

Health Canada, Cost Recovery  
and  
Small Business

RECOMMENDATIONS  
to the  
Departmental Executive Committee

*March 30, 2001*  
From Health Canada's  
Working Group on Small Business and Cost Recovery

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## 1 DECISIONS REQUIRED

The Departmental Executive Committee consider the recommendations in this report, and, if approved, assign responsibility as appropriate to ensure implementation.

## 2 BACKGROUND

The recommendations in this Report are the result of an initiative undertaken by Health Canada to increase the Department's appreciation of the concerns of small business<sup>1</sup> that must work with Health Canada's cost recovery initiatives. Health Canada is seeking to identify issues of concern to small business and develop practical, workable responses that are, from the Department's perspective, fiscally sound and operationally viable.

To ensure that this initiative stayed open, transparent and apprised of all relevant considerations, a working group ("the Working Group") was convened that was comprised of six individuals representing the interests of the small business sector and Health Canada's cost recovery management.<sup>2</sup>

The discussions and deliberations of the Working Group were supported by information gathered from interviews with a select sample of small businesses and from the networks brought to the table through the industry association Working Group members. This report highlights the findings and presents the recommendations of this Working Group.

### 2.1 Challenges for Small Business

By way of background, the interviews and discussions within the Working Group revealed that small business often supplies specialty products for Canadians that are otherwise unavailable, and, that many of the small businesses active in this sector belong to those who are active in designing and developing innovative products that help the people of Canada maintain and improve their health .

Interviews with small business conducted over the autumn of 2000 provided the Working Group with insights about challenges for small business working within this sector (with and without the pressures introduced by cost recovery). Among the challenges identified were the following:

- ***Fees have a disproportionate impact on smaller companies***

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<sup>1</sup> Small firms employ six out of ten working Canadians, and seventy-eight percent of all businesses in Canada employ less than five people. (Source: Canadian Federation of Independent Business and Statistics Canada ) For the purposes of this initiative, small business is defined as companies with less than 50 employees. During this initiative distinctions within this grouping have been recognized and indicate a need to examine the sector more closely in order to ensure that recommendations are appropriate to the concerns of the various sub-groups (e.g., the very small businesses) within the larger grouping that the term small business represents.

<sup>2</sup> The members of the Working Group are Andy Butterfield, Therapeutics Products Programme; Brian Glabb, Corporate Services Branch; Kevin Murray, Medical Devices Canada; Garth Whyte, Canadian Federation of Independent Businesses; Robert Woods, Pest Management Regulatory Agency; and Jean Szkotnicki, Canadian Animal Health Institute.

Smaller businesses typically survive within niche markets with a relatively low volume of sales. For small business, fees often represent a disproportionate cost (of fees to gross revenues) – especially when compared with the cost, on a proportionate basis, where larger volumes of product sales are concerned. For example, a fee reduction to 3% of gross sales as allowed under one set of Health Canada fees still represents more than 30% of the net revenues for some small businesses. Since the cost of fees cannot be passed onto customers in many of the highly competitive niche markets within this sector, this level of impact on profits can be extremely damaging to company viability.

- ***Smaller companies have limited resources***

Small businesses have fewer internal resources to dedicate to administrative and management challenges. These challenges include: obtaining information necessary to better understand program requirements; preparations for meeting the regulatory requirements associated with regulatory programs; and, managing customer demands for, and expectations about, the availability of products from sources within Canada.

- ***Smaller companies are more vulnerable to loss of market opportunities***

In the relatively small market that Canada offers, smaller businesses tend to rely on the revenues of a few select product lines. With a smaller customer base, small business cannot survive losing many customers to rival suppliers or losing opportunities to develop market share. The prospects for small business are therefore closely tied to both the impact of fees and to the timely receipt of regulatory review results. The revenues from these few product lines are generally insufficient to carry a company over delays of up to several years that are now associated with some Health Canada regulatory review and approval processes.

## **2.2 Issues for Health Canada Programs**

The Health Canada program management interviewed over the autumn of 2000 noted the following factors that posed a challenge in responding to the challenges for small business. These include:

- ***Absence of consistent or explicit direction***

There are no consistent or explicit departmental or central agency policy or guidelines about: the basis for addressing the concerns of small businesses; any equity considerations that may come into play; and, the extent of the federal government's commitment to supporting small businesses through *differential* (as opposed to "preferential") measures on either a short term or long term basis.

- ***Constraints on program design***

In the absence of central agency support and direction, the Department has limited flexibility in developing cost recovery initiatives to better support services and to improve program delivery. The design of (or revisions to) fee structures are also subject to a number of constraints. Among these are following: fees cannot be designed in such a way that they could be

construed as a “tax” as discussed in the “Eurig” decision about Ontario’s probate fees; Treasury Board’s cost recovery policy states that cross subsidization must be avoided; and, implementing modifications to fee schedules is resource intensive and time consuming.

- ***Inadequate program support***

Some programs within Health Canada appear to be unable to meet current commitments to the timely delivery of services for which fees have been paid. This appears to be attributable, by and large, to the scope of existing resources for such programs and related infrastructure concerns (e.g., need for improved/revised procedures).

- ***Need for more information***

Health Canada program management identified the need for more detailed information about the small businesses regulated by Health Canada. There is a need for more information about the numbers and characteristics of small companies, about the characteristics of the markets affected by the regulatory processes (e.g., ability to pass costs through), and, above all, about the impacts from limited product availability (and loss of product development that small businesses would otherwise support) on Canadians seeking to maintain and improve their health.

### **3 RECOMMENDATIONS**

The recommendations of the Working Group have been the product of vigorous discussion about how Health Canada can more effectively address the concerns of small business. The Working Group is cognizant of the fact that most of the recommendations set out below will also be helpful to all businesses working with Health Canada’s regulatory programs – small or large.

#### **3.1 The Health Portfolio Cost Recovery Committee be assigned responsibility for coordinating the implementation of the recommendations of the Working Group.**

The recommendations of this report will need strategic support and direction within the Department to be effectively carried out. The Health Portfolio Cost Recovery Committee (HPCRC) is comprised of managers from each program undertaking cost recovery under the authority of the Minister of Health. This committee has already sponsored a number of initiatives that have advanced thinking about cost recovery within the Health Portfolio and thus is well suited to supporting the development of consistent approaches within the Department and further forward thinking initiatives, such as those outlined below. In addition, the HPCRC is favourably positioned to establish partnerships and information sharing initiatives with other departments and agencies (e.g., Industry Canada) which could be useful in developing effective initiatives for small business. Each member of the HPCRC shall report to their individual program’s ADM, and, each ADM, in turn, will report to DEC.

#### **3.2 DEC consider ways and means to reduce the disproportionate impact of fees on small business on a temporary as well as a long term basis.**

Health Canada needs to explore ways to minimize the disproportionate impacts of fees on small business who must work with regulatory programs within the Department. It is proposed that Health Canada consider temporary relief immediately on an administrative basis, and pursue formal regulatory changes and approval of a Fee Remission Order to address the charges that would have been required but for a temporary reductions measure.

Since each Health Canada program has unique characteristics, the specific requirements of the temporary fee reduction should be developed for each program individually within the parameters of the objectives of this reduction, these being to ensure that small companies who can provide evidence of disproportionate impact (e.g., viability of small business at substantial risk) survive the period that fee structures are being reviewed. The decisions of each program about the basis for extending such temporary fee reductions will be submitted to DEC, or a designated sub-Committee thereof, for approval.

### **3.3 Health Canada improve the delivery of services for which fees are paid and adopt a policy which links payment of fees as closely as possible to the actual delivery of the services.**

In general, fees are considered acceptable when associated with timely provision of services with which they are associated. Since this is not the case in several areas, Health Canada needs to improve the delivery of services to ensure negotiated performance standards are met.

Recognizing that achieving acceptable performance levels cannot in some programs be accomplished immediately, Health Canada should consider introducing a departmental policy that programs not require payment of fees until the service for which the fee is paid begins (i.e., active review of an application begins).<sup>3</sup> And that this policy be incorporated as soon as possible in changes to existing regulations.

### **3.4 Health Canada establish additional effective, timely and affordable options for resolving disputes arising in relation to fee paying programs.**

Small business have identified the need for an affordable and neutral third party (i.e., objective and independent) review option to support effective and timely resolution of fee disputes. While initial attempts to resolve disagreement over fees should remain a Program responsibility, the Working Group recommends that Health Canada assign responsibility for a second (and binding) level of appeal to an office without direct program management responsibilities within the Department to coordinate and support resolution of fee related disputes. To ensure that resources are not wasted, criteria should also be developed to ensure disputes that are frivolous and vexatious are not supported. The Office of Revenue and Costing is recommended.

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<sup>3</sup> In some programs (e.g. Therapeutic Products, Veterinary Drugs) fees must be paid when submissions are accepted for review despite the fact that actual review may not start for months, or even years. For small businesses the costs of paying for a place in the queue are too high to sustain given their cash flow pressures.

The Working Group has also noted the importance of increasing the availability of information for stakeholders about the various process options (including information about best practices in resolving disputes) that are available within the Department. This should be a priority task assigned to the Office assigned responsibility for offering additional dispute resolution options.

### **3.5 Health Canada improve the availability of information about programs across the Department.**

For small business, the importance of direct access to designated, knowledgeable staff is critical to ensuring that appropriate and consistent information is provided to, and about, Health Canada's regulatory programs. Larger firms can afford to maintain in-house expertise or to contract with consulting firms who specialize in providing regulatory advice and services, but this option is often not economically feasible for small companies.

While many programs within the Department do provide good information about program requirements and regulatory processes, Health Canada should ensure that a consistent approach is developed across the Department. Elements of a consistent approach include: working with industry to ensure critical information gets to small business; developing simpler forms (e.g., "lite" applications); setting up toll-free numbers within programs (for those programs that have not done so already), establishing a single window access point for information about cost recovery for the department which could also direct callers to specific program contacts; better training of program staff to ensure authoritative and consistent information is provided; and, centralized (and on-line) access to information about the status of applications under review.

The costs of *not* ensuring that timely and appropriate information is available are high for regulatory programs in view of the higher cost of undertaking remedial activities to promote compliance and pursue enforcement.

### **3.6 Health Canada improve consultation with small business.**

The industry Working Group members identified elements that support meaningful consultations for business participating in consultations. As a matter of departmental policy, the Working Group recommends that Health Canada ensure that its consultations ensure adequate opportunity for involvement by small business (and their associations), and conform with the following principles:

- Stakeholders are provided sufficient background information (and time) to enable effective participation.
- Consultations identify at the outset any constraints or limitations on flexibility.
- The consultation is designed to result in action plans for program improvement.
- There is genuine commitment to receiving, and working with, the contributions offered by stakeholders.

- The consultation ensures follow-up and supports feedback from small business as to the success of the action plans implemented.

### **3.7 Health Canada explore improvements to legislative and regulatory provisions in order to better support the integrity of the Canadian regulatory process and, at the same time, also ensure that responses to non-compliance with regulatory requirements are prompt, efficient and effective.**

There are a number of long standing legislative and regulatory issues that have been problematic for small business, the impacts of which have been exacerbated by the introduction of cost recovery. An example from the veterinary drugs sector serves to illustrate. Currently, federal legislation and regulations permit veterinarians to use or food producers to import non-approved veterinary products – active pharmaceutical ingredients, sold as final products, which have not satisfied Canada's risk assessment approval processes, nor originated from manufacturers who have met establishment licensing or Good Manufacturing Practice (GMP) requirements. Such practices simultaneously provide a loophole in existing risk management practices and serve as a counter-incentive to regulatory and cost recovery compliance. There may be other examples within Health Canada that need to be explored in terms of impacts on health and safety and disincentives to complying with requirements to pay fees and submit products and establishments to review processes.

Supporting effective and equitable compliance is also a key concern for small businesses who do comply with regulatory requirements – including the paying of fees – when many of their competitors do not. Health Canada needs to support a level playing field for firms actively meeting Canada's regulatory requirements. Health Canada must ensure that consequences to non-compliance effectively discourage firms and individuals from circumventing Canadian regulatory requirements.

The Working Group also recommends that the Departmental Executive Committee ensures that:

### **3.8 Health Canada request direction and support from Treasury Board in addressing the challenges of small business working with regulatory programs charging fees.**

How departments and agencies work with small business is a government-wide issue and Health Canada would prefer to act consistently with practices adopted across the federal government.

Health Canada requires direction from Treasury Board concerning such specific matters as: the scope of the Department's responsibilities respecting small business; appropriate criteria for use in developing any differential treatment initiatives; and, additional flexibilities to improve program design.

The Working Group recommends that Health Canada's Deputy Minister send a letter to the Secretary of the Treasury Board describing the need for direction and additional flexibilities to address the impacts of cost recovery on small business, particularly in the



health sector. Health Canada should ask that the current Treasury Board Secretariat Review of its Cost Recovery Policy include within its review the issues relating to small business working with regulatory programs and provide guidance on funding of mitigation measures (e.g., fee reductions or caps), guidance about when mitigation is required, and guidance on selection of local mitigation measures versus more systemic approaches (e.g., grants or tax measures).