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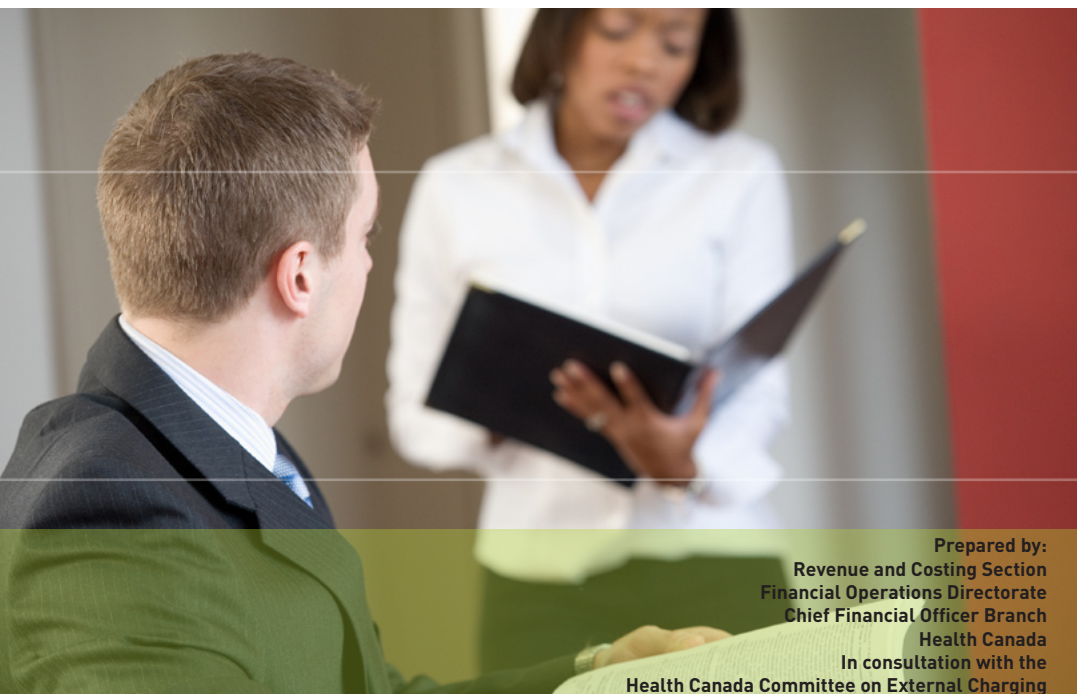
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HEALTH CANADA EXTERNAL FEE GUIDELINES

## Fee Mitigation

This is one in a series of documents developed to supplement the Health Canada Policy on External Charging and provide Health Canada managers with guidance on issues related to the use of fees.

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Canada

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## FEE MITIGATION

### 1. Purpose and Scope

- 1.1. This is one of a series of guidelines developed to provide Health Canada managers with guidance on issues related to the use of fees. The guidelines are intended to be applicable to most Health Canada programs, but it is the responsibility of the user to consider the specific circumstances in each case and adapt the guidance accordingly.
- 1.2. This guideline explores in depth issues related to deciding whether and how to limit undesirable effects of fees on specific individuals or groups of fee payers and should be read in the context of the Health Canada External Charging Policy, related Health Canada guidelines, the Treasury Board Policy on Service Standards for External Fees and the *User Fees Act*.
- 1.3. This guideline on fee mitigation supplements the Guideline on Fee Structure, which focuses primarily on issues related to the overall design of fees.
- 1.4. This guideline assumes net voted funding authority.

### 2. Introduction

- 2.1. It is Health Canada policy to charge fees if activities represent a benefit to an identifiable group, unless there are extenuating reasons not to.
- 2.2. Once the decision has been taken to pursue user fees for a particular Program activity (See Guideline on Navigating the External Fee Process), and the fees have been set, there may be a need to minimize any unintended consequences the fees may have on stakeholders. While recognizing that mechanisms for doing this – fee exemptions, reductions, caps or by other means – may be part of the design of the fees themselves, they can also be applied under very special circumstances and with sufficient justification after the fee has been designed and implemented. Minimizing any unintended consequences is the subject of the Guideline on Fee Mitigation.
- 2.3. It should be recognized that, at a minimum, fee mitigation will result in an additional administrative cost to the department that needs to be recouped or paid for, and any revenue foregone must be offset by alternative sources of funding. The implications of approving a fee mitigation request must be fully understood and the source of alternative funding determined before the request is approved.

### 3. Discussion

- 3.1. While recovery of all identifiable costs is the initial goal, there are circumstances under which the Department will choose for valid reasons to charge less than the full amount. This relates to fee setting. Fee mitigation occurs to provide further relief to specific groups or individual fee payers.
- 3.2. Before deciding to mitigate a fee, the program should consider the following basic principles:
  - 3.2.1. *Fairness* – A fee should be fair to all stakeholders, including the program. There may be some stakeholders that will be unduly penalized by a fee and valid and justifiable grounds for some dispensation can be identified and supportable evidence produced. This can be accomplished at the time of establishing the fee structure or through mitigation. In either case, care must be taken to ensure that reducing or exempting a fee for one specific individual or group of fee payers does not result in cross subsidization of that individual or group by the remainder of the fee payers that are paying the full fee. The additional cost to administer fee mitigation and any revenue foregone will be funded by sources other than external charging.

- 3.2.2. *Consistency* – Fee mitigation should be applied consistently and without prejudice to all fee payers within a group of fee payers.
- 3.2.3. *Transparency* – Information, including the individual or group of fee payers and the reasons for the mitigation should be readily available. The decision should withstand public scrutiny.
- 3.2.4. *Supportable* – The decision to mitigate a fee should be fully justified by the fee payer. No mitigation should be contemplated without fully supported evidence as to the undue impact the fee would present.
- 3.3. Because of the financial implications of fee mitigation on Health Canada, Treasury Board should be involved at an early stage in the process when mitigation is being contemplated. Should additional funding not be available and reallocation of funds internally could compromise other objectives or result in unacceptable cross subsidization, mitigation may have to be denied.
- 3.4. Internal reallocation of funds could result in a perception that paying stakeholders are given priority over other Health programs.
- 3.5. For planning purposes, program managers should consider establishing a cap or cut-off point for fee mitigation at the time of designing the fee beyond which revenue foregone could not be absorbed internally, and discuss options for additional funding with Treasury Board.
- 3.6. In all cases, when a program wishes to reduce a charge to specific groups or individual fee payers, the reduction should be justified for one of the following reasons:
  - 3.6.1. Specific public or program policy objectives
  - 3.6.2. Impact on the financial position of groups of fee payers
  - 3.6.3. Cumulative impact of fees
- 3.7. In the first instance, charging fees for all identifiable related costs would compromise specific public or program policy objectives. This would apply when the Government announces that a specific group of fee payers will be exempt from paying fees. Examples of common “program or public policy objectives” of potential importance to Health Canada include:
  - 3.7.1. Access to therapeutic products (e.g. drugs, medical devices),
  - 3.7.2. Compliance with health related regulations,
  - 3.7.3. Support for research/innovation, and
  - 3.7.4. Support for the economy (in this context, primarily small business).
- 3.8. Charging a fee may have a significant detrimental impact on the financial position of groups of fee payers.
  - 3.8.1. The financial position of groups of fee payers could be affected by the nature of the business, the limited sales potential of the product it manufactures, the size of the business, the structure of the business, etc.
  - 3.8.2. A fee that impacts on the financial viability of a particular business or group of businesses could be contrary to a general Government objective to support small business and/or could also compromise program objectives by threatening the availability of products of concern to Health Canada.
- 3.9. Cumulative fees can result when a single fee payer is subject to fees from different organizations or multiple fees from a single organization for a single service. For example, this could occur when a service covers multiple product lines or activities with multiple departmental jurisdictions.

## 4. Fee Mitigation Mechanisms

- 4.1. *Exemptions* – Address the need to define a group of potential payers who should be exempt from fees in their entirety. The usual reason for considering a fee exemption is for government policy reasons. For example, the underlying activity may primarily impact private sector firms but also involve government organizations, such as public hospitals or charities, for which fees may be inappropriate. Since hospitals are publicly funded, it would simply become a reallocation of tax dollars. Fees may be warranted for the majority of service recipients but not for all, and for the latter group, the appropriate action may be either partial or complete exemption from the fee.
- 4.2. *Reductions* – Could be used for a specific payer or group of payers meeting specific conditions. This would primarily apply to a financial criterion to take into account the nature of a business or a business structure. In contrast to exempting a whole group of fee payers due to the characteristics of the group (e.g. they are a public health institution), there are circumstances under which charging the full fee to payers within a group who meet certain criteria (e.g. the fee would amount to more than 5% of gross sales) may be inappropriate.

This is often relevant where charging the fee would result in a disproportionate impact on certain payers relative to the majority. For example, a fee of \$1,000 has a greater impact on a firm with sales of \$50,000 / year (fee is 2% of sales) than one with sales of \$5 M (fee is 0.02% of sales). While there is no hard and fast rule, existing Health Canada fees have used criteria that a reduced fee should apply if the full fee would represent more than 1-1.5% of gross annual sales (for annual fees). In another example the fees for evaluation of new drug products can be reduced if the full fee represents more than 10% of the anticipated sales of the product in the first 3 years of marketing. This provision addresses “orphan drug” situations, wherein a product with limited sales potential can be granted a reduced fee.

- 4.3. *Fee delays* – Can be applied when the fee payer fully intends to pay the full amount of the fee but is unable to do so within the allotted timeframes due to financial hardship. The full amount owing would not be affected but the timeframe within which the amount would be paid would change. A fee delay may ultimately result in a more efficient collection process and provide support to an innovation or research initiative but there may be an administrative cost involved in tracking the payment.
- 4.4. *Scheduling of payments* – Consideration should be given to allowing for scheduling payments when the approval process may take an extended period of time and/or when financial hardship can be determined in advance. A payment plan might include payments based on stages of completion or at regular intervals. This may improve cash flow for the fee payer and may also provide better planning for the program but there will be an administrative cost to the Department in the form of invoicing and tracking the payments and possible interest charges.
- 4.5. *Fee limits or caps* – Could be used where a payer meeting specified conditions would be harmed by the cumulative impact of fees. The potential exists for the total bill to represent a potentially severe economic burden, and for which some form of mitigation based on cumulative impact is appropriate. The question of cumulative impact for fees charged by Health Canada programs should be considered on a case-by-case basis to identify and address any instances where impact warrants mitigation.
- 4.6. *Combination of the above* – Any situation may call for any one or a combination of the above fee mitigation strategies. The final test should be whether the fee meets the principles established in Section 3.2.

## 5. Mitigation Requests from Payers

- 5.1. Where fee mitigation is requested, it will be necessary for the prospective fee payer to not only claim mitigation, but provide proof of eligibility. Careful consideration must be given to the proof required:
  - 5.1.1. Minimal Proof: It may be possible to require no or minimal proof. For example, information to justify exemptions of certain groups of payers may be available in program records, or the basis for the reduced fee may be obvious from the request (e.g. lower per unit fee for multiple items in the same request). Minimal evidence could include a request on the organization's letterhead.
  - 5.1.2. Appropriate Documentation: Where more than minimal proof of eligibility is required the degree or scale of justification should be commensurate with the scale of the fee. For example, a potential reduction in fee by thousands of dollars would justify requesting a greater degree of proof than a reduction of tens of dollars. In some cases, independent, or 3rd part confirmation, may be required.
  - 5.1.3. Readily Available Information: This recognizes that firms require certain information for other purposes (e.g. corporate tax, financial reporting) and where feasible it is good practice to accept evidence in a form that meets program needs without imposing additional costs on the payer.
  - 5.1.4. Consider Risk: Rather than force a payer to fully justify all fee mitigation requests, consideration should be given to accepting a lesser degree of proof to reduce the costs to both the payer and the program. The financial risks involved should guide the decision. An example would be where a firm is allowed to certify sales as the basis for claiming a reduced fee, but the option to request audited sales records is available to the department should there be reason to doubt certification, or simply to facilitate an audit program of a subset of payers. A balance must be achieved between the justification required and the cost of providing it.

## 6. Documentation

- 6.1. As discussed above, the amount of documentation required will depend on the type and impact of the mitigation. Once the decision is taken to include fee mitigation mechanism(s) in a fee structure the form and specific details must be defined. As a minimum, program documentation should include the following:
  - 6.1.1. The name of the fee
  - 6.1.2. The individuals or groups subject to the fee
  - 6.1.3. The name of the individual or group to which mitigation applies
  - 6.1.4. Reasons for the mitigation, including detailed justification from the individual/group
  - 6.1.5. Time period for which the mitigation applies
  - 6.1.6. Impact of the mitigation on the appropriation
  - 6.1.7. Impact of the mitigation on the program, i.e. levels of service, administrative burden, etc.

## 7. Other Considerations

- 7.1. Section 5.1, *User Fees Act* – Section 5.1 requires a reduction of a user fee if performance does not meet the standard established for the fee in a given year. In a situation where some payers are paying the full fee while others are paying a reduced fee due to fee mitigation, any reduction brought about by the application of Section 5.1 should be applied on a pro rata basis. The reduction will have an impact on the appropriation and should be documented accordingly.
- 7.2. The amount of fees foregone and replaced by other sources of funding as a result of fee mitigation should be reported every fiscal year in the Departmental Performance Report in order to ensure accountability and transparency and to demonstrate that performance standards are not affected by the mitigation.
- 7.3. A Checklist for deciding if/which fee mitigation mechanism(s) are required is provided in Appendix “A”.

## 8. Reference

- 8.1. Fees that currently include fee mitigation mechanisms:
  - 8.1.1. Authority to Sell Drugs Fees Regulations
  - 8.1.2. Drug Evaluation Fees Regulations
  - 8.1.3. Veterinary Drug Evaluation Fees Regulations
  - 8.1.4. Establishment Licensing Fees Regulations
  - 8.1.5. Fees in Respect of Medical Devices
  - 8.1.6. Regulations Prescribing the Fees to be paid for a Pest Control Product Application Examination Service Provided by or on behalf of Her majesty in Right of Canada, for a Right or Privileges to Manufacture or Sell a Pest Control Product
  - 8.1.7. New Substances Fees Regulations
- 8.2. Other References:
  - 8.2.1. *User Fees Act*
  - 8.2.2. Health Canada Policy on External Charging
  - 8.2.3. Guideline on Fee Structure
  - 8.2.4. Guideline on Navigating the External Fee Process
  - 8.2.5. Guideline on Complaint Resolution and Dispute Management for External Fees
  - 8.2.6. Treasury Board Policy on Service Standards for External Fees

## 9. Enquiries

Enquiries on this guideline should be directed to:  
Revenue and Costing Section  
Chief Financial Officer Branch  
[rsc\\_src@hc-sc.gc.ca](mailto:rsc_src@hc-sc.gc.ca)  
Tel: (613) 952-9936  
Fax: (613) 957-2292

### FEE MITIGATION CHECKLIST

	Yes	No
<p>1. There are specific and identifiable program objectives that will be compromised as a result of the fee:</p> <p style="padding-left: 40px;">a. Fee would reduce demand, thereby compromising Health Canada program objectives that fall within the Health Canada mandate. If yes, go to number 5.</p>		
<p>2. There are specific and identifiable public policy objectives that will be compromised as a result of the fee:</p> <p style="padding-left: 40px;">a. Fee would reduce demand, thereby compromising Government of Canada policy objectives, such as innovation and research. If yes, go to number 5.</p>		
<p>3. The fee has a significant financial impact on an individual fee payer or group of fee payers that would place them in financial hardship and have a detrimental effect on their ability to purchase goods or services from Health Canada. If yes, go to number 7.</p>		
<p>4. There is clear evidence that the cumulative effect of the fee(s) on an individual or group of fee payers is unwarranted. If yes, go to number 9.</p>		
<p>5. There is clear evidence that the individual or group should be exempt from the fee in its entirety. If yes, consider FEE EXEMPTIONS.</p>		
<p>6. There is clear evidence that the individual or group should be partially exempt from paying the full fee. If yes, consider FEE REDUCTIONS.</p>		
<p>7. The fee payer can demonstrate that delaying payment of the fee will reduce financial hardship to the extent that the fee payer can continue an innovation or research initiative. If yes, consider FEE DELAYS.</p>		
<p>8. The fee payer can demonstrate that scheduling payment of the fee over a period of time will reduce financial hardship to the extent that innovation or research can continue OR the program determines that the approval process will take an extended period of time to finalize. If yes, consider FEE SCHEDULING.</p>		
<p>9. The fee payer can demonstrate that the cumulative effect of fees charged by Health Canada programs imposes a severe economic burden. If yes, consider FEE CAPS.</p>		



FEE MITIGATION CHECKLIST

	Yes	No
10. If the answer is yes to more than one of numbers 5 to 10, consideration should be given to a combination of the mitigation mechanisms.		
<b>Note: If the answer is yes to one or more of numbers 5 to 10, continue to respond to the checklist.</b>		
11. The fee mitigation has been fully documented, including: <ul style="list-style-type: none"> <li>a. The name of the fee</li> <li>b. The individuals or groups subject to the fee</li> <li>c. The name of the individual or group to which mitigation applies</li> <li>d. Reasons for the mitigation, including detailed justification from the individual/group</li> <li>e. Time period for which the mitigation applies</li> <li>f. Impact of the mitigation on the appropriation</li> <li>g. Impact of the mitigation on the program, i.e. levels of service, administrative burden, etc.</li> </ul>		
<b>Once the fee mitigation has been designed, the original fee and any fee mitigation should be reviewed and assessed against the following principles:</b>		
12. The fee mitigation is fair to all stakeholders, including the program. Fee mitigation does not result in cross subsidization of any individual or group by an individual or group paying the full fee.		
13. The fee mitigation is consistently applied across all like groups of fee payers.		
14. The process is transparent in its application. The decision to mitigate fees will withstand public scrutiny.		
15. All decisions are fully supported by detailed documentation that will withstand audit.		