Institut national d'excellence en santé et en services sociaux
Québec

Drug and Technology Assessment Directorate
for Reimbursement Purposes

NOTICE TO MANUFACTURERS OF DRUGS, MEDICAL DEVICES RELATED TO DRUG ADMINISTRATION, AND BLOOD SYSTEM PRODUCTS

DATE: July 13, 2026

SUBJECT: Updates to Certain Evaluation Procedures and Processes

Evaluation of a Request for Exemption from the Lowest Price Method (LPM)

INESSS wishes to inform you of certain changes made to the process for evaluating a request for exemption from the lowest-price method. Specifically, step 3 of the procedure for INESSS's receipt of these requests has been revised.

The changes are shown on INESSS Web site and in bold below:

- The request for exemption from the application of the LPM submitted by a manufacturer whose innovator drug is already listed must comply with the requirements described in Checklist 13, which applies specifically to a first request for exemption from the application of the LPM. **Please consult the Submission Guide for Drugs, BSP and MD** to learn about **applicable requirements. These requirements differ from the criteria governing listing in Schedule V, which may include drugs with one or more of the following characteristics:**
  - **a drug that is highly toxic or has a narrow therapeutic index;**
  - **a drug with onset of action and absorption rate are clinically important;**
  - **a drug with a specific presentation or use.**
- INESSS assesses the admissibility of the application and informs the manufacturer of its decision.
  - **If the application is deemed admissible, the manufacturer will first receive confirmation of admissibility. The manufacturer will then be notified of the start of the review process** and of the fees charged by INESSS for this type of evaluation. Furthermore, the project will be included in INESSS's work plan, thereby triggering a consultation period. Please note that INESSS will not offer the possibility of a meeting for this type of application.
  - **If the application is deemed not admissible, the manufacturer will be informed of the reasons for the decision and will have 15 calendar days to submit the missing information. A brief meeting may be held if necessary. Upon receipt of the additional information, INESSS will have a further 15 working days to re-evaluate the application's eligibility.**
  - **If, following this re-evaluation, the request is still deemed not admissible, the manufacturer must wait until the first multisource drug is listed on the**

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drug lists before resubmitting to INESSS a request for reassessment of listing status in accordance with the requirements of Checklist A.

- **It should be noted that frivolous or manifestly unfounded requests will not be deemed admissible for the purposes of this process.**

- **The manufacturer of the multisource product will be informed that INESSS has received a request for an exemption from the application of the LPM and will also be informed of the outcome of the admissibility assessment, whether the request is deemed admissible or not.**

Product labels

Effective immediately, INESSS may submit a recommendation to the Minister of Health regarding a drug, a medical device related drug administration, or a blood system product, even if the final product labels bearing the Drug Identification Number (*Drug Identification Number*, DIN) or confirmation of Health Canada's approval of the labels have not been provided to complete the registration application. However, INESSS expects to receive these documents from manufacturers as soon as they become available.

This change does not alter the requirements set out in the Registration checklist under the "Labels" section. The following documents must still be provided when submitting a registration application:

- draft labels for any application submitted before Health Canada issues a Notice of Compliance or close to the date on which it is issued;
- labels for any application submitted after Health Canada has issued a Notice of Compliance, including those on the bottle or cardboard packaging;
- package inserts to be included in the packaging, if applicable.

Therefore, to submit a recommendation to the Minister of Health, **INESSS must now have the following two final documents:**

- the notice of compliance or the medical device licence issued by Health Canada;
- the official product monograph or, in the case of a medical device, the user manual.

These changes will be incorporated into the INESSS Application Submission Guide during its next update, scheduled for 2027.

Thank you for your cooperation.

Directorate of Drug and Technology Assessment for Reimbursement,
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