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HEALTH CANADA EXTERNAL CHARGING GUIDELINES

## **Guideline on Navigating the External Fee Process**

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

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Prepared by:  
Revenue and Costing Section  
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Chief Financial Officer Branch  
In conjunction with  
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# NAVIGATING THE EXTERNAL FEE PROCESS

## 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 presents a series of questions to assist managers in navigating the external fee process and should be read in the context of the Health Canada External Charging Policy, the Treasury Board Policy on Service Standards for External Fees, and the *User Fees Act*.
- 1.3. The questionnaire in Appendix I should be completed to:
  - 1.3.1. Document steps taken to implement, amend or update a fee for future reference or to provide support in the event of a dispute;
  - 1.3.2. Provide program managers with a summary of the steps required by the *User Fees Act*, the TBS Policy on Service Standards for External Fees and the Departmental External Charging Policy;
  - 1.3.3. Provide information to allow senior management to make a decision on the appropriateness and feasibility of the fee; and
  - 1.3.4. Assist departmental staff in performing monitoring and evaluations and to independently assess the appropriateness and financial viability of fees.

## 2. Introduction

- 2.1. The Health Canada Policy on External Charging states that fees should be charged if activities represent a benefit to an identifiable group, unless there are extenuating reasons not to.
- 2.2. As new initiatives are identified, consideration should be given to the introduction of new fees. Similarly, fees have to be updated from time to time in keeping with the changing environment. There is a need for the fee sponsor to consider all identifiable elements relating to the update or introduction of a new fee, including the reasons for introducing it, the initial and ongoing costs and the monetary and non-monetary benefits.
- 2.3. As there may be subsequent changes to organizational structures, activities and/or other related costs, fees need to be reviewed on a regular basis. Section 6.1.6 of the Health Canada External Charging Policy states that a timetable for such review must be established at the time of introducing or amending a fee. Periodic adjustment is allowed under Section 19.2 of the *Financial Administration Act (FAA)*.

- 2.4. When an existing fee is to be assessed or a new/updated fee is to be proposed, the program manager should complete the questionnaire in Appendix 1 and forward it to the Chief Financial Officer Branch.
  - 2.4.1. In the role of Champion for External Charging, the Chief Financial Officer would provide a challenge function to ensure all aspects of the fee update/initiation have been considered and assess the financial merits of the assessment/proposal.
  - 2.4.2. Figure 1 provides a pictorial summary of the questions to be asked in introducing/updating/assessing a fee.

### 3. Discussion:

- 3.1. Introducing fees:
  - 3.1.1. The federal government funds most activities through taxation. Ensuring tax dollars (appropriations) are used to fund the optimum mix of programs requires attention to prioritization, cost avoidance, cost reduction and alternate funding. One mechanism for alternative funding is charging fees.
- 3.2. Consider other service providers:
  - 3.2.1. In the event Health Canada is *not* the sole provider, there should be regular comparison of fees charged by Health Canada and other provider(s), as well as assessment of the difference between the revenue received and all identifiable cost to Health Canada and Government of Canada of providing the service. There may be instances where it may be more appropriate for Health Canada to consider discontinuing the activity (or divesting it to some other party).
- 3.3. There should be a benefit to an identifiable external group:
  - 3.3.1. The prerequisite for charging fees in Health Canada's External Charging Policy is that "activities...benefit identifiable external recipients more than the general public".
  - 3.3.2. At least one of the following conditions must be met before an external charge can be established:
    - 3.3.2.1. A product, service or the use of a facility is provided by the Department to identifiable external recipients with benefits beyond those consumed by the general taxpayer;
    - 3.3.2.2. The Department delivers a service. The purpose of which is to regulate activities of an identifiable external recipient;
    - 3.3.2.3. A right or privilege is granted, or access to or use of a departmentally owned or controlled resource is provided to identifiable external recipients.
  - 3.3.3. External charging, including user fees, differs from taxation in that the charge is linked to what an identifiable external party receives, over and above what the general taxpayer receives, or to the costs of regulating an activity or providing a service.

### 3.4. Other Considerations:

- 3.4.1. Generally, fees should not be charged when the potential monetary and non-monetary benefits of a proposed fee are less than the projected cost of introducing and managing it.
- 3.4.2. Developing and implementing fees is a relatively complex and costly exercise, involving such activities as policy analysis, costing, service standard development, consultations, to name a few.
- 3.4.3. Program managers must consider all costs, which in many cases are continuing incremental costs, in addition to start-up costs, before proceeding with the implementation of a fee.
- 3.4.4. If fees already exist or are planned in a Program, sharing resources may allow for amortizing some costs across the organizational structures. The apportioned cost of developing and implementing a specific fee may be less as a result.
- 3.4.5. There could be non-monetary benefits to be gained from charging for the activity. For example, if fees would moderate demand for previously “deemed” free activities or if fees would have an appreciable impact on compliance with regulations, there may be reason to consider fees despite the cost of implementing them.
- 3.4.6. Fees should not be charged if a strong argument exists for the federal government to fund the activity or program from appropriations. When a program represents a benefit to an identifiable group over that received by taxpayers in general, it could then be argued that the charging of fees makes sense. However, there are various reasons not to charge, including:
  - 3.4.6.1. Health Canada regulations require a program to provide legal access to non-licensed drugs and to charge for them would be inappropriate;
  - 3.4.6.2. Charging of fees to recover Health Canada costs could be an incentive for manufacturers to charge more; and
  - 3.4.6.3. It could be in the public interest (e.g. humanitarian grounds) to fund the service without charge and treat the service as “public good”.
- 3.4.7. If there is concern that fees might represent a disincentive for the introduction of useful new products, design of the fee structure may address this concern by including provisions whereby fees could be reduced if warranted.
- 3.4.8. A closely related issue is the impact of fees on compliance with health and safety regulations. Wherever possible, fees should be structured to encourage and support compliance.
- 3.4.9. Examples of the types of issues, which need to be considered in evaluating the condition that fees do not compromise broader objectives include:
  - 3.4.9.1. Scientific research
  - 3.4.9.2. Small business
  - 3.4.9.3. Practice of medicine

## 4. Conclusion

- 4.1. As the preceding sections and examples demonstrate, a comprehensive analysis of the situation is required and it goes beyond simply applying the primary criteria for charging – i.e., there is an identifiable beneficiary beyond the general public. Figure 1, External Fee Decision Chart, combines the criteria and conditions discussed above into a flowchart, showing that deciding to charge fees involves a number of additional steps, including consideration of whether there are reasons not to charge, which cannot be mitigated through appropriate mechanisms. Appendix 1, Questionnaire on Fee Process, can be used to assess existing fees periodically or to assess new fee proposals or proposals to amend fees.

## 5. References

*User Fees Act* (March 2004)

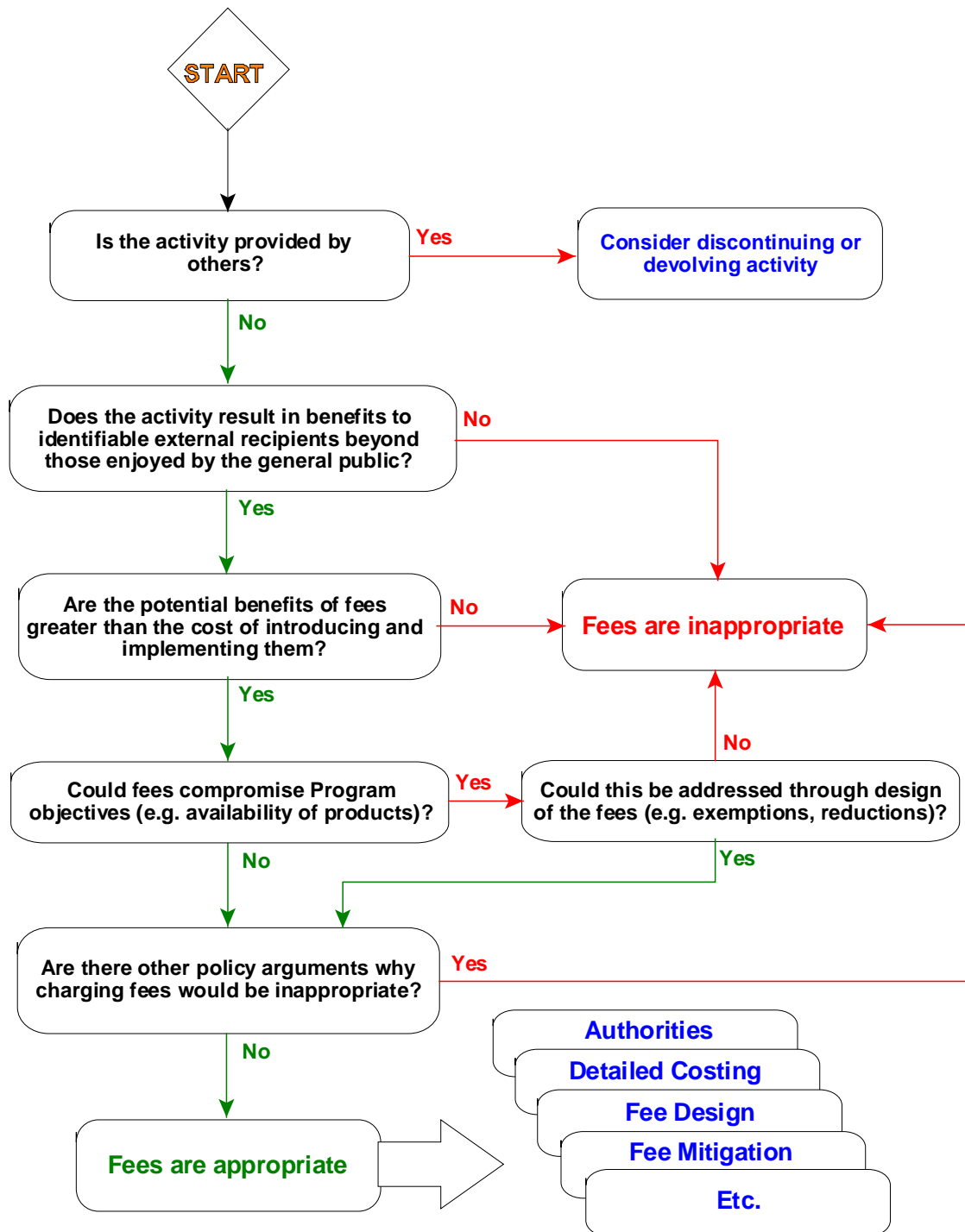
Policy on Service Standards for External Fees – Treasury Board Secretariat (November 2004)

## 6. Enquiries

- 6.1. Enquiries 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) 957-7759

Figure 1: External Fee Decision Chart



## APPENDIX I: Questionnaire on the Fee Process

Fee Name: \_\_\_\_\_

Program Manager: \_\_\_\_\_

1. Is the action to be taken meant to:
  - 1.1. Assess an existing fee \_\_\_\_\_
  - 1.2. Introduce a new fee \_\_\_\_\_
  - 1.3. Increase a fee \_\_\_\_\_
  - 1.4. Decrease a fee \_\_\_\_\_
  - 1.5. Expand the application of a fee \_\_\_\_\_
  - 1.6. Decrease the application of a fee \_\_\_\_\_
  - 1.7. Increase the duration of a fee \_\_\_\_\_
  - 1.8. Decrease the duration of a fee \_\_\_\_\_
  - 1.9. Other (please describe) \_\_\_\_\_
  
2. Is the fee for a:
  - 2.1. Product \_\_\_\_\_
  - 2.2. Regulatory process \_\_\_\_\_
  - 2.3. Authorization \_\_\_\_\_
  - 2.4. Permit or license \_\_\_\_\_
  - 2.5. Facility \_\_\_\_\_
  - 2.6. Service \_\_\_\_\_
  - 2.7. Other (please specify) \_\_\_\_\_
  
3. Is the activity identified in 2) above, for which a fee is/will be charged, available from any other organization, either private or public? Please be specific.  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
  
4. If the answer to 3) is “yes”, what is the rationale for providing the activity?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
  
5. Is there a direct benefit or advantage to any one identifiable external person or group?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If “yes” who is the client?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



6. Which of the following benefits apply?
- |   |       |
|---|-------|
| Reduced risk and liability to client            | _____ |
| Improved market access for products or services | _____ |
| Enhanced credibility as suppliers               | _____ |
| Enhanced public confidence in the industry      | _____ |
| Compliance and enforcement                      | _____ |
| Other (please describe)                         | _____ |
- 
- 
7. Under what authority is the fee being/to be charged, i.e. Financial Administration Act, Department of Health Act, and Minister's Inherent Authority to Contract?
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8. When is the fee scheduled to be updated/introduced?
- 
9. Is the program resourced to undertake the update to or development of the fee? Would external resources be required? Please provide details.
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10. What is the expected cost of updating/initiating the fee? Please attach estimates.
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11. Could the fee be updated/introduced sooner if more resources were available? Please provide details.
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12. Have full costing and revenue estimates been calculated for the fee for the current year and at least the following two years? Yes \_\_\_\_\_ No \_\_\_\_\_
- Please attach estimates. Note: For assistance with costing, please contact the Revenue and Costing Section, Corporate Financial Officer Branch.

13. How was the fee determined?
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14. Does the amount of expected revenue equal the full costs of the product/service etc. being provided?  
Yes \_\_\_\_ No \_\_\_\_
15. If the answer to 14) is 'yes', is the anticipated revenue expected to keep pace with costs over the life of the fee?  
Yes \_\_\_\_ No \_\_\_\_
16. If the answer to 14) is "no", is the anticipated revenue expected to exceed the cost of the product/service etc.?  
Yes \_\_\_\_ No \_\_\_\_
17. If the answer to 16) is "yes", please provide analysis that warrants and defends this situation.
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18. If the revenue does not equal the costs related to the fee, are there reasons for continuing/proceeding with the fee? Yes \_\_\_\_ No \_\_\_\_
- 18.1. Are there non-monetary benefits to be gained from charging for the activity? If so, what are they?
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- 18.2. Are there other reasons for charging the fee? If so, what are they?
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19. If part or all of the cost of the fee is to be funded out of the appropriation, is a plan in place to continue to fund from the appropriation and to deal with inflation? Please provide details.
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20. Is there a projected shortfall resulting from the establishment or updating of the fee require a TB Submission? If so, what is the proposed approach and expected timeframe for preparing a Submission?
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21. Is a plan in place to review/update the fee periodically?
- 21.1. What is the proposed timeframe for regular updates, for example, annually? Every two years? Other? What is the rationale for the timeframe?

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22. Is there a chance the new/amended fee will be a disincentive to the introduction of useful new services/products? If so, how has this been addressed?

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23. Are you aware of a need to consider fee mitigation for any group of clients/stakeholders? If so, describe who they are and the process being followed.

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24. Have service standards been prepared in accordance with Treasury Board's *Policy on Service Standards for External Fees* (effective November 29, 2004)?

Yes \_\_\_\_\_ No \_\_\_\_\_

If "no", when will they be available? \_\_\_\_\_

25. Have the standards been compared to those of other countries with which a comparison is relevant and against which performance can be measured?

Yes \_\_\_\_\_ No \_\_\_\_\_

If "yes", please provide details.

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26. Have reasonable measures been taken to consult with clients/stakeholders and other departments with similar clientele? Please describe the nature of the consultations and the result.

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27. If the fee is subject to the *User Fees Act*, has an independent advisory panel been established to address complaints submitted by clientele?

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28. If it is an existing fee, is a dispute resolution mechanism in place at the branch level? Please describe.

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29. Is the establishment or revision of the fee a temporary measure related to a specific issue? If so, please explain.

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30. Has appropriate accounting been defined for the fee under the Program Activity Structure, to ensure that the revenue can be matched against the related costs and accurately and completely reported?

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