HOUSE OF COMMONS
CANADA

CHAPTER 8 OF THE NOVEMBER 2006 REPORT OF THE AUDITOR GENERAL OF CANADA – ALLOCATING FUNDS TO REGULATORY PROGRAMS – HEALTH CANADA

Report of the Standing Committee on Public Accounts

Hon. Shawn Murphy, M.P.
Chair

June 2007

Also available on the Parliamentary Internet Parlementaire: http://www.parl.gc.ca

Available from Communication Canada — Publishing, Ottawa, Canada K1A 0S9

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THE STANDING COMMITTEE ON PUBLIC ACCOUNTS

has the honour to present its

EIGHTEENTH REPORT

Pursuant to Standing Order 108(3)(g), the Standing Committee on Public Accounts has considered the Chapter 8 of the November 2006 Report of the Auditor General – Allocating Funds to Regulatory Programs – Health Canada. The Committee as agreed to table this Report as follows:

INTRODUCTION

The most vital role of government is to protect the health and safety of its citizens. One of the means of doing this is through regulating products available in the market place. Health Canada is the one of the most important departments of the federal government in this regard. It regulates drugs, medical equipment and other health products, cosmetics, pesticides, and hazardous substances in the workplace. These products touch on almost every area of our lives. It is thus of utmost importance that Health Canada fulfills its responsibility as regulator by ensuring that products vital to the health and well-being of Canadians are available and that those products do not pose undue risk to the health and safety of Canadians. Consequently, Health Canada must ensure that its regulatory programs are well managed and have sufficient resources to fully meet their responsibilities.

After an audit of the medical devices program in 2004,[1] the Auditor General became concerned with the way that Health Canada allocated funds to its regulatory programs. Subsequently, the Office of the Auditor General undertook an audit of three of Health Canada's regulatory programs—product safety, drug products, and medical devices—to determine: whether Health Canada allocated resources based on sound financial and performance information; whether program managers reported information on sources of funding, program costs, and results; and whether Health Canada could demonstrate that it allocated adequate funds to meet its regulatory responsibilities.

Given the importance of this issue for the health and safety of Canadians, on February 12, the Committee met with Sheila Fraser, the Auditor General of Canada and other officials from her Office—Ronnie Campbell, Assistant Auditor General; and Louise Dubé, Principal. Health Canada was represented by Morris Rosenberg, Deputy Minister and Accounting Officer; Susan Cartwright, Associate Deputy Minister; Neil Yeates, Assistant Deputy Minister, Health Products and Food Branch; Susan Fletcher, Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch; and Richard Charlebois, Director General, Financial Operations Directorate.

[1] Auditor General of Canada, March 2004 Report, *Chapter 2 – Health Canada – Regulation of Medical Devices*.

OBSERVATIONS AND RECOMMENDATIONS

A. Action Plan

The Auditor General makes numerous recommendations in her performance audit reports and departments are given the opportunity to respond to those recommendations within the text of the report. The Committee has, unfortunately, become accustomed to seeing responses that are quite vague—it is either unclear whether the department agrees with the recommendation or if the department does agree, what the department intends to do to implement the recommendations, or when it hopes to make the changes.

By contrast, the responses by Health Canada to the audit of its regulatory programs were clear, to the point, and included timelines. The Deputy Minister of Health Canada, Morris Rosenberg, provided this response to the audit:

> Let me say that we agree with the Auditor General's recommendations, and that in fact the department has already started work to address some of the very issues that were raised. In light of the report, we are preparing a detailed action plan, which we would be pleased to share with the committee over the course of the next couple of weeks.[2]

Indeed, several weeks after the hearing, the Committee received the promised action plan. This plan indicates how Health Canada intends to take a number of actions in response to the audit. Health Canada will undertake comprehensive reviews of its regulatory programs and develop a financial management control framework, which would include improvements to: operational planning processes, performance measurement frameworks, the departmental budget management framework, costing strategies, and cost-recovery strategies/user fees. While the action plan provided to the Committee is neither as detailed nor precise as it could be, it is clear that Health Canada is planning to do a sweeping review and revision of its planning processes. Mr. Rosenberg spoke of the response to being audited, “I think one of the benefits of an Auditor General’s report is that it does tend to focus the mind.”[3] The Committee hopes that Health Canada’s follow through is as serious as its intentions. As the Committee would like to monitor the implementation of this action plan, and Mr. Rosenberg indicated that his department could provide the Committee with progress reports, the Committee recommends that:

[2] Meeting 38, 15:35.
[3] Meeting 38, 16:45.

RECOMMENDATION 1

Health Canada provide the Public Accounts Committee with progress reports every six months on the implementation of recommendations made by the Auditor General in her November 2006 Report, beginning in September 2007 and continuing until the recommendations are fully implemented.

Part of Health Canada's action plan is to conduct comprehensive reviews of its regulatory programs, which should indicate the extent to which Health Canada is meeting its regulatory responsibility to protect the health and safety of Canadians and where improvements need to be made. The Committee is interested in seeing the results of these reviews and recommends that:

RECOMMENDATION 2

Health Canada provide the Public Accounts Committee the results of its comprehensive reviews of its regulatory programs immediately upon completion.

The Committee fully supports the report of the Auditor General and the recommendations made therein. Thus, the Committee truly appreciates the proactive stance of Health Canada and its Deputy Minister to the audit and to the Committee's expectations for an action plan, which is all too rare. Too often Committee members must closely question witnesses in order to fight through vagueness and ambiguity. If departments disagree with the conclusions and recommendations of the Auditor General, they should be clear and upfront about it and provide cogent reasons for that disagreement. If not, the Committee fully expects that departments, and more importantly, Accounting Officers, will appear before the Committee with a detailed action plan of how they intend to implement the Auditor General's recommendations and be willing to provide progress reports on the implementation of that plan.

B. Program Baselines

A program baseline is a fundamental aspect of good planning and decision-making. A good program baseline specifies the level of activities required to meet regulatory responsibilities, the targeted performance of activities and the resources needed. The audit found that none of the directorates examined at Health Canada had all the elements of a good program baseline. The consequence of not having adequate program baselines is that Health Canada does

not know if it is fully meeting its regulatory responsibilities as the regulator of product safety, medical devices, and drug products. It does not know what activities are needed, the resources required to fund those activities, and the adequacy of performance its programs.

Health Canada commits in its action plan to conduct comprehensive reviews of the regulatory programs examined by the audit. According to the action plan, these reviews will respond to the need for baselines, performance indicators and targets, and program costs. The Committee is encouraged that Health Canada will be addressing this important issue, and Mr. Rosenberg also indicated that there are lessons from the audit that could be applied across all regulatory programs within his department.

The Committee goes further and believes that there are lessons that could be applied across the government. When asked if all regulatory programs should have a program baseline, the Auditor General responded:

> If you haven't established the level of activity—which of course can vary over time, as risks change and situations change—if you haven't established the baseline, then how do you know if you're allocating enough resources to it or not, and how do you know if you're carrying out the level of activity you think is appropriate? So I would say yes.[4]

Given the importance of regulatory programs to the health and safety of Canadians and the important role that program baselines play in good planning and decision-making, the Committee recommends that:

RECOMMENDATION 3

Treasury Board develop a policy by 31 December 2007 requiring all regulatory programs of the Government of Canada to establish clear program baselines that set out the required level of activities, performance, and resources needed to meet regulatory responsibilities.

C. Risk Analysis

The audit identifies a number of compliance and enforcement activities that program managers indicated to their branch management as being insufficient to meet Health Canada's regulatory responsibilities (exhibits 8.4 and 8.5). This greatly concerns the Committee because there could be consequences to the health and safety of Canadians, such as exposure to unsafe,

[4] Meeting 38, 17:00.

ineffective, or dangerous therapeutic products. There is also an increased possibility of legal liability.

However, in his testimony before the Committee, Mr. Rosenberg discounted the opinions of program managers. He said, "The question is whether the view of the program manager that there are inadequate resources is dispositive—that it's the final word on the issue. In other words, because a program manager says so, does it mean it's so? . . . [I]f you ask a program manager whether they have enough resources, they might say, well, I could always use more resources."[5] Mr. Rosenberg went on to say that the issue is how one manages risk. He commented, "Health Canada is in the business of managing risk. Are we doing it appropriately? We have to have this dialogue with our managers about that."[6]

Yet, the Committee wonders on what basis the Deputy Minister makes these remarks because there were no program baselines for the programs and no risk analysis has been done to determine the appropriate level of activities or concentration of efforts. If program managers are not the best situated to determine this, then who is? If the issue is really over the appropriate way to manage risk as opposed to the opinions of program managers, then one would assume that the comprehensive program reviews would focus on risk, but the action plan provided to the Committee contains almost no mention of risk.

The Committee realizes that it is not possible to eliminate risk entirely and Health Canada will have to make difficult decisions about the appropriate level of activities needed to minimize risks to the health and safety of Canadians. These decisions, though, should be based on a thorough risk assessment of the consequences to not carry out activities deemed to be insufficient by program managers. Consequently, the Committee recommends that:

RECOMMENDATION 4

In accordance with its action plan for the implementation of the Auditor General's recommendations, Health Canada make risk assessments an integral part of the comprehensive reviews of its regulatory programs.

[5] Meeting 38, 16:10.
[6] Meeting 38, 16:20.

D. Cost Recovery

The Committee was told that the Health Products and Food Branch at Health Canada, which is responsible for the drug products and medical devices programs, will be updating its cost recovery regime, whereby the department recovers a portion of its costs for regulatory programs from users of services or clients, which in this case are the manufacturers of drugs and medical devices. The current fees were set in 1993-94 and have not been updated since. Neil Yeates, Assistant Deputy Minister for the Health Products and Food Branch, noted that in comparison to other countries Canada was on the low end of the proportion of the budget that is made up from fees, about 25%, so there is room to grow in this regard.

It is not clear at this point, though, where any new funds from changes to the cost recovery regime will be directed. This is important because when the drug products and medical devices programs received additional funding for special initiatives, the funds were used to help eliminate a backlog of submissions made by manufacturers seeking review and authorization to market a product. However, most of the examples of regulatory activities considered by program managers to be insufficient were in the area of compliance and enforcement, or after a product had already been approved, i.e. post-market. While removing the backlog of submissions is important, there remain potential risks to the health and safety of Canadians from products that are already on the market.

The Committee is concerned that any changes to the cost recovery regime could lead to further pressures on the pre-market, or approvals, side of regulatory programs because it is the manufacturers of drugs and medical devices who pay these fees and have an interest in having their products approved in a timely manner. The Committee would like to know more about Health Canada's plans in this area, which can be done through the *User Fees Act*. This Act requires departments to consult with Parliament for any changes to user fees. Ministers must table in each House of Parliament a proposal outlining the changes and their rationale. In addition, departments must establish performance standards, which are now reported in their departmental performance reports, along with actual performance levels. As the Committee would like to know how Health Canada plans to distribute any new funds collected from user fees and have an appropriate balance between pre-market and post-market activities, the Committee recommends that:

RECOMMENDATION 5

Health Canada's proposal to Parliament regarding changes to its user fees for the Health Products and Food Branch clearly indicate how the funds will be allocated amongst pre-market and post-market activities and what proportion of program funding will be based on user fees.

CONCLUSION

Health Canada has significant regulatory responsibilities for products that are vital for and impact on the health and safety of Canadians. It is thus of utmost importance that Health Canada manages its regulatory programs in an effective manner. The recent audit by the Auditor General found a number of areas where Health Canada can improve its planning and decision-making with respect to its regulatory programs. It greatly concerns the Committee that any issues were found because Health Canada did not know if it was fully meeting its regulatory responsibilities as the regulator of product safety, medical devices, and drug products. However, the Committee was encouraged by the response of Health Canada to the Auditor General's recommendations and hopes other departments will respond in a similar fashion. All Accounting Officers should be prepared to provide the Committee with an action plan on the implementation of recommendations when they appear before the Committee to discuss an audit.

On the other hand, the Committee was troubled that the Deputy Minister of Health Canada appeared to doubt the opinion of the program managers of these regulatory programs who had indicated to their branch management that the department was not carrying out sufficient activities to meet their regulatory responsibilities. In order to have a better understanding of the risks involved, Health Canada should base such an opinion on a thorough risk assessment. The Committee would also like to be assured that any changes to the cost recovery regime will maintain an appropriate mix of pre-market and post-market activities. Lastly, the Committee believes that there are lessons from this audit that should be applied to all regulatory programs managed by government.

Witnesses List

Chapter 8, Allocating Funds to Regulatory Programs - Health Canada of the November 2006 Report of the Auditor General of Canada

Organizations and Individuals	*Date*	*Meeting*
Department of Health Susan Cartwright Associate Deputy Minister	2007/02/12	38
Department of Health Richard Charlebois Director General Financial Operations Directorate (FOD)	2007/02/12	38
Department of Health Susan Fletcher Assistant Deputy Minister Healthy Environments and Consumer Safety Branch	2007/02/12	38
Department of Health Morris Rosenberg Deputy Minister	2007/02/12	38
Department of Health Neil Yeates Assistant Deputy Minister Health Products and Food Branch	2007/02/12	38
Office of the Auditor General of Canada Ronnie Campbell Assistant Auditor General	2007/02/12	38
Office of the Auditor General of Canada Louise Dubé Principal	2007/02/12	38
Office of the Auditor General of Canada Sheila Fraser Auditor General of Canada	2007/02/12	38

REQUEST FOR GOVERNMENT RESPONSE

In accordance with Standing Order 109, the Committee requests that the Government table a comprehensive response to the report.

A copy of the relevant *Minutes of Proceedings* (Meetings Nos. 38, 56 and 61 including this report is tabled).

Respectfully submitted,

Hon. Shawn Murphy, M.P.
Chair