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

NOTICE TO MANUFACTURERS OF DRUGS, STABLE BLOOD PRODUCTS AND TECHNOLOGIES

DATE: November 30, 2020

SUBJECT: Establishment of a waiting list for scientific evaluations and instructions for filing a listing request electronically

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Establishment of a waiting list for scientific evaluations

Given the COVID-19 health crisis, the Direction de l'évaluation des médicaments et des technologies à des fins de remboursement of the Institut national d'excellence en santé et en services sociaux (INESSS), in collaboration with experts in the health and social services system, is actively engaged in providing rapid responses to questions from the Ministère de la Santé et des Services sociaux (MSSS). Moreover, there is no indication that the pace will ease in the coming months with the marketing of new products administered for the treatment of this disease.

Along with these priority items, INESSS is currently receiving a large number of scientific evaluation requests from manufacturers, many of which are in progress. While every effort is being made to carry out these activities, INESSS is unable, with the currently available resources, to process requests within the timeframe it has committed to.

Consequently, INESSS is announcing today, November 30, 2020, the creation of a waiting list for the scientific evaluation of drugs, stable blood products and technologies.

The terms and conditions for this waiting list are as follows:

- Manufacturers can submit their listing requests to INESSS at any time;

- Their admissibility will be assessed as soon as possible on a first-come, first-served basis;

- With a waiting list in place, INESSS commits to informing the manufacturer of its admissibility decision within the 15 working days after the request is filed. Please note that this applies to listing applications received by INESSS on or after November 16, 2020.

- INESSS will inform manufacturers of its admissibility decision by means of a letter sent by e-mail. The manufacturer may be informed that its request is:

  - Not admissible
    or
  - Admissible and has been put on the waiting list
    or
  - Admissible and that the evaluation has begun

- When an admissible request is put on the list of requests awaiting evaluation by INESSS, the information is made public on the work plan with the status "Waiting for review";

- INESSS will begin the evaluation process as soon as it can. When it does, it will notify the manufacturer by means of a letter sent by e-mail.

- The following criteria are used to determine the order of priority for evaluating wait-listed requests:

Clinical criteria:
- The drug is intended to treat a serious health problem;
- The available data suggest that the drug significantly improves patients' health relative to the treatment options on the *List of Medications* (for the RGAM, the basic prescription drug insurance plan) or the *List of Medications – Institutions,* or those available through special funding from the Ministère de la Santé et des Services sociaux.

or

Economic criterion:
- The potential to generate savings within the health and social services system.

- When the scientific evaluation of an admissible request is started, the information is made public on the work plan with the status "Currently under review";

- A manufacturer may request that priority be given to its request. The "Expedited request being considered" section of the mandatory advance notice must be completed, and the cover letter submitted with the request must indicate this;

- Subject to INESSS's decision, if the criteria are met, requests will be evaluated on a first-come, first-served basis before those requests awaiting evaluation that have not been given priority;

- A recommendation can be sent to the Minister only if all the required items have been submitted to INESSS.

Instructions for filing a listing request electronically

To support the telework measures put in place by the government at the beginning of the pandemic, INESSS has implemented a temporary e-filing solution using the MSSS's secure ShareFile platform. This filing method has been available since March 27, 2020 for drug listing requests that meet the requirements indicated on checklists 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 13, A, B and C, and for blood system products and technologies, according to the usual requirements.

INESSS has observed that with electronic submissions, the number of documents submitted in listing requests filed in this manner has increased significantly. In fact, this is making the teams' evaluation work and the internal management of documents shared with the experts consulted more complex. In this regard, INESSS would like to reiterate and suggest certain instructions for filing requests electronically:

- Please be sure to carefully separate the documents according to the different evaluation sections (administrative, clinical, economic and other), as indicated on the request checklists, if applicable;

- For the CLINICAL section, please select only the **5 most relevant publications** and rename the files to be submitted electronically by indicating the order, the author, and the year and title of the publication (usually the name of the study). Example:
  1- Author_Year_Title
  2- Author_Year_Title
  3- Etc.

- The summary tables in the clinical section of the form entitled "Summary Submission Description" must be completed based on the 5 publications selected as being the most relevant ones for the evaluation;

- Be sure to provide the clinical study reports (CSRs) for the main clinical studies published or submitted for publication (manuscripts), if applicable. Please create a subfolder named "CSRs";

- If posters or conference abstracts are available in connection with the 5 most relevant publications, whether published or submitted for publication (manuscripts), please create a subfolder named "Posters or abstracts";

- If it is necessary to provide additional publications relevant to the evaluation in accordance with the requirements set out in the Guidance Document for Submitting a Request to INESSS, please create a subfolder named "Other publications";

- If two pharmacoeconomic studies are submitted with the request, please complete the form entitled "Summary Submission Description" accordingly by filling out the two summary tables in the ECONOMIC section.

If you have any questions, please contact us at inscription@inesss.qc.ca.

We hope you and your family stay healthy during this health crisis, and we thank you for your cooperation.

Best regards,

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