SELECTING MEDICATION FOR COVERAGE IN QUEBEC

A Responsible, Transparent Process

Information on the Scientific Evaluation Process of Medication

Conseil du médicament
CONSEIL DU MÉDICAMENT

SELECTING MEDICATION FOR COVERAGE IN QUEBEC: A RESPONSIBLE, TRANSPARENT PROCESS

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INTRODUCTION

Drugs take up a large place in healthcare services, and this place is growing year by year. Medication now fills many functions. Indeed, medication is not only associated with treatment, but also for preventing, stabilizing or even delaying a health problem. It can still replace traditional treatments which are at a better cost and provide better conditions for patients. Thus, treatments that in the past required hospitalization can today be carried out on a walk-in basis. In short, medication has become the main component in optimizing healthcare services and improving the health and well-being of the population.

In 1997, Quebec set up a drug insurance plan for the entire population. The plan allowed to greatly improve access to medication for everyone based on the needs of a given health condition, as is the case for all healthcare services.

Quebec manages two Formularies: the Régime général d’assurance médicaments (RGAM) Formulary\(^1\) and the Drug Formulary for Institutions\(^2\). These lists are updated according to a schedule established by the Ministre de la Santé et des Services sociaux. Currently, this schedule allows three updates a year. As well, a listing request from a manufacturer may be evaluated as a priority, i.e., not following the established schedule, for one of the following reasons: if the Conseil believes that the normal evaluation period could result in patients who must receive this medication experiencing a rapid and irreversible progression of their disease, which could lead to serious harm, and that no other therapeutic option appears in the RGAM Formulary or the Drug Formulary for Institutions, or if the evaluation process for a drug, patented or not, is likely to delay in substantial savings for the RGAM.

How are products evaluated by the Conseil before the Minister decides whether they will be listed on the insured drug formularies? Are they re-evaluated once they have been listed? These questions are of primary importance from several perspectives. First, citizens want to have a guarantee of access to the largest possible number of medications known to be safe and effective. Secondly, people with a specific disease or health problem want to have access to better known treatments. Lastly, taxpayers and the community demand that resources dedicated to medication and to healthcare in general are well managed. Therefore, we must find the best possible balance between these three perspectives.

The evaluation of medication for the purposes of listing is one of the two major functions of the Conseil du médicament, like helping the Ministre de la Santé et des Services sociaux in updating the formularies. This function is based on scientific data. The Conseil is also in charge of monitoring the use of drugs and promoting their optimal use. These two major functions are inter-related and complementary. We should point out that the Conseil sends its recommendations for listing (with or without restrictions\(^3\)) to this Minister, who has the ultimate responsibility of drawing up and updating the formularies.

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\(^1\) This refers to the list of medications covered by the plan under Section 60 of the Act Respecting Prescription Drug Insurance (RQG, ch. A-29.01).

\(^2\) This refers to the list of medications that can be used in Quebec health institutions under Section 116 of the Act Respecting Health Services and Social Services (L.R.Q., c. S-4.2).

\(^3\) Products recommended without restriction are listed in the “Regular Drug” section of the RGAM Formulary. Products with restrictions are listed in the “Exception Drug” section of the RGAM Formulary and Drug Formulary for Institutions, specifying the criteria for use recognized by the Conseil.
1. **VALUES GUIDING THE CONSEIL IN EVALUATING MEDICATION**

The evaluation of medication is a demanding process. Above all, the Conseil wanted this function to be based on the values largely shared by the community and to which its members, employees and partners completely adhere. These fundamental ethical values are thoroughness, scientific credibility, impartiality, transparency and integrity.

As a government agency, the Conseil also believes that the public interest should remain at the top of its priorities and at the heart of all its activities.

2. **EVALUATION ACTIVITY OBJECTIVES**

Activities for evaluating medication have the following four objectives:

- To offer the population a wide range of medication whose therapeutic value has been recognized.
- To act diligently so that the available medication are constantly updated in order to take advantage as much as possible of scientific advances.
- To base the listing of any new medication on the concept of “added value”, whose assessment is based on therapeutic value, analysis combined with a fair price and the evaluation of the pharmacoeconomic study results, as well as health, budgetary and organizational repercussions (organization of healthcare services).
- To enable citizens to have access to the drugs required by their health condition regardless of the place in which the services are offered to them: in a healthcare institution, in a walk-in clinic or at home.

3. **EVALUATION FRAMEWORK**

Evaluation requires a strict framework and specific rules. The medication evaluation framework of the Conseil encompasses the following:

- Evaluation criteria set by the legislator.
- A shared understanding by all partners concerned of the content and scope of each criterion.
- Specific methods of application.

This evaluation framework was designed to support a strict evaluation process, a process that is based on relevant information from the manufacturer, in accordance with the requirements outlined by the Conseil.

We should point out that the Conseil applies this evaluation framework to all medication and to certain medical supplies, which are submitted by manufacturers for listing on one of the two formularies in effect or that could, if already listed, be

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4 For example, dressings, nutritional formulas, diagnostic agents.
subject to re-evaluation. This framework also applies to any medication that is submitted to the Conseil for evaluation by the Minister.

3.1 Criteria

The Act Respecting Prescription Drug Insurance specifies the aspects on which the Conseil gives notice to the Minister when updating the RAMQ Formulary. Article 57.1 states:

“For the purpose of updating the list referred to in section 60, the council shall first assess the therapeutic value of each medication concerned. If the council considers that the therapeutic value of a medication has not been established to its satisfaction, it shall send the Minister a notice to that effect.

If the council considers that the therapeutic value of a medication has been established, it shall send the Minister an advisory opinion after assessing the following aspects:

1° the reasonableness of the price charged;
2° the cost effectiveness ratio of the medication;
3° the impact that entering the medication on the list will have on the health of the population and on the other components of the health care system; and
4° the advisability of entering the medication on the list with regard to the purpose of the basic plan.”

3.2 Content and Scope of Criteria, and Methods of Application

The Conseil, along with the partners concerned, has worked on establishing a shared understanding of the criteria set by the legislator, and on specifying its content and scope. This shared understanding has led the Conseil to define methods of application for each criterion.

3.2.1 Therapeutic Value

In order for the listing of a medication to be evaluated by the Conseil, the product must first be approved under Health Canada’s Therapeutic Drug Program and bear a drug identification number (or DIN) issued by this organization. Once this condition has been met, the manufacturer can present the submission to the Conseil.

In addition to taking into account a drug’s benefits and risks, the therapeutic value of a drug includes potential therapeutic advantages related to route of administration, ease of use, dosage fostering various degrees of medication compliance, and ability to enable walk-in treatment, etc. As well, the fact of having an additional therapeutic option for a given medical condition may be considered as adding therapeutic value to a product.

The Conseil accepts several choices of comparative drugs. The medication that is generally recommended or the most commonly used for treating the same medical condition, or that is recognized as being the most cost-effective, is comparative.
medication that can be kept. A drug in the same chemical class, i.e., having the same mechanism of action or one used at the same treatment step for a given medical condition is also possible. Thus, the clinical studies analyzed can then be used to back up the various comparisons.

The Conseil evaluates the therapeutic value of the medication on evidence based data.

- **Means of Application**

The therapeutic value of a product is determined based on clinical studies, provided by the manufacturer and on the available evidence based data. The Conseil uses all studies or additional information deemed necessary. Moreover, we should point out that the Conseil not only accesses the level of proof based on specifications from studies submitted, but also accesses the quality of methodology and the consistency of the results among the different studies.

In certain cases, for example, a rare or orphan disease for which clinical studies are available, but whose level of proof is not the one required, the Conseil does not rule out the possibility of, in exceptional cases, supporting its recommendations on the basis of less substantive studies. In certain situations in which randomized controlled studies cannot be conducted, the Conseil does not rule out relying on its recommendations with practice standards that may have a consensus with clinical experts. Moreover, the Conseil du médicament will develop an evaluation framework for drugs marketed and used in the treatment of rare hereditary metabolic diseases, as announced by the Ministre de la Santé et des Services sociaux in the Politique du médicament.

**3.2.2 Reasonableness of the price and Cost-Effectiveness**

Although Article 57.1 of the Act Respecting Prescription Drug Insurance discusses reasonableness of the price and cost-effectiveness separately, consultations with partners have confirmed the position of the Conseil according to which the reasonable pricing of a drug cannot be considered alone. It must be examined at the same time as another closely related concept: the relationship between cost and effectiveness. This requires comparing the resources invested with the therapeutic results.

Comparing a new drug with other, known, therapeutic options allows to measure a differential therapeutic value (DTV) and a differential economic value (DEV).

- **Methods of Application**

The reasonableness of the price is evaluated by comparing treatment costs for the drug with other drug strategies or other therapeutic interventions. Since the comparative drugs that could be used are the same as those identified as comparative drugs for therapeutic value, however, they must already be listed on the formulary to compare pricing reasonableness. As well, the doses used for each medication must be equipotent (equivalent). In all cases, the manufacturer must justify the choice(s) made. Lastly, when it is impossible to compare a drug with other therapies, the manufacturer must provide supporting justification.

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6 Generally established based on the guaranteed sales price (GSP) of the drug, as defined in Appendix 1 in this document in accordance with the terms and conditions stipulated in Appendix 1 of this document under “Treatment Cost”.
The evaluation of the relationship between cost and effectiveness allows to compare the amount of resources to be invested against the expected therapeutic results for any potentially therapeutic intervention or technique. Pharmacoeconomic studies are used to make these comparisons. The Conseil uses the following types of studies: cost-consequences, cost-minimization, cost-effectiveness and cost-utility. In every case where possible, the Conseil favours a societal perspective (See Appendix 1).

3.2.3 Consequences of Listing a Drug on the Formulary on the Health of the Population and on Other Components of the Healthcare System

The following criterion is used to assess the net impact of listing a new medication on the various health-related aspects of the general public, and on the organization of healthcare services (potential gains in interventions, budget impact analysis, etc.). As with the evaluation of the relationship between cost and efficiency, this criterion has the advantage of avoiding compartmentalization, and bypasses the silo approach, according to which the budgetary repercussions of listing a drug should be considered only from the narrow viewpoint of the budget of the Régie de l’assurance maladie du Québec (RAMQ) related to medication. Now we know that introducing a new drug therapy often involves changes, which are sometimes major, in a way to provide, use and organize certain services. This criterion allows to reflect the reality as accurately as possible.

Methods of Application

To evaluate the net impact of listing a new drug, the Conseil looks at a number of factors, in particular, clinical benefits, foreseeable variations in the number of prescriptions, costs related to treatment monitoring, potential savings or additional costs for other healthcare services (diagnostic tests, hospitalization, accommodation, walk-in services, home care, etc.), and organizational impact on providing healthcare. Epidemiological data related to the given medical condition are also taken into consideration.

In all cases, the use of a new medication must meet recognized medical needs and not entail any change to the therapy profile, which would lead to non-optimal use7-8.

Moreover, the analysis does not always allow to dissipate any doubts as to the long-term effects of a new drug on health and savings or additional costs resulting from its use. In this case, one or more additional studies could be required of the manufacturer to confirm advances in an actual situation.

3.2.4 Advisability of entering the medication on the list with regard to the purpose of the basic plan9

Implementation of this criterion is a complex undertaking, because it refers to major social issues, in particular: what would be a reasonable volume of resources to

7 Optimal use of medication: Use that maximizes the benefits and minimizes the risks for the population’s health by taking into account the various possible options, costs and available resources, patient values and social values.
8 The follow-up and optimal use of medication represent a major component of the Conseil’s activities and they imbue all its actions. The purpose of work in this area is to document the use by practitioners and the public of insured medication. Descriptive studies, evaluative research and drug usage review, in addition to actual observations, allow to propose or implement, along with, if necessary, intervention strategies and approaches to promote the optimal use of medication.
9 Section 2 of the Act Respecting Prescription Drug Insurance defines the RGAM object as “to ensure a reasonable and fair access to the medication required by people’s health condition.”
dedicate to a particular problem taking into account all the population’s healthcare needs? If, for example, a problem affecting many people requires considerable resources, how far can we reasonably go? On the contrary, if a problem affects a very limited number of individuals, but also requires a very substantial volume of resources, how much money should the government allocate, while remaining fair to all the other diseases, and more generally to the population? These questions force to consider the drug not only on its own, but as part of the healthcare system and, more broadly, to think about social steps for improving the health of the general public.

- **Methods of Application**

To apply this criterion, the Conseil has opted for a two-phase strategy. First, it looks at the evaluation process as a whole, according to proven data, carried out thoroughly and transparently, which are primarily based on the concept of “reasonable and fair access.”

- The requirement of a well-established therapeutic value helps evaluate the benefits for the health condition of individuals.

- The requirement of promoting the societal perspective in pharmacoeconomic studies meets the need of identifying the repercussions of listing a drug on the formularies by taking into account of its consequences for all society.

- Taking into account the costs related to listing a drug and savings that could be made in the other components of the healthcare system further expands the analysis perspective.

- Lastly, the fact of looking at the net impact of the drug when it has been well established provides another argument to support the reasonableness of listing a new medication.

Therefore, in practice, the previous criteria help to confirm or not in the majority of cases the reasonableness and fairness of providing access to the drug evaluated.

Secondly, for litigious issues, the Conseil sets the following starting points:

- Listing a new medication cannot be justified by factors other than the health care needs of the individual and population (by respecting the first three criteria). “Factors other” should be understood as a socioeconomic category, an interest group or an interrelated group.

- Any indication for using a drug must target a health condition, i.e., prevent, relieve, heal or postpone a difficult health condition. The exclusion of indications for the treatment of alopecia and baldness as well as indications for use for aesthetic or cosmetic purposes is in accordance with this premise. The exclusion related to infertility treatment and erectile dysfunction is the result of ministerial decisions made over time.

- The concept of reasonableness and fairness applies to the status of the medication evaluated as well as to “recognized indications for payment purposes”, which accompany the drugs listed in the Exception Drug section of the RAMQ Formulary.
Furthermore, for any dispute that does not fall under these categories, the Conseil intends to develop an ethical argument to back up each of its recommendations. In addition, transparency, which underlies the Conseil’s approach and is supported by the publication of its evaluation schedule and the opinions of patient groups, clinicians and their representatives at each Formulary update, will stimulate public debate on the society’s choice for this process, and thus gradually enrich the starting points. With time, the Conseil will be able to put together jurisprudence that will help it further specify these criteria. This approach has the virtue of taking into account diversity, innovations and the development of social values.

In appendices 2 and 3, the components of the evaluation making up the evaluation framework are presented schematically.

**In summary**

- The first criterion is used to assess the therapeutic value of the medication under evaluation.

- The following criteria help:
  - establish a relationship between the differential therapeutic value and the differential economic value of the drug under evaluation based on one or more comparative drugs, if necessary.
  - measure the net impact. The net impact is measured by looking side by side the therapeutic and economic contribution of new medication with epidemiological data related to the specific medical condition as well as data on the use of health resources resulting from the use of this medication.

  In cases where there are comparators, the assessment of added value is based on all these items.

- The final criterion is used to assess the reasonableness and fairness of listing the drug while taking into account the societal aspect.

### 4. Evaluation Process

All requests to list a drug go through the same procedure. The evaluation process is carried out in a series of rigorous steps (See Appendix 4).

First, the Conseil determines the acceptability of the file submitted by the manufacturer. The file is acceptable if the documents and information required are submitted within the time limits and are deemed complete and relevant (see Appendix 1). Any file considered incomplete will not be evaluated within the scheduled period for the update for which it was submitted.\(^{10}\)

Second, the Conseil makes its work schedule public. From this moment and for a period of thirty (30) days, citizens and clinicians, through their respective associations or groups, who want to submit their comments are asked to send them

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\(^{10}\) An incomplete file is maintained pending missing items for a period of one (1) year following the date it is received by the Conseil. Once this period has elapsed, a new complete request must be submitted.
to the Conseil. Given the tight deadlines, note that the Conseil is not responsible for considering notices or opinions that are not sent within the time limits set out in its recommendations.

Third, the Conseil determines whether the therapeutic value—the first criteria—is demonstrated based on meaningful data. This is a fundamental condition. If the drug evaluated does not respect this criterion, the Conseil will recommend that the Minister refuse its listing and will send him a notice to this effect.

Fourth, from this step and until the end of the evaluation process, all criteria are considered together. To put it plainly, it involves measuring whether the medication evaluated—whose therapeutic value has been shown—has added value in terms of all criteria. Thus, in theory, an unfavourable evaluation regarding a criterion could be offset by a very positive evaluation of another item based on another criterion. In all these cases, the Conseil’s decision takes into account the overall repercussions of listing the drug on the formularies.

Based on the qualitative and quantitative decision made, four types of recommendations will result:

- Listing without restriction
- Listing in the Exception Drug section: in the traditional sub-section or in the sub-section with follow-up
- Refused listing
- File under study

In order, the steps in the evaluation process are:

- evaluation of each file by the Scientific Listing Committee and associated experts
- preparation of an evaluation report outlining the recommendations of the Scientific Listing Committee
- preparation of Capsules, which summarize the main advice of the Conseil produced while updating formularies
- the submission of an evaluation report and Capsules to the Conseil members to assessment
- the decision of Conseil members
- the transmission of the final notice from the Conseil to the Minister

In addition to these steps, the documents required for regulatory changes are prepared by the RAMQ along with the Conseil. Once the ministerial orders have been signed by the Minister and based on the publication date in Quebec’s Official Gazette, information is conveyed as follows:

- The Conseil conveys its decisions to concerned manufacturers.
- The RAMQ informs the healthcare professionals and healthcare institutions through a news release; the RGAM Formulary and the Drug Formulary for Institutions are distributed through separate news releases.
- The Conseil provides electronic versions of Capsules in its Web site, as well as print versions.
The RAMQ publishes and regularly distributes an electronic version of its formularies through its Web site as well as a printed version.

Because of its rigorous approach, the evaluation process must be based on quality scientific information. Although, for these evaluations, the Conseil uses the information provided by the manufacturer, the Conseil also relies on any complementary study or information it deems necessary.

The evaluation process, the criteria on which this process is based, the steps that are involved, the related requirements and lastly the concomitant concern for transparency constitute a combination of elements that enable the Conseil du médicament to exercise the soundest judgement possible regarding the drugs it evaluates to provide guidance regarding the decision of the Minister in the best interest of the people of Quebec.
February 2007

GUIDE FOR SUBMITTING APPLICATIONS FOR LISTING MEDICATION ON FORMULARY

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This guide and all related documents are available on the Web site of the Conseil du médicament (www.cdm.gouv.qc.ca).

For any additional information, please contact the Conseil:

CONSEIL DU MÉDICAMENT
Direction scientifique de l’inscription
1195, avenue Lavigerie, bureau 100, 1er étage
Québec (Québec) G1V 4N3
Telephone: 418 643-3140
Fax: 418 646-8349
APPLICATION FOR LISTING MEDICATION ON FORMULARY

IMPORTANT: Each listing application and all related documents must be submitted in an electronic version and in a print version in five copies for new medication and two copies for generic drugs. Please use a form for each pharmaceutical format and each content. The Conseil reserves the right to request extra copies.

To fill in the form, refer to the Application for Listing Medication on Formulary Guide

A. Description of the Medication

<table>
<thead>
<tr>
<th>DRI identification No. Medication:</th>
<th>Reserved for the Conseil</th>
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<tbody>
<tr>
<td>Name of Manufacturer:</td>
<td></td>
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<tr>
<td>Brand Name:</td>
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</tr>
<tr>
<td>Generic Name:</td>
<td></td>
</tr>
<tr>
<td>Format:</td>
<td></td>
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<tr>
<td>Content:</td>
<td></td>
</tr>
<tr>
<td>AHFS Class:</td>
<td></td>
</tr>
<tr>
<td>ATC Code:</td>
<td></td>
</tr>
</tbody>
</table>

Category of Medication (check please): □ Pr □ non-Pr □ Controlled Drug □ Narcotic □ Targeted Substance

B. Formulary Concerned

Are you asking to list on:
the RAMQ Formulary? □ YES □ NO
the Drug Formulary for Institutions? □ YES □ NO

C. Therapeutic Indication Requested


D. Manufacturing

Is the product manufactured by the applicant? □ YES □ NO
If not, specify the name and address of manufacturer:


Consul du médicament
ON-DW (02.2007)
### E. Guaranteed Selling Price (GSP) for Each Format

<table>
<thead>
<tr>
<th>Format</th>
<th>GSP for Pharmacists</th>
<th>GSP for Wholesalers</th>
<th>% of Discount for Wholesalers</th>
<th>Authorization for Adjustment to Lowest Price</th>
<th>Sales Price for Institutions</th>
</tr>
</thead>
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<tr>
<td></td>
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<td>□ YES □ NO</td>
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<td>□ YES □ NO</td>
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</tr>
</tbody>
</table>

### F. Contact of Applicant and Attestation

Name of Applicant: ____________________________

Address: ____________________________________

____________________________________________

City: _________________________________________

Postal Code: _________________________________

I attest that all information provided complies with the terms and conditions of the commitment from our company.

Signature of the person to contact: ____________

Name: ____________________________

Title: ____________________________

Telephone Number: ____________________________

Date: ____________________________

### G. Send to the following address:

**Conseil du médicament**

**Direction scientifique de l'inscription**

1195, avenue LaSage, 1st étage, bureau 100

Québec (Québec) G1V 4N8

Telephone: 418 643-3140

Fax: 418 646-3340

### H. Section reserved for Conseil

**Program Code(s):**
- 01 STD Program
- 02 Tuberculosis Program
- 03 RGAM - Regular Formulary
- 04 Institution Formulary
- 01 RGAM - Exception Formulary
- 42 Drug Formulary for Institutions with Recognized Criteria
- other ______________________

**Nature:**
- MAG Product for magistral preparation
- SUP Dietary supplement (nutritional formulas)
- ADJ Excipient, solvent or adjuvant
- PHO Supply with professional fees
- FSH Supply without professional fees

**Maximum margin:**
- □ YES □ NO

By: ____________________________

Date: ____________________________

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Conseil du médicament

CN-DM (02-2007)
GUIDE FOR FILLING IN THE
“APPLICATION FOR LISTING MEDICATION ON FORMULARY” FORM

The CM-DIM (02-2007) form must be filled in for all applications for listing a pharmaceutical product (medication, dressing, nutritional formula, supplies, etc.). It contains all the administration information to establish the identity of the manufacturer and product concerned. This information is used for listing in the RGAM Formulary and Drug Formulary for Institutions.

The form also is a legal attestation by which the manufacturer guarantees the sales price of medication that he wants to list on the RGAM Formulary.

A separate form must be filled in for each dosage form and strength of the product. Certain items in this form may not be applicable to all products.

The form contains the following sections:

A. Description of the Medication
B. Formulary Concerned
C. Therapeutic Indication Requested
D. Manufacturing
E. Guaranteed Selling Price (GSP) for Each Packaging Format
F. Contact Information of Applicant and Attestation
G. Mailing Address for Application to Conseil
H. Section Reserved for the Conseil

A. Description of the Medication

- Write the drug identification number (DIN) assigned by Health Canada.
- Write the name of the applicant.
- Write the brand name (trade name) of the drug.
- Write the generic name (common name) of the drug.
- Write the pharmaceutical dosage form of the medication (e.g.: tablet, capsule, syrup, ointment, cream).
- Specify the medication strength (e.g.: 1 mg, 250 ml, 5%).
- Specify the AHFS class (American Hospital Formulary Services classification, published in AHFS Drug Information).
- Specify the ATC code (Anatomical, Therapeutic, Chemical classification of the World Health Organization [WHO]).
- Check the category of the medication (prescribed [Pr] or non-prescribed [nonPr], controlled drug, narcotic or targeted substances).
B. Formulary Concerned

By selecting one or more of the appropriate boxes, specify whether you are requesting that your product be listed on the RGAM Formulary, Drug Formulary for Institutions or on both formularies.

C. Therapeutic Indication Requested

Specify the therapeutic indication(s) you are applying for.

D. Manufacturing

Specify whether the product is manufactured by the applicant. If not, specify the name and address of the manufacturer.

E. Guaranteed Selling Price (GSP) for Each Packaging Format

For each packaging format of the product:

- Specify the packaging format (e.g.: 100, 500, 1,000, 10 x 1 ml, 30 g, 100 g).
- Write the guaranteed selling price for direct sales for pharmacists. If the product is only sold through a wholesaler, leave this space blank.
- Write the guaranteed selling price for sales to wholesalers.
- Write discount percentage given to wholesalers (difference between the GSP for pharmacists and the GSP for wholesalers), if applicable. The maximum authorized difference is 9% (subject to change).
- Agree or disagree to authorize the lowest price adjustment. Note that if YES is selected, the price will be automatically adjusted to the lowest price submitted by other manufacturers of this medication. This new adjusted price will become your GSP. Unless otherwise indicated, this authorization will be valid for subsequent updates of the RGAM Formulary.
- Specify the sales price to healthcare institutions (hospitals) in Quebec.

F. Contact Information of Applicant and Attestation

- Write the applicant's contact information.
- Sign and date the attestation stating that all information provided complies with the terms and conditions that the applicant has agreed to. Write the contact information of the person who has signed the attestation. This person will be contacted if additional information is required.

I. G. Mailing Address for Application to Conseil

The application and all necessary documents must be sent to the address on the form.

H. Section Reserved for the Conseil

Leave this section blank.
ITEMS REQUIRED FOR LISTING APPLICATIONS (RECORDS)

This document presents the four records listing the items that must included with the different types of applications for listing a drug:

**RECORD 1**
**FIRST APPLICATION**
**FOR A NEW MEDICATION OR**
**FOR A NEW INDICATION OF A MEDICATION ALREADY LISTED**

**RECORD 2**
**RE-EVALUATION APPLICATION**
**FOR A NEW MEDICATION OR**
**FOR A NEW INDICATION OF A MEDICATION ALREADY LISTED**

**RECORD 3**
**FIRST APPLICATION**
**FOR A GENERIC MEDICATION**

**RECORD 4**
**RE-EVALUATION APPLICATION**
**FOR A GENERIC MEDICATION**

The records indicate when each item must be submitted to the Conseil in order for the application to be considered complete. They also outline the items to only be submitted if necessary for a re-evaluation application. It could, for example, involve different items than those submitted during a previous application. The records take into account documents likely to be asked for by the Conseil when the file contains certain specific information. These documents can be attached to the listing application.

These records use the following abbreviations:

- **R** = Required by the submission deadline.
- **30 d** = Required within 30 business days following the submission date.
- **SD** = The Conseil is likely to ask for this document when the file has certain specific information. You can include it in the submission to avoid any delays in your application.
- **SN** = If necessary, depending on the context of the application (e.g. new data, updated data).
## RECORD 1
**FIRST APPLICATION**
**FOR A NEW MEDICATION OR**
**FOR A NEW INDICATION OF A MEDICATION ALREADY LISTED**

Unless otherwise indicated, each of the documents required must be included in the submission by the application deadline date in order for the listing application to be considered complete. Please refer to the “Description of the Items Required” for more details on the information requested.

### ADMINISTRATIVE COMPONENT

<table>
<thead>
<tr>
<th>Item</th>
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<tbody>
<tr>
<td>“Application for Listing Medication on Formulary” form</td>
<td>R</td>
</tr>
<tr>
<td>Notice of compliance issued by Health Canada (when applicable)</td>
<td>R</td>
</tr>
<tr>
<td>Product labels</td>
<td>30 d</td>
</tr>
<tr>
<td>Proof of marketing: A copy of the “Declaration of a Medication” form duly completed, dated and signed</td>
<td>30 d</td>
</tr>
<tr>
<td>Certificate of availability of a product in sufficient quantity (See sample letter proposed by the Conseil)</td>
<td>30 d</td>
</tr>
<tr>
<td>Letter of authorization for access to information</td>
<td>R</td>
</tr>
<tr>
<td>Status of listing in other provinces</td>
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### THERAPEUTIC VALUE COMPONENT

<table>
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<td>Clinical studies</td>
<td>R</td>
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<tr>
<td>Comprehensive summary – Clinical studies section</td>
<td>R</td>
</tr>
<tr>
<td>Clinical Reviewer’s Report –Clinical studies section</td>
<td>SD</td>
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<tr>
<td>Official monograph</td>
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### ECONOMIC VALUE COMPONENT

<table>
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<th>Item</th>
<th>Requirement</th>
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<tr>
<td>Price justification</td>
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### CONSEQUENCES ON POPULATION’S HEALTH AND ON OTHER HEALTH-CARE SYSTEM COMPONENTS

| Item                                                           | Requirement |
|                                                               |             |
| Information on effects on health                               | R           |
| Net impact analysis                                            | R           |
| Budgetary impacts                                             | R           |
| Promotional material                                          | R           |

**Legend**

- **R** = Required by the submission deadline.
- **30 d** = Required within 30 business days following the submission date.
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RECORD 2
RE-EVALUATION APPLICATION
FOR A NEW MEDICATION OR
FOR A NEW INDICATION OF A MEDICATION ALREADY LISTED

Unless otherwise indicated, each of the documents required must be included in the submission by the application deadline date in order for the listing application to be considered complete. Please refer to the “Description of the Items Required” for more details on the information requested.

ADMINISTRATIVE COMPONENT

☐ “Application for Listing Medication on Formulary” form
☐ Notice of compliance issued by Health Canada (when applicable)
☐ Product labels
☐ Proof of marketing: A copy of the “Declaration of a Medication” form duly completed, dated and signed
☐ Letter of authorization for access to information
☐ Updated status of listing in other provinces

THERAPEUTIC VALUE COMPONENT (Submit these items if the therapeutic value has not yet been recognized.)

☐ Clinical studies: new clinical study with or without argumentation
☐ Comprehensive summary – Clinical studies section
☐ Clinical Reviewer’s Report – Clinical studies section
☐ Updated official monograph

ECONOMIC VALUE COMPONENT (Submit these items if the therapeutic value has not yet been recognized.)

☐ Price justification
☐ Appropriate pharmacoeconomic studies
☐ Updated status of the study of file at the Patented Medicine Prices Review Board (PMPRB)

CONSEQUENCES ON POPULATION’S HEALTH AND ON OTHER HEALTH-CARE SYSTEM COMPONENTS

☐ Information on effects on health
☐ Net impact analysis
☐ Updated budgetary impacts
☐ Promotional material

Legend

R = Required by the submission deadline.
30 d = Required within 30 business days following the submission date.
SD = The Conseil is likely to ask for this document when the file has certain specific information. You can include it in the submission to avoid any delays in your application.
SN = If necessary, depending on the context of the application (e.g. new data, updated data).
**RECORD 3**  
**FIRST APPLICATION**  
**FOR A GENERIC MEDICATION**

Unless otherwise indicated, each of the documents required must be included in the submission by the application deadline date in order for the listing application to be considered complete. Please refer to the "Description of the Items Required" for more details on the information requested.

### ADMINISTRATIVE COMPONENT

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<tr>
<td>Notice of compliance issued by Health Canada (when applicable)</td>
<td>R</td>
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<tr>
<td>Product labels</td>
<td>30 d</td>
</tr>
<tr>
<td><strong>Proof of marketing:</strong> A copy of the “Declaration of a Medication” form duly completed, dated and signed</td>
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<td>Certificate of availability of a product in sufficient quantity (See sample letter proposed by the Conseil)</td>
<td>30 d</td>
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<tr>
<td>Letter of authorization for access to information</td>
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<td>Status of listing in other provinces</td>
<td>SD</td>
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### THERAPEUTIC VALUE COMPONENT

<table>
<thead>
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<th>Requirement</th>
<th>Requirement Status</th>
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</thead>
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<td>Official monograph</td>
<td>R</td>
</tr>
<tr>
<td>Proof of bioequivalence</td>
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### ECONOMIC VALUE COMPONENT

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<th>Requirement</th>
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<tbody>
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<td>Price justification</td>
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<tr>
<td>Estimated market shares</td>
<td>30 d</td>
</tr>
</tbody>
</table>

Legend

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RECORD 4
RE-EVALUATION APPLICATION
FOR A GENERIC MEDICATION

Unless otherwise indicated, each of the documents required must be included in the submission by the application deadline date in order for the listing application to be considered complete. Please refer to the "Description of the Items Required" for more details on the information requested.

ADMINISTRATIVE COMPONENT

☐ “Application for Listing Medication on Formulary” form  SN
☐ Notice of compliance issued by Health Canada (when applicable)  SD
☐ Product labels  SD
☐ Proof of marketing: A copy of the “Declaration of a Medication” form duly completed, dated and signed  SD
☐ Letter of authorization for access to information  SN
☐ Status of listing in other provinces  SD

THERAPEUTIC VALUE COMPONENT

☐ Updated official monograph  SN

ECONOMIC VALUE COMPONENT

☐ Price justification  R
☐ Estimated market shares  30 d

Legend

R = Required by the submission deadline.
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SN = If necessary, depending on the context of the application (e.g. new data, updated data).
DESCRIPTION OF REQUIRED ITEMS

Note: The underlined terms are defined in this section.

AHFS Class: A category of the classification system developed by the American Hospital Formulary Service. This is the pharmacotherapeutic classification currently used to publish the RGAM Formulary and the Drug Formulary for Institutions. This classification is available on various Web sites.

Application for Listing Medication on Formulary: Form developed by the Conseil du médicament that must be presented with each application to list a medication. It is used for registrations on the RGAM Formulary as well as on the Drug Formulary for Institutions. The form also serves as a legal attestation by which the manufacturer guarantees the sales price of the medication that he would like to list on the RGAM Formulary. This is the guaranteed selling price (GSP). A formulary must be used for each pharmaceutical dosage form and strength of a medication. The form and guide for filling it in are available on the Conseil’s Web site (www.cdm.gouv.qc.ca).

“Application for Listing Medication on Formulary” Form: See Application for Listing Medication on Formulary.

ATC Code: Anatomical, Therapeutic and Chemical classification system of the World Health Organization (WHO). This classification brings together drugs based on the system or organ on which they act, as well as their chemical and therapeutic properties. It is available on different Web sites.

Budgetary Impacts: Estimate of changes in sales volume of the new drug showing possible changes in the volume of use of the drug in the short and medium term, i.e., for each of the first three 12-month periods following listing. The estimate of changes in costs related to the listing of the new medication (gross impact) must take into account the overall costs of the therapeutic class (net impact), and therefore the effect of this listing on the entire Régime général d’assurance médicaments (RGAM) and on other budgets.

For a time horizon of three 12-month periods following the listing, the evaluation of these budgetary impacts must take into account various aspects:
- costs for all the RGAM, i.e., the private and public portions of the plan
- the costs of drugs that will be borne by the Régie de l'assurance maladie du Québec (RAMQ) for the public portion of RGAM
- costs that could be borne by the province’s healthcare institutions where relevant

The evaluation of the potential expansion of the entire market of drugs used for a given medical condition is also presented, if applicable. It is recommended that electronic spreadsheets be provided.

Certificate of Availability of a Product: Document confirming that the product is available commercially on the Quebec market in sufficient quantity and that the manufacturer may respond to the demand that can be reasonably anticipated in Quebec. A sample letter serving as a certificate of availability is proposed by the Conseil. This document must be signed by the person who signed the Application for Listing Medication on Formulary form.

Clinical Reviewers’ Report – Clinical Studies Section: Clinical section of the Health Canada reviewers’ report that comments and analyzes the clinical studies submitted by the manufacturer to Health Canada for a request for certification of the product or changes to the monograph.
Clinical Studies: At least one clinical study looking at the key clinical issues of the medical condition targeted by the medication is required. At least one of the studies submitted must be a randomized, controlled clinical trial, published or accepted for publication (with proof from the editor). Double-blind clinical studies are preferred. The required level of proof for clinical trials corresponds to Level 1, except in exceptional cases. Supporting documents must be submitted along with a study that is not Level 1. A maximum of five (5) clinical studies can be submitted. Other publications may be appended. Publication abstracts are not accepted.

Comprehensive Summary – Clinical Studies Section: Clinical section of the document sent by the manufacturer to Health Canada for a request for certification of the product or changes to the monograph.

Cost-Consequences Analysis (CCA): Economic evaluation method presenting separately in detail the costs and results of a strategy without aggregating them. Any weighting or aggregation is the responsibility of the user of the study.

Cost-Effectiveness Analysis (CEA): Economic evaluation method involving linking the costs of a strategy to its consequences measured using natural indicators expressed in natural units (e.g.: reduction clinical event avoided, life-years gained), and in which the cost per unit for the result is calculated.

Cost-Minimization Analysis: Economic evaluation method using the hypothesis that the two strategies to compare have the same advantages or are not significantly different. Taking into account similar efficacies, the evaluation aims to determine which option is the least expensive.

Cost-Utility Analysis (CUA): Economic evaluation method linking the costs of a strategy with its qualitative and quantitative consequences are measured as health-related preferences. The best known measurement is quality adjusted life years (QALY). The options are compared in terms of cost-utility ratios (for example, the cost per QALY gained).

Epidemiological Data: Data on the prevalence and incidence, information on determinants of the disease or other relevant data on the health problem targeted by the medication in the application. This data must be relevant to the existing situation in Quebec or at least in Canada.

Estimated Market Shares: Estimate of the proportions of market shares that a generic drug will have versus brand-name drugs and other generic medication following its listing.

Evidence based Data: Conclusions drawn from the studies and other knowledge, which can be used for making decisions in the area of public health and healthcare11.

Guaranteed Selling Price for Pharmacists: Guaranteed selling price by the manufacturer for each product packaging format that it wants to list on the Drug Formulary. The number of the formats is generally limited to two. The price submitted must take into account the prices for the quantities that are multiples of these two packaging formats. It is possible for the therapeutic use of more than two formats be established in the case of certain drugs, such as oral suspended antibiotics, eye drop solutions, creams, or topical unguentums. The manufacturer can then submit a guaranteed selling price for a maximum of four formats. In accordance to the agreement that it subscribed to upon its recognition, the manufacturer agrees to maintain the guaranteed selling price for the validity period of the Formulary. The guaranteed selling price can be different for sales to pharmacists and wholesalers. Note that it is the guaranteed selling price for pharmacists that is listed on the RGAM Formulary.

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11 Definition from the World Health Organization (WHO).
Guaranteed Selling Price for Wholesalers: Guaranteed selling price for wholesalers when it is different from that guaranteed for pharmacists. For each packaging format, in addition to the price in dollars, the difference existing between the price asked by pharmacists and that by wholesaler must be specified in percentage. The sales price that a manufacturer guarantees to wholesalers must be the same for all recognized wholesalers. A manufacturer can guarantee for wholesalers a different price than that guaranteed for pharmacists for all its products or for only some of them. As well, this price differential may differ between products. Lastly, this price differential cannot exceed 9% (subject to change). The difference granted must be specified under the “% of discount for wholesalers” section in the Application for Listing of Medication on Formulary.

Information on the Effects on Health: Epidemiological data regarding a health condition targeted by the medication and the related effect on health. The relevant information may include the following concepts: the burden of illness, the duration and evolution of the disease or targeted health condition, the duration of therapy, clinical development following the use of the drug, actions required for monitoring the healthcare condition, the follow-up needed for using the product or for controlling the adverse effects, the organizational repercussions on the way to provide healthcare if the drug under study changes the process, etc.

The effect on the health services offering must be documented, in particular if a transfer of patients from the hospital setting to a walk-in clinic, for example, is expected.

The effect on the service offering must be viewed based on a timeline. An evaluation of the time of appearance of the beneficial effects must be carried out, if applicable (e.g.: prevention of osteoporosis).

Letter of Authorization for Access to Information: A document authorizing the exchange of information between the Conseil du médicament du Québec and other organizations and the publication of certain items forwarded with the submission on the product. As well, this letter authorizes the Conseil du médicament to use in its publications any non-confidential information on the product, in particular the fact that it received an application for listing. Lastly, the document allows the authorization to disclose data from the unpublished pharmacoeconomic studies submitted. A sample letter of authorization for access to information is proposed by the Conseil. This document must be signed by the person who signed the Application for Listing Medication on Formulary form.

Lowest Price: For certain medication (common names) listed on either of the Formularies for 15 years or longer, and produced by two or more manufacturers, the lowest price method is used to established the price to pay. The lowest price method is based on the guaranteed selling price for pharmacists that is the lowest price submitted by a manufacturer for a given packaging format.

Medical Device Licence: Document issued by the Medical Devices Bureau of the Therapeutic Products Directorate of Health Canada under Section 36 of the Medical Devices Regulations. The expression medical devices, as defined in the Food and Drugs Act, covers a wide range of medical devices used in the treatment, reduction, diagnosis or prevention of a disease or a physical disorder (dressing, glucometer bands, etc.).

Net Impact Analysis: Examination of the repercussions of listing a medication, taking into account the potential costs and savings that its use may involve in the various healthcare system components. This is a detailed presentation of the economic repercussions of the drug in terms of use of healthcare resources and costs on the healthcare system for the Quebec government. The level of detail of items to be considered and the scope of affected components in the healthcare system are based on the effect of medication on a given medical condition.
Note that this information can be included as an intermediate step in presenting the results of the pharmacoeconomic study provided.

**Notice of Compliance Issued by Health Canada:** Notification issued under Paragraph C.08.004(1)(a), which indicates that the manufacturer or proponent complies with sections C.08.002 or C.08.003 and C.08.005.1 of the Food and Drug Regulations. A notice of compliance is issued by Health Canada if the presentation is deemed to comply after a full examination. Please note that you must inform the Conseil du médicament when issuing a new notice of compliance for a change or for new indications for the product. See also Medical Device Licence.

**Official Monograph:** A document approved by Health Canada, which describes a medication and includes essential information on it, in particular on the approved indications. A French version must be provided.

For products that do not have a monograph, include a document that presents the product profile and its prescribing information.

**Other Publications:** Documents that are added to the maximum of five clinical studies required and then can be appended. Additional publications that can be appended include in particular documents describing the scales and questionnaires used in the clinical trials, review articles, and expert guidelines.

**Pharmacoeconomic Study:** At least one pharmacoeconomic study must be provided. The studies must meet the methodological requirements of the Canadian Agency for Drugs and Technologies in Healthcare (CADTH)\(^\text{12}\), formerly the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) which concerns the different methodological directives. The manufacturer must justify a different presentation. Whenever possible, the Conseil favours the adoption of a societal perspective in carrying out these studies. The manufacturer must justify any other perspective.

The pharmacoeconomic studies can be carried out by the manufacturer, a third party paid by the manufacturer or by independent researchers. The information on the independence of the authors of the study related to methodology and to the right of publication must be provided. In the case of unpublished studies, the Conseil considers them acceptable as long as the names of the authors and the exact relationship with the manufacturer are clearly identified.

Pharmacoeconomic studies are added to the five clinical studies that the manufacturer can submit for evaluation of the therapeutic value.

**Price Justification:** Rationale justifying the price and comparative analysis of the price(s) submitted against those of comparative drugs already listed or eligible for listing. Should there be no comparative drugs, the comparative analysis is done against medical interventions or other medical procedures used in the same area of therapy as the product studied. Price justification must allow to evaluate the cost of treatment related to the drug by taking into account its differential cost versus the costs of other drug strategies used in the same area of therapy or not. This difference can be expressed as the gross monetary value or as a cost difference proportion.

**Product Labels:** Labels or cardboard package of the container for different product formats. Printer proofs are accepted as long as the drug identification number (DIN) appears on it.

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\(^{12}\) Current version at the time of submission of the Canadian Agency for Drugs and Technologies in Health. Guidelines for the Economic Evaluation of Health Technologies: Canada, third edition. Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); 2006. Available online at [http://www.cadth.ca](http://www.cadth.ca).
**Promotional Material:** Promotional items approved or submitted to the Pharmaceutical Advertising Advisory Board (PAAB) and used in Quebec. It involves promotional items for healthcare professionals and drug users, if applicable.

**Proof of Bioequivalence:** Document that demonstrates that the generic product is bioequivalent to the brand-name product in accordance with the standards of Health Canada. This document may be a notice of compliance on which the reference product is mentioned, the summary reports of results from bioequivalence studies submitted to Health Canada to obtain the notice of compliance or a letter from both manufacturers confirming that the product is cross-licensed with an already listed product.

If the DIN was issued without indication of a reference product in the notice of compliance of Health Canada, explanations must be presented to the Conseil.

It can involve a clinical study that establishes the clinical equivalence in cases requiring it (e.g.: inhaler).

**Proof of Marketing:** A copy of the “Drug Declaration Form” duly completed, dated and signed by the manufacturer and sent to Health Canada. If the product does not have a DIN (e.g.: dressing, nutritional formula), provide a bill that proves the sale of the product to community pharmacists, wholesalers or healthcare institutions.

**Reduction Discount for Wholesalers:** Difference, in percentage, between the guaranteed selling price submitted for wholesalers and that submitted for pharmacists.

**Sensitivity Analysis:** Process by which the robustness of the economic model conclusions are evaluated by examining how the results of the analysis vary when key variables are modified within a given interval of values. This technique allows to account the uncertainty around the economic evaluation.

**Status of Listing in Other Provinces:** List of product listing status in other provinces, including special programs and products under the responsibility of cancer organizations. If this is a conditional listing, provide the list of criteria to respect for these drugs. If changes in status occur during the evaluation period, send the information to the Conseil.

**Study Status of File at the Patented Medicine Prices Review Board (PMPRB):** Information on the status of the product file as part of the work of the PMPRB, any decision or any review situation.

**Treatment Cost:** The cost that combines the quantity of drug units required for a given period of time and the price per unit of medication. This is the guaranteed selling price (GSP) listed or that will be listed on the Formulary, the lowest price or the actual price of acquisition per unit of medication, to which is added the wholesaler’s mark-up if applicable, multiplied by the number of units needed based on the recommended or regular dosage for a given period of therapy time. It does not take into account the financial contribution of insured people who obtain this medication, or the cost of professional pharmacist services. However, these professional pharmacist services may be taken into account in certain situations. The price used is that for comparable packaging formats, preferably the largest one. As well, if appropriate, an average weighted cost of relevant comparative drugs can be used.
### SUMMARY TABLE OF REQUIRED DOCUMENTS

<table>
<thead>
<tr>
<th>Application for Listing Medication on Formulary Form</th>
<th>New medication First application</th>
<th>New medication Re-evaluation application</th>
<th>Generic medication First application</th>
<th>Generic medication Re-evaluation application</th>
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### TERMS AND CONDITIONS OF EVALUATING AND APPLYING BY MEDICATION TYPE

#### TYPE OF MEDICATION

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<thead>
<tr>
<th>CRITERIA</th>
<th>NEW CHEMICAL ENTITY</th>
<th>NEW DRUG ASSOCIATION</th>
<th>NEW DOSAGE FORM</th>
<th>NEW STRENGTH</th>
<th>GENERIC MEDICATION</th>
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<tbody>
<tr>
<td>THERAPEUTIC VALUE (essential condition)</td>
<td>• At least one published clinical study, with good quality methodology</td>
<td>• Efficacy: proven for each active product; ≥ to that of the total efficacy for each of the compound products</td>
<td>• Therapeutic value at least similar to that of the original formulation</td>
<td>• Therapeutic value present</td>
<td>• Proof of bioequivalence</td>
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<tr>
<td></td>
<td>• Comparative efficacy with the relevant comparative drugs</td>
<td>• Assessment of recognized therapeutic value</td>
<td>• Assessment of benefits and relevance of the new dosage form</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Assessment of a therapeutic value recognized as being clinically significant</td>
<td>• ≥ for that of the use of the two products taken separately</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### FAIR PRICING AND COST-EFFECTIVENESS

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>NEW CHEMICAL ENTITY</th>
<th>NEW DRUG ASSOCIATION</th>
<th>NEW DOSAGE FORM</th>
<th>NEW STRENGTH</th>
<th>GENERIC MEDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAIR PRICING: CONCEPT OF TREATMENT COST</td>
<td>• Assessment of a cost differential between the medication and the comparative drug(s)</td>
<td>• Check that the daily treatment cost is ≤ to that of the original formulation for the therapeutic value ≤</td>
<td>• Check that the daily treatment cost is ≤ to that of the original formulation for the therapeutic value ≤</td>
<td>• Cost of daily treatment ≤ compared to that of the original corresponding drug</td>
<td>• Based on the ceiling price in the drug policy</td>
</tr>
<tr>
<td></td>
<td>• Takes into account the BPS of a comparative drug that the Conseil deems eligible for listing</td>
<td>• Takes into account the BPS of a comparative drug that the Conseil deems eligible for listing</td>
<td>• Takes into account the BPS of a comparative drug that the Conseil deems eligible for listing</td>
<td>• Professional pharmacist services must be taken into account if relevant</td>
<td></td>
</tr>
<tr>
<td>PHARMACOECONOMIC STUDY</td>
<td>• Acceptability and validity of pharmacoeconomic study</td>
<td>• Interpretation of the results of the study</td>
<td></td>
<td></td>
<td>No requirement to provide a pharmacoeconomic study</td>
</tr>
<tr>
<td></td>
<td>• Interpretation of the results of the study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### FOR ALL TYPES OF MEDICATION, EXCEPT GENERIC

<table>
<thead>
<tr>
<th>CONSEQUENCES ON HEALTH OF POPULATION AND OTHER HEALTHCARE SYSTEM COMPONENTS</th>
<th>NEW CHEMICAL ENTITY</th>
<th>NEW DRUG ASSOCIATION</th>
<th>NEW DOSAGE FORM</th>
<th>NEW STRENGTH</th>
<th>GENERIC MEDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Potential costs or savings for healthcare system components</td>
<td>• Must meet recognized medical needs</td>
<td>• Estimation of use of drug/budgetary impact(s)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>• Repercussions on the overall cost to the healthcare system: net impact analysis</td>
<td></td>
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<tr>
<td>• Effect on health documented (epidemiology) and organizational repercussions on therapy that certain types of healthcare are provided</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

#### EVALUATION OF THE ADDED VALUE FOR THESE TYPES OF MEDICATION (IF COMPARATIVE DRUGS) IN ORDER TO MAKE A RECOMMENDATION

<table>
<thead>
<tr>
<th>REASONABLE AND FAIR ACCESS TO DRUGS REQUIRED FOR PEOPLE’S HEALTH CONDITION</th>
<th>NEW CHEMICAL ENTITY</th>
<th>NEW DRUG ASSOCIATION</th>
<th>NEW DOSAGE FORM</th>
<th>NEW STRENGTH</th>
<th>GENERIC MEDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Priority in preventing and restoring physical and mental health (no lifestyle indications)</td>
<td>• Well-known therapeutic efficacy</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>• Reasonable character of accessibility to medication</td>
<td>• Societal perspective for the pharmacoeconomic study including all components of the healthcare system</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Equity for access to medication: fair distribution of resources</td>
<td>• Interpretation of the relevance to intervene for a given health condition</td>
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<td></td>
</tr>
</tbody>
</table>

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Legend: <br> 
≥ greater or equal, ≤ less than or equal, = equal<br> 
February 2007