includes both services provided by **health care professionals** and **therapeutic products** such as medical devices. Medical devices play an important role in all stages of the delivery of quality health care. Exhibit 2.1 shows how important medical devices are to health care.

**2.13** The manufacture and sale of medical devices are subject to the *Food and Drugs Act* and the Medical Devices Regulations. According to the *Food and Drugs Act*, a medical device is defined as “any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in human beings and animals for:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms,
- restoring, correcting or modifying a body function or the body structure,
- diagnosis of pregnancy, or
- care during pregnancy and at, and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.”

#### Exhibit 2.1 Medical devices are important to health care: The example of a patient with cardiovascular disease

Cardiovascular diseases are a leading cause of hospitalization in Canada. Statistics Canada has estimated a 36 percent increase each decade until 2026 in the number of hospitalizations for heart attack. Projections for caseload at the University of Ottawa Heart Institute are even more dramatic. Between 2003 and 2005, the Institute is projecting a 100 percent increase in defibrillator implants, and a 60 percent increase in pacemaker implants (both class IV medical devices).

A cardiac patient who needs a medical device like a stent or pacemaker may depend on over 400 devices, during non-invasive cardio exams, open heart surgery, and post-operative care. These devices are often highly complex, computerized machines, upon which the survival of a patient may depend.

For diagnosis, devices like a blood pressure monitor, diagnostic imaging equipment such as magnetic resonance imaging (MRI), or a stethoscope, would be used. If a patient needs a stent installed, some of the devices required would include an X-ray machine, an angiograph, catheters, a stent and balloon, and special monitors for temperature and pulse. If a patient needs a pacemaker, the surgery would involve at least 40 devices for anesthesia and between 100 and 200 devices for the surgery. Some examples include a fluoroscope to view the patient’s heart and blood vessels, catheters, an array of special instrumentation, a bypass machine, ventilators, vaporizers, oxygenators, and multiple-infusion pumps. After surgery, a new set of devices are introduced for post-operative care.

Source: University of Ottawa Heart Institute

**Examples of the four classes of medical devices****Class I**—Bandage, toothbrush, hospital bed**Class II**—Condom, tampon, surgical gloves, magnetic resonance imaging equipment**Class III**—Home glucose test kit, hip replacement implant, ultrasound diagnostic imaging equipment**Class IV**—HIV test kit, implantable defibrillator, pacemaker**Health care facilities**—Places where health care is provided, such as hospitals, clinics, nursing homes, and doctors' and dentists' offices.

**2.14** The Medical Devices Regulations apply only to devices intended for human use. The Regulations categorize medical devices into **four risk classes** based on potential to cause harm. Class I represents the lowest-risk; class IV represents the highest-risk. All manufacturers of class I devices who do not sell through a licensed establishment, all importers, and all distributors require an establishment licence to sell their products in Canada. Manufacturers of class II, III, and IV devices require a device licence for each device or grouping of devices to sell their products either to importers and distributors or directly to purchasers in Canada. All establishment and device licences must be renewed annually.

**2.15** Canadians consume \$5 billion in medical devices annually. Every Canadian who visits a doctor or dentist for an examination, has a diagnostic test, or undergoes surgery will encounter many devices. It is estimated that, in 2001,

- 787,000 Canadians had a non-emergency CT (computed tomography) scan and 647,000 had a non-emergency MRI (magnetic resonance imaging) to assist in diagnosing a health problem;
- 100,000 Ontarians had an emergency CT scan;
- 70,000 Canadians received a heart valve or stent, and 10,000 received a pacemaker;
- 250,000 Canadians had the lens of an eye replaced with an intraocular lens; and
- 50,000 Canadians had an artificial joint implanted in a hip, knee, shoulder, or elbow.

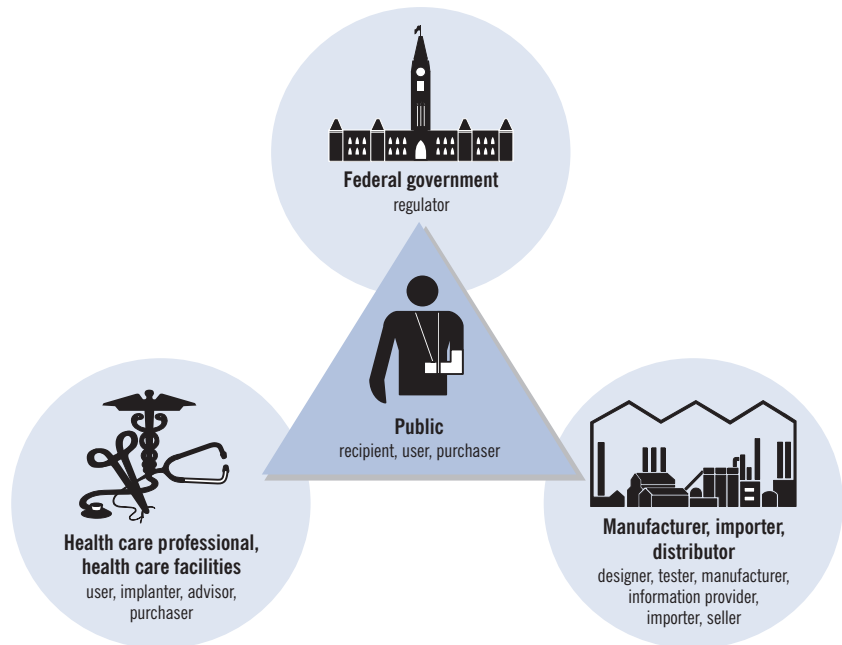
**2.16** Medical devices are largely based on technology. As advances are made in technology, the number of devices and their complexity will increase. For these reasons, it is expected that the medical devices industry will continue to grow in the future, both in size and in importance.

**Stakeholders in medical devices**

**2.17** There are four main stakeholders in medical devices. Exhibit 2.2 shows how their relationship is interdependent. The primary stakeholder is the public. Health care professionals and the **health care facilities** for which they work play an important role in the safety of devices. The medical devices industry—including manufacturers, importers, and distributors—and the federal government are also important in helping to ensure the safety of devices.

**2.18** The public uses medical devices to receive some health benefit. However, with this benefit comes some level of potential risk since the quality and safety of devices can never be absolutely guaranteed.

**2.19** The public has limited control over the risks and benefits to which they are exposed. Ultimately, they must trust others, such as health care professionals and manufacturers of therapeutic products, to provide safe and effective services and products. It is this need to trust manufacturers that defines the responsibilities of the federal government: to help protect the public from undue health and safety risks that are posed by therapeutic products and are beyond their influence.

**Exhibit 2.2** The four main stakeholders in medical devices

**Therapeutic effectiveness of products**—The effectiveness of a product to identify, eliminate, or reduce the effect of an illness.

**Adverse event**—An incident that has led or could lead to patient or user injury. It can be caused by failure of the device or improper use due either to human error or to inadequate labelling or directions.

**Safety concern**—A problem with a device that suggests that continued use could result in harm to the patient and consumer.

**2.20** Health care professionals play a critical role in relation to medical devices. To provide the public with information on the risks and benefits of a device and to learn how to use or install a device, the health care professional must rely on the manufacturer. And much like the public, health care professionals rely on government to help ensure the safety and **therapeutic effectiveness of products**.

**2.21** Health care professionals also play a significant role in helping to ensure the continued safety of medical devices for the public. They are often the first to become aware of an **adverse event** related to a device; this makes them the most important source of information on adverse events. When this information comes to their attention, they have a professional responsibility to pass it on to the manufacturer and/or the federal government. By doing so on a timely basis, they assist the federal government in assessing and communicating a **safety concern** so that future problems can be prevented.

**2.22** The legal responsibilities of the medical devices industry are clearly outlined in the Medical Devices Regulations. Consistent with the federal government's current approach to regulation, which involves increased reliance on industry, these Regulations place significant responsibility on the industry to do all it can to protect the health and safety of the public. Although the specific requirements in the Regulations vary among the four classes of devices and among manufacturers, importers, and distributors, in general the Regulations require that the industry

- be certified to operate a system that helps ensure quality in the design and manufacture process and that is in accordance with standards set by

the International Organization for Standardization (ISO) (class II, III, IV);

- obtain authorization from Health Canada to conduct investigational tests (class II, III, IV);
- possess evidence that a medical device meets the requirements for safety and therapeutic effectiveness to obtain authorization to sell that medical device in Canada (all classes) and provide this evidence to Health Canada for its evaluation before licensing (class III and IV);
- hold an establishment licence if they are an importer or distributor of medical devices (all classes) or a manufacturer of class I devices who do not sell them through a licensed establishment (class I);
- maintain records of all reports of adverse events and complaints received and the actions taken on these reports and complaints (all classes);
- report all serious adverse events to Health Canada (all classes); and
- maintain records of distribution for all devices (all classes) and a registration system for certain implantable devices (certain class IV devices).

**2.23** The federal government, as federal regulator, has a legislated responsibility that is outlined in the *Food and Drugs Act* to protect the health and safety of Canadians. In delivering on these responsibilities, the federal government helps ensure that the public has timely access to all available safe and effective devices; it also helps ensure the continued protection of the public by informing those who need to know of any safety concerns on a timely basis.

**2.24** As previously noted, the safety of a medical device can never be absolutely guaranteed. Given this, the role of the federal government is to assess the benefits derived from the use of a device against the associated risks. Based on this assessment, the federal government decides whether the health and safety of Canadians would be compromised by using the device.

**2.25** In recent years, courts have held that in some circumstances public authorities could be found to owe a duty of care to certain persons. In cases where a public authority did not exercise diligence, the public authority has been found negligent and liable to those injured by that negligence. Health Canada is defending a number of court challenges where it is alleged that the Department breached a duty of care it owed to a group of persons injured by medical devices. Specifically, Health Canada is defending class action lawsuits related to breast implants and jaw implants. This potential liability reflects an important aspect of the use of medical devices—that the public rely on the federal government to help protect them from health and safety risks that are beyond their influence.

**2.26** As one of the four main stakeholders involved in medical devices, Health Canada is being called upon more and more to explain to the courts its role as the regulator of medical devices and to defend against allegations that it is responsible for damages suffered by Canadians who claim to have been injured by a medical device. In other words, because it is one of the four

main stakeholders, Health Canada is sued along with other stakeholders in what are typically product-liability and medical-malpractice lawsuits.

### Health Canada's Medical Devices Program

**2.27** Health Canada is responsible for delivering programs to protect the health and safety of Canadians in relation to all therapeutic products, including medical devices. The Department's Health Products and Food Branch is responsible for the Medical Devices Program. This Program is delivered jointly by the Medical Devices Bureau, the Health Products and Food Inspectorate, and the Marketed Health Products Directorate. The authority for this Program comes from the *Food and Drugs Act* and the Medical Devices Regulations.



The intracardiac navigation system allows the surgeon to locate the intracardiac catheter inside a patient's heart.

Source: Medtronic of Canada Ltd.

**2.28** A report issued by the Medical Devices Review Committee in 1992 guided the development of the current Medical Devices Program. This Committee was established to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. Our audit examined how Health Canada implemented its new Medical Devices Program as compared to Health Canada's response to the Committee's report.

**2.29** The goal of the Medical Devices Program is to ensure that medical devices available in Canada are safe, effective, and of high quality. This is done through a regulatory framework, whereby the level of effort given to a device is dependent upon the risk class of the device and whereby the safety and effectiveness of medical devices are assessed through a balance of quality-systems requirements, pre-market activities, and post-market activities.

**2.30** In 2002 over 100 licences for new class IV devices, almost 550 licences for new class III devices, and almost 1,500 licences for new class II devices were issued in Canada. If a device is changed, Health Canada must authorize the changes. In 2002 Health Canada authorized amendments to 650 licences for class IV, 1,950 for class III, and 3,700 for class II devices. It recently reported that over 40,000 class IV devices, over 175,000 class III devices, and over 240,000 class II devices are currently licensed for sale in Canada. Health Canada has also issued close to 1,300 establishment licences to manufacturers of class I devices, importers, and distributors.

**2.31** The budget for the direct costs associated with the Medical Devices Program was \$7.4 million in 2002. The Program employed 95.5 full-time equivalent staff in 2002.

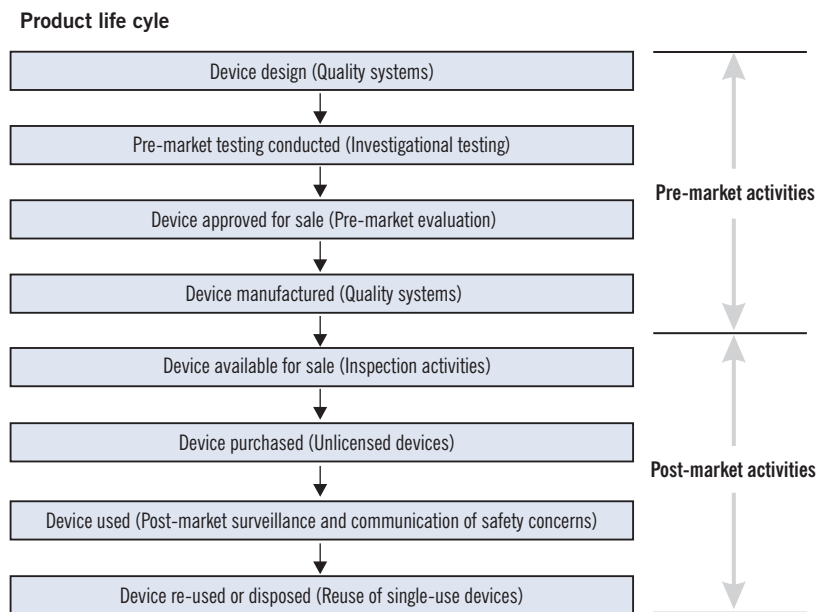
### Focus of the audit

**2.32** The focus of this audit was Health Canada's Medical Devices Program managed by the Health Products and Food Branch, and in particular the Program activities directed at class II, III, and IV devices. Our objectives were to determine whether Health Canada adequately manages the risks and benefits related to safety and therapeutic effectiveness of medical devices available in Canada, identifies weaknesses in the Program and takes action to address them, and measures and reports the results achieved by the Medical Devices Program.

**2.33** We reviewed the 1992 report issued by the Medical Devices Review Committee and the Development Plan for an Improved Medical Devices Regulatory Program prepared by Health Canada in response to that report. We also reviewed documents from the consultations with stakeholders that took place prior to the introduction of the new Regulations. We examined the activities Health Canada engages in to discharge its responsibilities. We made comparisons with the medical devices programs in the U.S. and the UK and with the Drug Program delivered by Health Canada. Finally, we considered the impact of the Medical Devices Program’s human and financial resources on Health Canada’s ability to adequately discharge its responsibilities.

**2.34** Our audit observations follow the product life cycle of licensed medical devices (Exhibit 2.3).

**Exhibit 2.3** Product life cycle of a licensed medical device

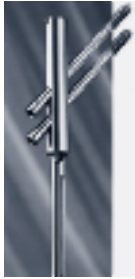


Source: Health Canada

**2.35** More information about the audit’s objectives, scope and approach, and criteria can be found in **About the Audit** at the end of the chapter.

## Observations and Recommendations

### The Medical Devices Review Committee



The interlocking nail medical device is used to repair fractures in long bones.

Source: Smith and Nephew Inc.

**2.36** The report issued by the Medical Devices Review Committee in 1992 contained many observations and recommendations. When these observations and recommendations are taken together, they provide a vision for a comprehensive medical devices program.

**2.37** That vision was for a program that had a number of key attributes and activities (Exhibit 2.4). It was suggested that the Program include regulations that placed significant responsibility on industry and, to a lesser degree, on health care professionals. The Committee recognized the importance of pre-market activities to help ensure the safety and therapeutic effectiveness of medical devices before the products are made available for sale to Canadians. It also recognized that the responsibility for the safety and therapeutic effectiveness of medical devices does not end once the devices are on the market; this acknowledges that post-market activities are critical to an effective regulatory program.

**2.38** Because the medical devices industry operates in a global economy, the Committee suggested that this Program include active participation in activities related to international regulatory co-operation.

**2.39** The Medical Devices Review Committee stressed the importance of providing adequate resources to deliver the Program. It recommended an increase in the resources allocated to the Program and suggested introducing fees to recover part of the cost of the Program; the revenue from this would be used to improve the Medical Devices Program.

### Health Canada's response to the Medical Devices Review Committee's report

**2.40** Health Canada responded to the report and, with additional help from the Committee, prepared a Development Plan for an Improved Medical Devices Regulatory Program, which proposed changes to its Medical Devices Program. It also engaged in consultations with stakeholders about the proposed changes to the Program. In its 1994–95 Part III Estimates, it informed parliamentarians about the Development Plan and some of the changes that were being introduced based on the Plan. Because Health Canada responded to the report and made efforts to implement changes, we used the Department's response as the standard against which we measured the Medical Devices Program. The Department accepted our use of this standard.

**2.41** The first significant change resulting from these efforts was the introduction of the new Medical Devices Regulations in 1998. In addition, Health Canada introduced some new activities and made improvements to some existing activities. These changes addressed some of the concerns contained in the report. In particular, it introduced

- a requirement for a quality system for manufacturers based on the standards of the ISO (International Organization for Standardization);



- establishment licensing of manufacturers of class I devices who do not sell through licensed establishments, importers, and distributors;
- a pre-market notification and licensing system for class II, III, and IV devices that is based on the risk class of the device;
- a mandatory system for problem reporting for manufacturers and importers; and
- cost recovery.

**Exhibit 2.4 The Medical Devices Review Committee's report provided a vision for a comprehensive medical devices program**

**Key attributes**

The Medical Devices Review Committee provided a vision for a comprehensive medical devices regulatory program with the following attributes:

- protects the patient and consumer,
- recognizes the responsibilities of industry, health care professionals and facilities, and the federal government,
- supports international regulatory co-operation,
- balances pre-market and post-market activities,
- is open, transparent, and cost effective, and
- incorporates the principles of risk and benefit management.

The Committee recommended that the program do the following:

**Pre-market activities**

- develop a requirement for a system to help ensure quality in the manufacturing of medical devices,
- develop a policy on managing the risks related to investigational testing,
- using a risk-based approach, evaluate a manufacturer's evidence of the safety and therapeutic effectiveness of a device before it is introduced on the market,
- issue a licence if the evaluation is favourable and renew the licence annually, and
- manage the evaluation process to prevent a backlog.

**Post-market activities**

- develop an active inspection program to help ensure industry is in compliance with the regulations and to publicly identify those that are not.
- develop a pro-active post-market surveillance system that provides sufficient adverse-events information to allow safety concerns to be identified. Suggestions include, but are not limited to, mandatory reporting of adverse events by manufacturers and health care professionals and ongoing surveillance processes, such as device registries.
- develop a communication plan and methods to disseminate information on health risks and benefits and safety concerns to health care professionals, and the public on a timely basis.
- amend the current legislation to provide additional enforcement options.
- promote education and training for health care professionals on devices.

Source: The Report of the Medical Devices Review Committee, 1992



**2.42** However, several significant concerns have not been addressed, which include

- limited progress in advancing international regulatory co-operation;
- limited inspection activity at the post-market phase and no public communication when industry does not comply;
- limited progress in improving the voluntary reporting system for adverse events;
- no risk communication strategy related to medical devices and limited improvement in the communication of safety concerns; and
- cost recovery that was revenue-neutral and therefore did not provide additional funds to support improvements to the Program.

These issues are discussed in greater detail in the following sections of the chapter.

## Pre-market activities

### Quality systems are a regulatory requirement

**2.43** It is recognized by medical devices stakeholders that many serious problems associated with devices are caused by poor design or manufacturing controls. It is also recognized that incorporating quality systems—that is, quality control and quality assurance—into the design and manufacturing processes is a good way to manage these problems (Exhibit 2.5).

**2.44** For these reasons, the Medical Devices Review Committee recommended that Health Canada introduce a requirement for quality systems in manufacturing based on international standards.

#### Exhibit 2.5 Using a quality system prevents problems in the design and manufacturing processes

The purpose of a quality system (quality control and quality assurance) is to prevent and control quality problems in the design and manufacturing processes.

The quality control aspect requires manufacturers to evaluate their processes to identify those activities that are critical to ensuring quality in their products. They then build in controls to help ensure that these activities function consistently to ensure quality during design and manufacture, thereby ensuring consistency in its quality. Examples of critical activities include:

- use of trained employees,
- regular calibration of equipment, and
- confirmation of specifications.

Once all critical activities and controls are identified, the quality system is designed, documented, and incorporated into the processes.

The quality assurance aspect requires the manufacturer to develop procedures for monitoring the controls to help ensure they are working effectively. Monitoring could involve:

- hourly tests of the control (for example, testing equipment calibration),
- daily observation of the control (for example, observing adjustment of equipment), and
- periodic audit of the control (for example, reviewing employee training records).

**2.45** We found that Health Canada incorporated a requirement for quality systems in the 1998 Medical Devices Regulations. The Regulations require manufacturers to incorporate quality systems (based on internationally accepted standards for quality systems) into the design process for class III and IV devices. They also require manufacturers to incorporate them into the manufacturing process for class II, III, and IV devices.

**2.46** We also found that to help ensure compliance with these regulatory requirements, Health Canada developed a third-party registration system. Health Canada, through the Standards Council of Canada, accredits international audit organizations to carry out certification audits of quality systems on its behalf. Each manufacturer must demonstrate to this accredited third-party registrar that it operates a quality system that complies with the international standards. Once this has been demonstrated, the registrar will issue a certificate, which the manufacturer must submit to Health Canada as part of the application for a device licence or for its annual renewal. Without this certificate, the device will not be licensed for sale in Canada. Certification must be renewed through re-certification audits every three years. Also annual surveillance audits are conducted to ensure that the manufacturer is continuing to respect the quality-system requirements. Finally, registrars must notify Health Canada within 15 days of any certifications that are suspended or not renewed.

#### **Investigational tests are not adequately monitored**

**2.47** Investigational testing, sometimes called clinical trials, determines the safety and therapeutic effectiveness of a medical device through controlled testing on human subjects. An investigational test is generally designed to

- verify that under specified conditions of use the device performs as intended by the manufacturer, and
- identify any adverse events under normal conditions of use to allow assessment of whether these events are acceptable when assessed against the intended benefits of the device.

**2.48** Conduct of investigational tests is important because failure to conduct them safely could result in harm to participants, and failure to conduct effective tests could result in inaccurate results about the safety and therapeutic effectiveness of medical devices. Further, this information plays an important part in Health Canada's decision whether or not to authorize the sale of devices.

**2.49** The Medical Devices Review Committee recognized that how investigational tests are conducted is important. Because it observed some confusion by the industry about some of the ethical and operational considerations in investigational tests, it recommended developing a policy to clarify the rules for high-risk devices. However, the Committee did not make direct recommendations about how to manage the risks related to investigational tests. We expected that Health Canada's approach to managing these risks would be consistent with the approach it is taking for

other therapeutic products and/or the approaches taken by other international jurisdictions in their medical devices programs.

**2.50** We found that the Medical Devices Regulations require manufacturers to seek authorization to use medical devices in conducting an investigational test before the test can begin and to report any serious adverse events that are identified during the test. Before authorization is given, Health Canada reviews, among other things, the test protocol and the credentials of investigators. This review provides Health Canada with information about how the manufacturer intends to conduct the investigational test. Finally, if Health Canada becomes aware of concerns, it can revoke the authorization that allows the device to be used in the test.

**2.51** However, we observed that once an investigational test begins, Health Canada does not monitor its conduct through, for example, inspection of the test. More specifically, we found that Health Canada does not

- regulate the conduct of investigational tests as a means to hold manufacturers accountable for the conduct of their investigational tests,
- inspect the tests to help ensure safe conduct in order to protect subjects in the test, or
- inspect the tests to help ensure effective conduct in order to verify the quality or integrity of the results of the investigational test.

Nor does Health Canada verify the quality or integrity of the results of the investigational tests when making its decision on whether or not to authorize the sale of devices.

**2.52** Also of concern is that Health Canada has not assessed the adequacy of its approach to investigational testing or the risks associated with its decision not to monitor the conduct of tests. We found that Health Canada's approach to testing medical devices is different from its approach to clinical trials for drugs and also to the U.S. Food and Drug Administration's approach to clinical trials for medical devices. Because of recognized risks related to the safe and effective conduct of clinical trials, drug manufacturers in Canada and medical device manufacturers in the U.S. are required by regulation to follow [Good Clinical Practices](#). In addition, both governments conduct inspections of the clinical trials. It is important that Health Canada consider the appropriateness of these approaches as a means to manage risks related to investigational testing of medical devices.

**2.53 Recommendation.** Health Canada should assess the risks related to the conduct of investigational tests for medical devices. Based on this assessment, it should take appropriate action to manage these risks.

**Department's response.** Agreed. Health Canada will assess the current regulatory requirements for the conduct of investigational testing for medical devices, in consultation with those who share in this responsibility, and will take action to manage any risks that are determined not to be fully addressed by the current regulatory framework. Health Canada will initiate consultations by Fall 2004 with the goal to complete these by Summer 2005.

**Good Clinical Practices**—An international standard for clinical trials for drugs, which ensures that the data and reported results are credible and accurate and the rights, integrity, and privacy of clinical trial subjects are protected.

### Pre-market evaluation process is consistently followed

**2.54** Consistent with the recommendations contained in the Medical Devices Review Committee's report, the Medical Devices Regulations require that all class II, III, and IV medical devices be licensed for sale by Health Canada. Before giving a licence, Health Canada evaluates information provided by manufacturers supporting their claim that the device meets the requirements of the Regulations. The nature of the information required from manufacturers and evaluated by Health Canada and the level of scrutiny of that information by Health Canada depend on the risk class of the device. For example, more extensive information is required for a heart valve than for surgical gloves, and the level of scrutiny of that information is more extensive. That evaluation helps ensure that the health and safety of Canadians will not be unduly compromised by a medical device.

**2.55** As previously mentioned, in Canada medical devices are classified into one of four risk classes based on their potential to cause harm, with class I representing the lowest risk and class IV the highest. Factors considered in classifying risk include

- how long the product is expected to be inside the patient (for example, one hour or 10 years);
- how invasive the product is into the body (for example, inserted temporarily or implanted fully); and
- how the device interacts with the patient (for example, a device that does not interact or one that delivers energy to the patient).

To help ensure proper classification, the Regulations provide specific rules for assigning risk class, which are supported by guidelines for both evaluators and manufacturers.

**2.56** Class II, III, and IV devices require a licence for each device or grouping of devices. A licence is issued only once Health Canada is satisfied that the device was designed and manufactured under a quality system and meets the safety and therapeutic effectiveness requirements (that is, that the risks have been identified and minimized and the device performs as intended).

**2.57** The authorization of a licence for class II devices is largely administrative. The manufacturer must submit an attestation that the device meets the requirements, which is reviewed by Health Canada.

**2.58** The authorization of a licence for class III and IV devices is much more involved. Manufacturers must submit evidence, such as investigational test results or laboratory test results, to demonstrate that they meet the requirements of the Regulations. This evidence is then evaluated by Health Canada before a licence is issued.

**2.59** If a Class III or IV device meets certain criteria—for example, if there is an emergency need for the device or it is a critical new device—Health Canada offers mechanisms to expedite access to the device. Both the Special Access Program and priority review will result in more immediate attention

for those devices that are urgently needed so that licensing is not a barrier to access.

**2.60 Evaluation process.** We found that Health Canada has a structured approach to evaluating the safety and therapeutic effectiveness of medical devices to be sold in Canada. The basis of the approach is the Regulations, which ensure that the level of scrutiny for devices increases with the risk class. It includes standard operating procedures and templates, which provide structure to the evaluators to help ensure consistency in their risk-based decisions on safety and therapeutic effectiveness.

**2.61** We examined the evaluation process for a random sample of 10 class II, III, and IV medical devices processed during 2001 and 2002 and 21 appeals and refusals (representing all completed appeals and refusals for 2002). We found that the process was consistently followed. Our review revealed that

- devices that represent the highest risk were subject to the highest level of review,
- reasons for decisions were documented,
- standards were referenced and applied, and
- expertise and experience were incorporated into the review process.

**2.62 Delays in authorizing licences.** While it is important that Health Canada take the necessary time to properly evaluate a device for safety and therapeutic effectiveness, delays in authorizing licences deny Canadians timely access to devices.

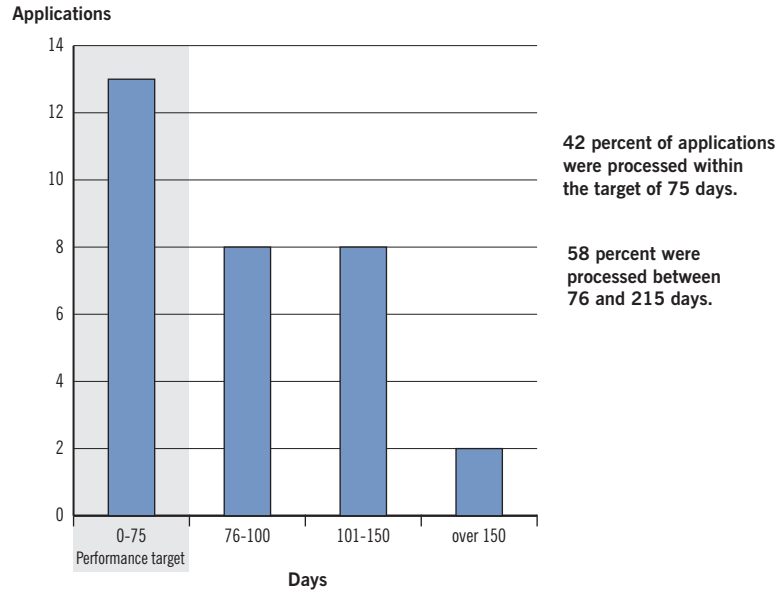
**2.63** Health Canada negotiated performance targets with the Canadian medical devices industry for authorizing licences within 75 days for class III devices and 90 days for class IV devices. Health Canada also determined that to meet these performance targets for class III and IV devices, it would require the full-time equivalent of 56 employees.

**2.64** We found, with a few exceptions, that Health Canada has consistently failed to meet its performance target for class III and IV devices. Since 2000, the quarterly average performance for new applications has ranged from 73 to 113 days for class III devices and 106 to 204 days for class IV devices. The average performance can fluctuate considerably because the number of applications received each quarter can be quite variable. We also found that Health Canada currently has the full-time equivalent of only 36.4 employees assigned to this task.

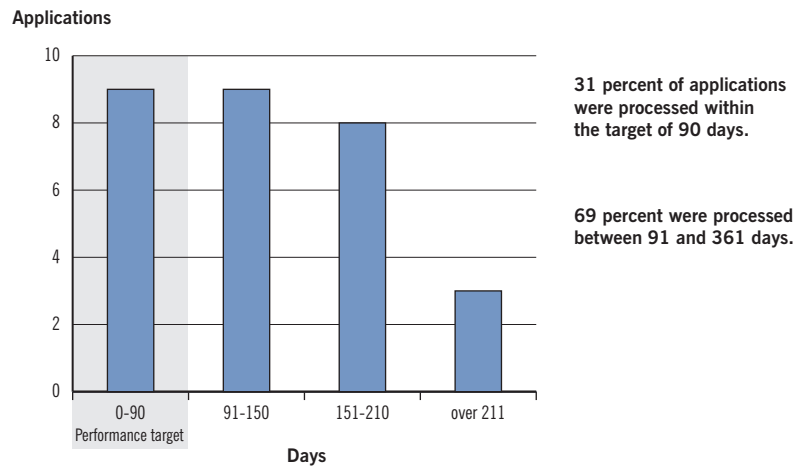
**2.65** To examine this issue more closely, we reviewed the authorization time—that is, the length of time it took to issue a licence after the application was received—for a random sample of 31 class III applications and 29 class IV applications processed during 2002. Because the time spent waiting for additional information from manufacturers is beyond the control of Health Canada, we excluded this time from our calculations. We calculated that for class III files, 42 percent were completed within the target of 75 days and 58 percent required between 76 and 215 days for authorization. The average number of days for authorization was 90; this is 15 days longer than the

performance target. For the class IV files reviewed, we calculated that 31 percent were completed within 90 days and 69 percent required between 91 and 361 days for authorization. The average number of days for authorization was 140; this is 50 days longer than the performance target (exhibits 2.6 and 2.7).

**Exhibit 2.6 Total time for authorizing licences for 31 class III applications, 2002**



**Exhibit 2.7 Total time for authorizing licences for 29 class IV applications, 2002**



**2.66** The two main stages in the authorization process are:

- screening—the time for administrative processing and review of the application for completeness upon receipt of the application; and
- review—the time taken to review the application in order to evaluate the safety and therapeutic effectiveness of the device.

There are two reasons why an application may be waiting for review:

- additional information—the time waiting for a manufacturer to provide missing or more complete information; and
- queue—the time that a file is sitting waiting for action.

Each of these influences the length of time it takes for an application to get from receipt of the application to issuance of a licence.

**2.67** To better understand the authorization process, we calculated the amount of time that these files spent at each stage in the process.

We excluded the time spent waiting for additional information.

Our calculations showed the following:

- screening—in 66 percent of the cases, screening was completed within 15 days; only 7 percent were in screening for more than 30 days.
- review—in 77 percent of the cases, review was completed within 10 days; only 5 percent were in review for more than 30 days.
- queue—in 66 percent of the cases, the application was sitting in the queue for 60 days or more; in 23 percent, the application was sitting in the queue for over 120 days (or four months).

**2.68** This analysis reveals that since the review of an application takes generally less than 10 days, the review itself does not contribute greatly to the delay. Further, we can conclude that much of the delay in issuing licences within the performance targets is due to files sitting in the queue. While there may be several reasons why Health Canada is experiencing delays, the fact that it is operating with a shortage of 19.6 full-time equivalents or 35 percent of the staff needed is most certainly contributing to these delays.

**2.69** Every day that a device is waiting for review, it is not available to Canadians and thus access to that device on a timely basis is compromised. In 2002, Health Canada received 5,000 requests through the Special Access Program, a 683 percent increase in the last four years. Since the staff who process requests through the Special Access Program are the same as those who conduct pre-market evaluations, time spent dealing with these requests is time taken away from working on pre-market evaluations. In order to ensure timely access to devices, Health Canada must deal with the delays in authorizing medical devices.

**2.70 International regulatory co-operation.** International regulatory co-operation involves the co-operation of international regulators in activities such as developing and adopting international standards, harmonizing regulations, conducting joint evaluations, and using mutual-recognition agreements. The Medical Devices Review Committee recognized the

advantages of international regulatory co-operation, namely, efficiencies in the program could be gained, requiring fewer resources to carry out the program; and the regulatory burden on manufacturers could be reduced, resulting in more timely access to a greater number of devices.

**2.71** In the Regulatory Impact Analysis Statement that accompanied the 1998 Medical Devices Regulations, Health Canada committed to harmonizing regulations with other jurisdictions and using mutual-recognition agreements to allow devices to be evaluated in one jurisdiction and placed on the market in all other jurisdictions without further evaluation.

**2.72** We found that while Health Canada has developed an international strategy, limited progress has been made in advancing this strategy. Work on harmonizing regulations is progressing slowly. Canada has three mutual-recognition agreements, with the European Union, Switzerland, and the European Free Trade Association; however, none of these have been operationalized. In addition, Health Canada is not formally using the evaluations of devices completed by other jurisdictions.

**2.73** Health Canada has faced a number of challenges in implementing its international strategy. These include the following.

- It can be difficult to get consensus among all players because each jurisdiction defines risk differently, has its own priorities for managing risk, and uses different approaches and standards for managing those risks.
- It can be difficult to exercise international influence because Canada is a small market.
- There is only limited guidance from the Canadian government on which models of international regulatory co-operation are the most efficient and effective and the most socially acceptable to Canadians.

**2.74** Because of the advantages of international regulatory co-operation, such as increased efficiency of the Medical Devices Program and reduced regulatory burden, it is important that Health Canada follow through on its international strategy. To manage the challenges of international regulatory co-operation, it is important that Health Canada prioritize its activities. It can continue with those activities that are high priorities and establish international relationships that allow it to benefit from the efforts of other jurisdictions for those activities that are lower priorities.

**2.75 Recommendation.** Health Canada should ensure that Canadians have timely access to all available safe and effective devices. More specifically, it should ensure that all devices are approved within the performance targets and should consider engaging in activities that would allow it to benefit from international regulatory co-operation.

**Department's response.** Agreed. Health Canada agrees that timely access to devices for Canadians is important and strives to achieve this, with due regard for the potential risk posed to the user and the time and expertise required to evaluate their safety and effectiveness. Health Canada is



undertaking a review of current performance targets and processes, particularly in light of the increasingly complex technologies, and corresponding financial resources to determine the reason(s) for not meeting performance targets, and it will implement corrective action. Health Canada's goal for completion of this review and initiation of corrective action is Spring 2005.

Health Canada will build on its history of strong international co-operation by continuing to explore opportunities to work with international regulatory partners to enhance performance. This includes opportunities to harmonize regulatory approaches and utilization of mutual-recognition agreements.

## Post-market activities

### Inspection strategy needs to be implemented

**2.76** Inspection activities involve visiting manufacturers, importers, and distributors to inspect their operations in order to verify that they are complying with the *Food and Drugs Act* and the Medical Devices Regulations. For example, Health Canada may inspect the distribution records of a manufacturer, importer, or distributor to ensure that the records respect the Regulations. It may also review the action taken by a manufacturer, importer, or distributor in response to an adverse event to ensure that the action taken respects the Regulations. Because the Medical Devices Regulations place significant responsibility for protecting the health of Canadians on the industry itself, it is particularly important that Health Canada assess their activities.

**2.77** The Medical Devices Review Committee recommended that Health Canada develop an active inspection program with public notification when industry does not comply.

**2.78** Health Canada's approach to verifying compliance with the Regulations focusses on three phases in the product life cycle of licensed medical devices: before the product is available at the investigational testing phase; at the manufacturing phase; and after the product is available at the post-market phase. Our observations on inspection at the investigational testing phase are discussed in paragraphs 2.47 to 2.52 and on certification audits (similar to inspections) at the manufacturing phase in paragraphs 2.43 to 2.46.

**2.79** Health Canada has an inspection strategy that identifies the importance of inspection activities. However, we found that Health Canada does not engage in any inspection activity at the post-market phase and does not know the extent to which the Regulations are being respected. More specifically, we found that Health Canada does not know the extent to which manufacturers, importers, and distributors are

- operating surveillance systems that are adequate to allow them to identify adverse events after the product is on the market;
- taking appropriate action in response to adverse events or complaints that come to their attention;

- reporting to Health Canada all serious adverse events that come to their attention;
- maintaining adequate distribution records to ensure successful recalls; and
- selling only licensed devices.

### Unlicensed devices need to be better managed

**2.80** According to the *Food and Drugs Act* and the Medical Devices Regulations, it is illegal to sell a class II, III, or IV device if it does not have a licence. However, we found some evidence that unlicensed medical devices are being offered for sale in Canada. We also found some evidence that it can be difficult to determine whether or not a device is licensed. Because there is no mark on the device or package to indicate whether or not a device is licensed, purchasers must find other means to verify the licence. Because unlicensed devices have not been evaluated by Health Canada for safety and therapeutic effectiveness, there is an increased risk of harm when they are used.

**2.81** In general, we found that Health Canada takes action against an unlicensed device only when it is brought to Health Canada's attention, for example, as a result of an adverse event or a complaint. We observed that often its response is to contact the seller to advise him or her to stop selling the product and, when appropriate, to advise him or her to issue a recall until a licence to sell the device is obtained from Health Canada. Both health care professionals and the medical devices industry itself are critical of Health Canada's approach to unlicensed devices. The medical devices industry is frustrated, as it believes that non-compliant sellers are not penalized in any significant way for selling unlicensed devices and therefore are not discouraged from continuing to sell unlicensed devices. Both health care professionals and the medical devices industry would like to see Health Canada take more severe action against those who sell unlicensed devices. Health care professionals are also frustrated because the onus falls on them to verify that a device is licensed—something that can be difficult to do. They believe Health Canada should help ensure that it is easy to verify that a medical device is licensed.

**2.82** In cases where Health Canada does prosecute the seller of an unlicensed device, the courts can impose fines of up to \$5,000 (the maximum under the *Food and Drugs Act*) or imprisonment.

**2.83** Health Canada and other international regulators have identified a number of possible options to help better manage the risks related to unlicensed devices. To help reduce the risk that a purchaser will buy unlicensed devices, these options include continuing to provide education to manufacturers and purchasers, using visual logos or bar code identifiers on licensed devices, or offering a whistle-blowing hotline. In November 2003, Health Canada developed a more user-friendly, searchable Web site to assist purchasers in verifying the status of licences for medical devices. To better deal with identified unlicensed devices, options include amending the

Regulations and the legislation to allow for the issuing of fines or tickets by Health Canada and to allow for larger penalties to be imposed by the courts.

### Post-market surveillance activities need to be improved

**2.84** Post-market surveillance involves collecting, analyzing, and interpreting information about adverse events. The information is gathered through ongoing monitoring of medical devices for concerns about safety and therapeutic effectiveness once they are available for sale. Health Canada's sources of information about adverse events include industry (which must operate its own surveillance systems as required by the Regulations), health care professionals, patients, consumers, and other international regulators. Based on the results of post-market surveillance, Health Canada may be required to take actions, either by itself or in co-operation with the manufacturer. These actions could include informing the public of safety concerns, recalling a device, or suspending or cancelling the licence for the device and removing it from the market completely.



This structure anchor is used to securely reattach soft tissue such as tendons and ligaments to the bone joint.

Source: Smith and Nephew Inc.

**2.85** The purpose of post-market surveillance is to continue to gather information on the safety and therapeutic effectiveness of medical devices in the “real life” marketplace. This builds on the information about safety and therapeutic effectiveness established during the pre-market testing, for example, investigational testing or laboratory testing. The information collected from pre-market testing can be limited because it is restricted. For example, investigational tests occur in a controlled setting with carefully selected subjects for a limited amount of time. Once the product is available to a much larger and unrestricted population for a much longer period of time, new information about safety and therapeutic effectiveness becomes available. This information is more revealing about the actual health and safety risks. Since this new information permits the ongoing assessment of products in wide use by a large number of Canadians, good post-market surveillance systems are an essential element of Health Canada's processes to manage risk.

**2.86** The Medical Devices Review Committee acknowledged the importance of post-market surveillance. The Committee observed the weaknesses in Health Canada's then-current system of collecting only voluntary reports of adverse events from manufacturers, health care professionals, and the public. As a result, the Committee suggested a combination of active collection of reports about adverse events from these groups and proactive monitoring of patients through mechanisms such as device registries. In its Development Plan, Health Canada committed to completing a feasibility study of these recommendations. Since then, Health Canada has completed several studies to assess weaknesses in post-market surveillance and options for addressing these weaknesses. Also, since the release of the Committee's report, a number of other reports—including those of the Commission of Inquiry on the Blood System in Canada in 1997 and the Working in Partnership—Drug Review for the Future in 1992—have also observed how important good post-market surveillance is and have made similar recommendations to those respective programs.

**2.87** We found that Health Canada has taken only limited action to improve the way it collects, analyzes, and interprets information about adverse events. In terms of improving collection, the only significant action taken by Health Canada has been to make it mandatory, through the Regulations, for manufacturers and importers to report in a timely manner serious adverse events that come to their attention. While it is recognized that health care professionals are most often the first to observe adverse events, we found that Health Canada has done little work to increase the number and quality of reports received from them. As a result, Health Canada is not able to adequately identify adverse events.

**2.88** Weaknesses in the analysis and interpretation of adverse events also continue to exist. Currently, when Health Canada receives a report about an adverse event, the information is entered into the national incident database. When Health Canada receives a complaint, it verifies details of the incident with the user and, if appropriate, investigates to determine whether corrective action is necessary. For adverse events or complaints identified as a particular concern, health hazard evaluations and laboratory evaluations are completed. However, there is no proactive system for identifying patterns in reports or complaints that could signal a serious safety concern.

**2.89** Exhibit 2.8 compares the rates of reporting of adverse events related to medical devices in Canada, the U.S., and the UK and indicates the lower level of reporting in Canada relative to the other countries. Health Canada acknowledges that its lower levels of reporting are due, in part, to its limited activities in the area of post-market surveillance.

**2.90** As a result of the studies to assess weaknesses in post-market surveillance, Health Canada is aware of the gaps and weaknesses in its approach and the importance of correcting them. However, very little has been done to correct them. Exhibit 2.9 provides a number of possible options available to Health Canada. Each is currently being piloted or used elsewhere with some success, including Health Canada's Drug Program and the medical devices programs of the U.S. and the UK.

**Exhibit 2.8** Reporting adverse events of a medical device in Canada, the U.S., and the UK, 2002

	Canada	U.S.	UK
<b>Mandatory—manufacturer</b>	730	141,000	2,000
<b>Mandatory—hospitals</b>	0	2,500	0
<b>Voluntary</b>	270	3,500	6,750
<b>Total</b>	<b>1,000</b>	<b>147,000</b>	<b>8,750</b>
<b>Population (millions)</b>	30	288	59
<b>Rate per million</b>	33	510	148

Source: Health Canada, U.S. Food and Drug Administration, UK Medicines and Healthcare Products Regulatory Agency

**Exhibit 2.9 Options available to Health Canada to improve post-market surveillance**

**Sentinel systems (U.S.)**—An active surveillance system which currently collects adverse events information from approximately 180 sentinel health care facilities (select health care facilities that volunteer to participate fully). Once fully implemented this program will include 250 sentinel facilities.

**Liaison officers (UK)**—A network of surveillance officers that are stationed in each hospital with responsibility for actively collecting adverse-events information and providing that information to the Medicines and Healthcare Products Regulatory Agency.

**Active surveillance systems (Canada)**—Health Canada is currently piloting an active surveillance system for pediatric drugs. Health Canada has developed arrangements with specific health care professionals and facilities that deal with children to have them actively collect information on adverse drug events and submit it to Health Canada.

**Registries (Sweden)**—Registries are data bases where clinicians provide data regarding patients who have the clinical conditions of interest. Data includes diagnosis and history, treatment, and related variables. Patient outcomes are monitored with a view to establishing the relationship between treatment and outcomes.

**Environmental scanning (UK)**—A regular and active scan of relevant domestic and international media.

**Inspection of manufacturers' post-market surveillance systems (U.S.)**—Inspection to ensure: that manufacturers are operating post-market surveillance systems that are adequate to identify adverse events; and that manufacturers are reporting all serious adverse events to the government.

**Integrated adverse-events reporting systems (Canada)**—Canada will use the U.S. Adverse Events Reporting System software to create its own database for Canadian adverse events. The Canadian database will be supplemented by de-identified U.S. data (data that contains no personal information) on a regular basis through downloads of the U.S. data.

Source: U.S. Food and Drug Administration, UK Medicines and Healthcare Products Regulatory Agency, Health Canada

**Communication of safety concerns may not be adequate**

**2.91** The government's responsibility related to safety concerns does not end with identifying concerns. Health care professionals and the public expect that the government will communicate safety concerns in a timely manner to those who need to know. Communication provided to the wrong people or received too late may not prevent the reoccurrence of an adverse event.

**2.92 Notifications of safety concerns.** The Medical Devices Review Committee observed that Health Canada's approach to communicating safety concerns was weak. As a result, it made three recommendations in this area: develop a communications plan, develop a strategy to expand its communications, and improve its communication methods.

**2.93** We observed that Health Canada has a number of tools to communicate safety concerns to health care professionals and the public. These include Web site notices, a newsletter, a [listserv](#), and letters to health

**Listserv**—An electronic communication system that provides subscribers with access to messages, especially related to topics of special interest.

care professionals. Health Canada also monitors high-risk recalls conducted by manufacturers to help ensure their effectiveness.

**2.94** However, we found that Health Canada has never developed a communications plan or a communications strategy for medical devices. As such, it cannot be confident that its methods of communication are the best, that its communications are reaching the right people, or that its communications are timely.

**2.95** We conducted a survey of biomedical engineers at 19 major urban hospitals in Canada, representing most urban hospitals in Canada. We solicited their views about Health Canada’s approach to communicating safety concerns. The individuals surveyed are responsible for investigating adverse events related to medical devices in their respective hospitals, as well as reporting adverse events related to medical devices to manufacturers and/or to Health Canada. Further, they are responsible for sharing with others in their hospital information that they receive about safety concerns. In general, those surveyed identified concerns about the timeliness of communication and the limited number of communications they receive from Health Canada. All of the 19 engineers surveyed stated that they do not rely on Health Canada as their primary source of information on safety concerns. When asked if the communications they received from Health Canada were timely, 12 answered no.

**What biomedical engineers said about how Health Canada communicates safety concerns**

“We don’t even get one-tenth of what is going on in the marketplace from Health Canada.”

“When we do get notices from Health Canada, we usually already know about it.”

**2.96 Tracking of certain implantable devices.** The purpose of tracking certain implantable devices is to enhance the ability of the manufacturer to locate the patient if the implantable device is recalled.

**2.97** We expected Health Canada to have a mechanism to track certain implantable devices in order to help ensure that patients are informed of any safety concerns. We found that for certain implantable devices the Regulations require health care professionals to complete two copies of a registration card once a device is implanted; one copy goes to the manufacturer and the other goes to the patient. This approach should allow the manufacturer to be able to locate the patient using the information on the registration card in the event of a recall.

**2.98** However, we also found that to respect the *Privacy Act*, health care professionals cannot identify the patient on the registration card unless they have received informed consent from the patient to do so. If health care professionals do not request consent, they cannot provide patient contact information and the manufacturers will not have the necessary information to contact the patient. As a result, patients may not be notified of a serious problem or recall related to their implanted device.

**2.99** There are a number of possible options available to address this weakness. One is to use device registries; another is to follow the U.S. approach to dealing with patient information for those devices subject to tracking. In the U.S., the regulations do not require that health care professionals obtain signed informed consent to provide patient contact information. As a result, they can provide manufacturers with all the

information needed to contact patients. Exhibit 2.10 discusses the automobile recall process. While the two industries are not directly comparable for a number of reasons, including the fact that information about personal health is more private and sensitive than information about vehicle ownership, the recall process for automobiles provides an interesting contrast to recalls of medical devices.

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**Exhibit 2.10 The automobile recall process**

Under the *Motor Vehicle Safety Act*, if a car manufacturer needs to issue a recall, it must notify all current owners.

The manufacturer first notifies all those individuals who have registered their car purchase with them. If it no longer has current information, the manufacturer is provided with access (through the Canadian Council of Motor Transportation Administrators) to the provincial licence registries to obtain the personal information necessary to establish contact. If the manufacturer is still unable to notify all owners, it must give notice of the defect by publication in two major daily newspapers covering six regions for five consecutive days.

Source: *Motor Vehicle Safety Act*

**2.100 Recommendation.** Health Canada should ensure that it manages the risks and benefits related to medical devices after they are available for sale. More specifically, it should

- engage in active inspection of industry operations at the post-market phase to verify compliance with the Regulations;
- take a more active approach to dealing with unlicensed devices by ensuring that they are easy to identify and that actions taken against sellers of unlicensed devices will discourage this practice;
- improve the collection, analysis, and interpretation of post-market surveillance information by increasing the number and quality of adverse events reports collected and by improving its analytical and interpretive capability; and
- improve its approach to communication of safety concerns so that those who need to know are informed in a timely manner.

**Department's response.** Agreed. Health Canada will continue to review its current level of activity in relation to these post-market issues and develop an action plan to address the gaps. Health Canada will review all options and determine which options best mitigate the risks associated with medical devices in the post-market phase. Specific responses to this recommendation will be considered in the context of the departmental response to the recommendation in paragraph 2.122. Health Canada's goal for the development of the action plan is Spring 2005.



**Critical-contact single-use devices**—Devices that come into contact with blood or normally sterile body cavities by penetrating the skin or mucous membrane, such as cardiac catheters or urinary catheters.

**Reprocessor of single-use devices**—Anyone who sterilizes or disinfects a used single-use device so it can be reused. This can include a company specializing in reprocessing or a hospital that reprocesses its own devices.

**Reprocessing of single-use devices**—The sterilization or disinfection of a used single-use device so that it can be reused.

## Reuse of single-use devices needs to be better managed

**2.101** In Canada, it is common for health care facilities to reuse single-use devices. A 2001 nation-wide survey indicated that 37 percent of acute-care hospitals reused **critical-contact single-use devices**. This survey was conducted jointly by one of the advisory committees to the Conference of Deputy Ministers of Health (federal and provincial) and a research contractor. The surveyors contacted 802 acute-care hospitals; 461 responded. The reuse of single-use devices is different from the reuse of devices designed for multiple uses because single-use devices were not intended to be reused. Thus, their reuse creates a number of potential risks that include poor functioning after multiple uses or reprocessing, as well as concerns about sterilizing and disinfecting medical devices properly. Other concerns include the lack of informed consent by the patient and the liability of the reuser should something go wrong because of reuse. The main reason that single-use devices are reused is to reduce costs.

**2.102** Recently the U.S. introduced new regulations covering the reuse of single-use devices to address these risks. Basically, **reprocessors of single-use devices** are subject to all the regulatory requirements applicable to the original device manufacturer. Under the U.S. Food and Drug Administration's new regulations for **reprocessing of single-use devices**, all single-use devices that required approval initially must now have pre-market approval for reprocessing. Should the U.S. Food and Drug Administration be satisfied that safety and therapeutic effectiveness of the device can be preserved with reprocessing, approval will be given.

**2.103** Because the reuse of single-use devices can put the health and safety of Canadians at risk and because Health Canada is one of the entities responsible for protecting the health and safety of Canadians, we expected that it would take action to deal with this issue. While we recognize that this issue is a shared responsibility among various jurisdictions and professions, it is important that Health Canada as the federal regulator take action to manage the health and safety risks related to the reuse of single-use medical devices.

**2.104** However, we found that Health Canada has not developed a position on managing the risks related to the reuse of single-use devices, although very recently it began examining its authority to regulate reuse practices. As a result, Canadians are not being protected from the health and safety risks created by the reuse of single-use devices. Canada's failure to develop a position on this issue has created a regulatory vacuum (Exhibit 2.11).

**2.105 Recommendation.** Health Canada should take action, such as regulating reprocessed single-use devices, to manage the health and safety risks related to the reuse of single-use medical devices.

**Department's response.** Agreed. The safety of medical devices in Canada is a shared responsibility, with some authority falling under the jurisdiction of the provinces and territories. Health Canada will undertake a review of the current federal statutory/regulatory authorities to determine its ability to



**Exhibit 2.11 Canada does not have a position on the reuse of single-use devices**

The U.S. regulations for reprocessing of medical devices are quite recent, and to date, only a few devices have been granted pre-market approval. Critical-contact single-use devices (see margin definition on page 26) are among those that have not yet been approved. Canadian hospitals are interested in having devices, including critical-contact devices, reprocessed by American reprocessors. However, before the U.S. will allow shipment of any “unapproved” reprocessed devices out of the U.S. and back to Canadian hospitals, it needs a letter from Health Canada stating that the device “...complies with the laws of that country” (as required by the U.S. Food and Drug Administration *Export Reform and Enhancement Act of 1996*).

As a result, Health Canada has prepared a “Letter of No Objection” for reprocessors that may want to import reprocessed devices into Canada. To date this letter has not been used. The letter states that Health Canada is aware that the reprocessor has reprocessed devices belonging to the Canadian health care facility. It further states that Health Canada is aware that these devices have not been approved by the U.S. Food and Drug Administration for reprocessing. And finally, the letter notes that the shipment of the reprocessed devices does not contravene Canadian law. In essence, the letter is not stating that Health Canada agrees with the practice but rather that the practice is not breaking Canadian law. Thus, devices that have not yet been approved for reprocessing by the U.S. Food and Drug Administration could be reprocessed and imported to Canadian hospitals.

Source: Health Canada, the U.S. Food and Drug Administration, and other sources

regulate the reprocessing of single-use medical devices. Additionally, Health Canada will consult with stakeholders, in particular its provincial and territorial partners, who share in the responsibility for the delivery of health care, to determine the best approach to minimize the health and safety risks related to the reuse of single-use medical devices. Health Canada’s goal for completion of these consultations is Spring 2005.

**Capacity issues exist in the program**

**2.106 Cost recovery.** The Medical Devices Review Committee recommended implementing a cost recovery program, with fees collected for the pre-market approval of devices to provide resources for improving the Medical Devices Program.

**2.107** Between the Committee’s report in 1992 and the introduction of the Medical Devices Regulations in 1998, Health Canada participated in the 1994 government-wide Program Review. During Program Review, it was concluded that the services provided by the Medical Devices Program were a private benefit, and therefore private beneficiaries should pay a portion of the cost of the service. It was determined that fees could be charged and, as a result, the Program was required to give up \$5.6 million of its government funding.

**2.108** Health Canada initially introduced cost recovery for medical devices in 1996, immediately after Program Review. However, it expanded its cost recovery in 1998 with the introduction of the Medical Devices Regulations. The Regulatory Impact Analysis Statement accompanying the 1998 Fees in

**Direct costs**—Costs of the Program that are directly related to the service activity, for example, the cost of an evaluator to evaluate an application.

**Indirect costs**—Costs of the Program that are not directly related to the service activity, for example, the cost of negotiating international agreements.

**A-base funding**—Funds that are provided to Health Canada to support ongoing programs.

**Revenue**—Fees collected from the industry for services provided to it.

**Funding for special initiatives**—Additional resources that are requested by a minister and approved by the Cabinet or the Treasury Board for special initiatives.

**Resource reallocations**—Funds that have been collected through a “levy” on programs within the Department and reallocated within the Department to support departmental priorities.

Respect of Medical Devices Regulations noted that fees had been set so the Program could recover \$7.7 million per year.

**2.109** However, we found that because of problems in setting fees, in 2002–03 the actual revenue for **direct costs** was \$4.6 million and for **indirect costs** was \$1.7 million, for total revenues of \$6.3 million. This is significantly below what was estimated as necessary. We determined that this shortfall happened because the estimate of the direct and indirect costs of the program had been significantly below the actual costs; then the fees were not set high enough to recover the estimated costs; and then the fee structure was changed after negotiations with the industry, resulting in even less revenue. Further, we found that because of Program Review, cost recovery became a means to replace lost government funding and not a means of collecting funds to improve the Program.

**2.110** Because of this funding shortfall, the level of resources engaged in pre-market evaluation activities has been significantly below the level Health Canada estimates is needed to effectively deliver these activities. It has estimated that it requires 97 full-time-equivalent staff for its pre-market activities, including managing its quality-systems activities and class II, III and IV device-licensing activities. However, it currently has only 58 employees.

**2.111 Recommendation.** Health Canada should resolve the problems in its cost recovery program. It should determine the actual costs of the program and set fees based on those costs.

**Department’s response:** Agreed. Health Canada is committed to a cost recovery program consistent with the Treasury Board Secretariat’s External Charging Policy, including required consultation with industry. Health Canada is currently implementing its 2002 Cost Recovery Initiative 2 Action Plan, part of which is the development of a revised costing model that will allow Health Canada to more accurately determine the costs of delivering its regulatory activities, appropriately price its fees, more accurately estimate the revenues, and more fully report on its activities. Health Canada initiated the development of a costing model in 2003, with a goal of providing revenue and cost information through the Performance Report in 2005.

**2.112 Financial resources.** Exhibit 2.12 provides a breakdown of funding sources in 2002–03 for direct costs only. Indirect costs are included elsewhere in Health Canada’s costs. The Medical Devices Program receives funding from four sources: **A-base funding**, **revenue**, **funding for special initiatives**, and **resource reallocations**.

**2.113** In its 1992 report, the Medical Devices Review Committee concluded that Health Canada did not have enough resources to support the necessary program changes. As previously discussed, the Committee recommended the introduction of cost recovery as a means to provide resources for improving the Program. It also recommended that once the new program was ready to be introduced, Health Canada should provide an additional 40 staff positions (representing about \$1.8 million in 1992) and \$2.2 million for operational

costs, for a total of about \$4.0 million in 1992 dollars. Health Canada was also advised to reassess its resource requirements after two years. This would have brought the total amount of A-base funding required for the new program to \$7.4 million (existing 1992 A-base of \$3.4 million plus additional A-base of \$4.0 million). Health Canada did not respond to this recommendation in its Development Plan.

**2.114** In the 1998 Regulatory Impact Analysis Statement accompanying the Fees in Respect of Medical Devices Regulations, it was noted that fees had been set so the program would collect revenue of \$7.7 million per year. It was further noted that this amount, combined with the A-base funding that remained after the 1994 Program Review money was taken away, was expected to be sufficient to deliver the new Medical Devices Program. The 1998 A-base funding was about \$1.5 million per year.

**2.115** As noted in Exhibit 2.12, the A-base funds allocated to the Medical Devices Program in 2002–03 were \$403,000. This was significantly below the amounts that the Medical Devices Review Committee estimated were necessary for a new Program. The Committee estimated an amount of \$1.8 million (\$7.4 million as suggested, less \$5.6 million lost as part of 1994 Program Review). The 2002–03 A-base funds were also significantly below the \$1.5 million that Health Canada estimated was necessary when the new Program was actually introduced in 1998.

**2.116 Erosion of capacity.** As required, the Department conducts an annual resource reallocation exercise in which it collects money in the form of a levy from each Branch. The funds are then reallocated to departmental priorities as determined by senior management at Health Canada. The levy is passed on to programs within the branches. As required, the branches also conduct a resource-reallocation exercise in which they collect money from each program in addition to the money paid to cover the departmental levy, and then reallocate it to branch priorities as determined by branch management.

**2.117** We determined that between these two levies, the Medical Devices Program lost \$424,000 in 2002–03. We also determined that the Program received \$514,000 from the reallocation for specific activities. Most of its other priority projects, which include a feasibility study of a high-risk cardiac implant registry and a breast implant registry, were not considered priorities for funding. This process creates instability in funding and erodes the Program's ability to carry out its responsibilities.

**2.118** Also of concern is that for the year 2003–04, levies were applied to funding for special initiatives and to revenue from fees paid by industry for services. Additional funds provided by the Cabinet or the Treasury Board are for specific initiatives. Funds taken in the form of levies and redirected no longer directly support the activities that the Cabinet or the Treasury Board agreed to support. Further, revenues from fees for a service that are taken and redirected are no longer going directly to support the delivery of that service.

**2.119** Further, funds provided to the Health Products and Food Branch to cover collective bargaining salary increases in its programs were held back at the Branch level and not provided to the programs. The programs were

forced to cover the collective bargaining increases out of their annual budgets. At the end of the year, any salary deficits in the programs were covered by the Branch from funds that included the collective bargaining increases that had been held back.

**2.120 Balancing resources.** The Medical Devices Review Committee recommended that the Medical Devices Program balance its focus between pre-market and post-market activities. In its specific observations and recommendations, the Committee presented suggestions for activities in both areas that would achieve this goal. However, while some weaknesses remain in the pre-market activities, the most significant gaps and weaknesses are in the post-market activities. Exhibit 2.12 provides a comparison of resources allocated to pre-market and post-market activities.

**Exhibit 2.12** Funding sources for direct costs and full-time equivalents allocated to pre-market and post-market activities in 2002–03

Funding (\$ thousands)	Pre-market	Post-market	Total
A-base funding	0	403	403
Revenue	2,677	1,966	4,643
Special initiatives	1,726	510	2,236
Resource reallocations	21	69	90
<b>Total</b>	<b>4,424</b>	<b>2,948</b>	<b>7,372</b>
Full-time equivalents	58	37.5	95.5

Source: Health Canada

**2.121** The funding allocated to post-market activities is significantly less than is allocated to pre-market activities. Because of the limited resources available to engage in post-market activities, the 37.5 staff equivalents involved in this activity are significantly below the 73 staff that Health Canada has estimated it needs for a good post-market system.

**2.122 Recommendation.** Health Canada should either provide adequate human and financial resources to allow for delivery of the Medical Devices Program as it is designed or redesign the Program to allow health and safety risks to be adequately managed in other ways that require fewer resources.

**Department's response.** Agreed. Health Canada will undertake a review of the Medical Devices Program in consultation with stakeholders to determine the appropriate level of program delivery, the appropriate program design, the associated resource requirements, and possible funding sources. This review will be supported by the findings and recommendations stemming from concurrent activities in such areas as the cost recovery program and performance measurement framework (noted in the responses following

paragraphs 2.111 and 2.127 respectively). Health Canada's goal for completion of this review is Summer 2005.

**2.123 Recommendation.** To inform Parliament, in two years Health Canada should assess its progress and challenges in making changes to the Medical Devices Program. The results should detail what improvements were made and how they were made as well as the gaps that remain and the reasons why they remain. Significant findings should be included in Health Canada's annual reporting to Parliament.

**Department's response:** Agreed. Health Canada's response to the Medical Devices Review Committee's report was the Development Plan for an Improved Medical Devices Regulatory Program. Health Canada will assess, in two years, its progress and challenges in making improvements to the Medical Devices Program based on this response and include significant findings in its annual reporting to Parliament.

**Evaluation, performance  
measurement, and reporting to  
Parliament**

**2.124** Program evaluation and ongoing measurement of performance tell management what has worked to produce desired results and what has not. The government needs this information for planning and setting priorities. Reporting performance information to Parliament enables parliamentarians to make informed decisions about the program.

**2.125** We expected that Health Canada would adequately evaluate the Program as well as measure and report the results achieved. Given the challenges that the Program faces and the gaps and weaknesses that exist, we expected Health Canada to bring these issues to the attention of Parliament in its reports.

**2.126** We found that the Medical Devices Program has not been evaluated recently. Health Canada has developed and is implementing a performance management framework, which includes performance indicators relevant to the Medical Devices Program. However, presently the only performance measures used at Health Canada are the amount of time taken to authorize device licences and the number of new and amended licences authorized and renewed annually. Our review of Health Canada's previous three reports on plans and priorities and its performance reports, including the 2002–03 Performance Report, found minimal mention of the targets, performance, and weaknesses of the Medical Devices Program. When performance is weak, as is the case in the Medical Devices Program, parliamentarians need to know it is weak and why it is weak so they can support needed improvements.

**2.127 Recommendation.** Health Canada should adequately evaluate, measure, and report the results of the Medical Devices Program—both its achievements and challenges.

**Department's response.** Agreed. Steps are currently being taken to improve our ability to report program results. Health Canada is developing a measurement framework for the Medical Devices Program to provide a balanced view of performance, and it commits to enhancing public reporting on our actions. Health Canada's goal for completion of this measurement framework is Spring 2005.

## Conclusion

**2.128** Equal and timely access to quality health care is a priority for Canadians. This includes timely access to medical devices, which play an important role in all stages of the delivery of quality health care.

**2.129** The Medical Devices Review Committee was established in 1991 to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. Health Canada responded to the report and, with additional help from the Committee, prepared a Development Plan for an Improved Medical Devices Regulatory Program, proposing changes to its Medical Devices Program. Health Canada also consulted with stakeholders on the proposed changes. Because Health Canada responded to the report and made efforts to implement changes, we have used the Department's response as the standard against which we have measured the Medical Devices Program. The Department has accepted that we are using this standard.

**2.130** In 1998 Health Canada introduced new regulations, introduced some new activities, and made improvements to some existing activities. However, a number of gaps and weaknesses remain, particularly in its activities to manage risks and benefits after devices are approved for sale. Health Canada is aware of these gaps and weaknesses but has made limited effort to address them.

**2.131** More specifically, we are concerned that Health Canada does not

- play a role in the conduct of investigational tests once they have begun;
- proactively inspect industry operations at the post-market phase to verify that they are in compliance with the Medical Devices Regulations;
- have a system that provides sufficient information on adverse events, conduct adequate analysis of the adverse-events information it does collect, or communicate safety concerns in a timely manner;
- act to address the health and safety risks related to the reuse of single-use devices; and
- act to improve timely access to all available medical devices.

**2.132** Limited financial and human resources and limited progress in advancing international regulatory co-operation prevent Health Canada from delivering the Medical Devices Program as designed. Failure to discharge its responsibilities under this Program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk—risk of both injury and liability.

**2.133** While elements of the Program are acceptable, there are significant shortfalls, which indicate that the current program is not sustainable. Therefore Health Canada must make a choice. It must provide adequate resources to deliver the Program as designed, based on the Committee's

report or redesign the Program and the Regulations to allow health and safety risks to be managed in a way that requires fewer resources.

**2.134** Health Canada needs to improve its evaluation, measurement, and reporting of results of its Medical Devices Program. This is especially important given the questions about whether to continue with the current Program or redesign it.

**2.135** Our final concern relates to the Medical Devices Program's ability to deal with future demands. It is expected that medical devices will become increasingly complex and that the medical devices industry will grow in both size and importance. Health Canada will need to adapt its program to accommodate this increase in the number and complexity of devices. The gaps and weaknesses that exist now raise concerns about how it will manage in the future.



## About the Audit

### Objectives

The objectives of this audit are to determine whether Health Canada adequately

- manages the risks and benefits related to safety and therapeutic effectiveness of medical devices available in Canada;
- identifies weaknesses in the Medical Devices Program and takes action to address them; and
- measures and reports the results achieved by the Medical Devices Program.

### Scope and approach

The focus of this audit was Health Canada's Medical Devices Program managed by the Health Products and Food Branch, and in particular the Program activities directed at class II, III, and IV medical devices.

We examined the activities Health Canada engages in to discharge its responsibilities. We reviewed the 1992 report issued by the Medical Devices Review Committee and the Development Plan for an Improved Medical Devices Regulatory Program prepared by Health Canada in response to the Committee's report. We also reviewed the documentation from the consultations with stakeholders that took place prior to the introduction of the new Regulations. We made comparisons with the medical devices programs in the U.S. and the UK and with the Drugs Program delivered by Health Canada. Further, we considered the impact of the Medical Devices Program's human and financial resources on Health Canada's ability to adequately discharge its responsibilities.

We carried out extensive interviews with Health Canada staff involved in the Medical Devices Program. We met with several different stakeholder groups. We reviewed documentation, including legislation, regulations, program documents, studies, public communication, and device evaluation, hazard analysis, and investigation files. Finally, we met with staff involved in the medical devices programs of the U.S. Food and Drug Administration and the UK Medicines and Healthcare Products Regulatory Agency, and with Health Canada staff involved in the Drugs Program.

### Criteria

We expected that Health Canada would

- have an approach to identify, manage, and communicate risks and benefits to Canadians in a timely, efficient, and effective manner;
- have designed and implemented a regulatory process to manage the risks related to the safety and therapeutic effectiveness of medical devices;
- have adequate resources, both human and financial, to discharge its responsibilities;
- work co-operatively with other international jurisdictions to improve the efficiency of the Medical Devices Program;
- identify gaps and weaknesses in the Program and have plans to address them;
- develop plans to amend regulations and adapt the program to new and emerging circumstances; and
- adequately measure and report the results achieved by the Medical Devices Program.

### Audit team

Assistant Auditor General: Ronnie Campbell

Director: Linda Anglin

Theresa Bach

Jo Ann Little

Marc Simard

Alex Smith

For information, please contact Communications at (613) 995-3708 or 1-888-761-5953 (toll-free).



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