23th Annual

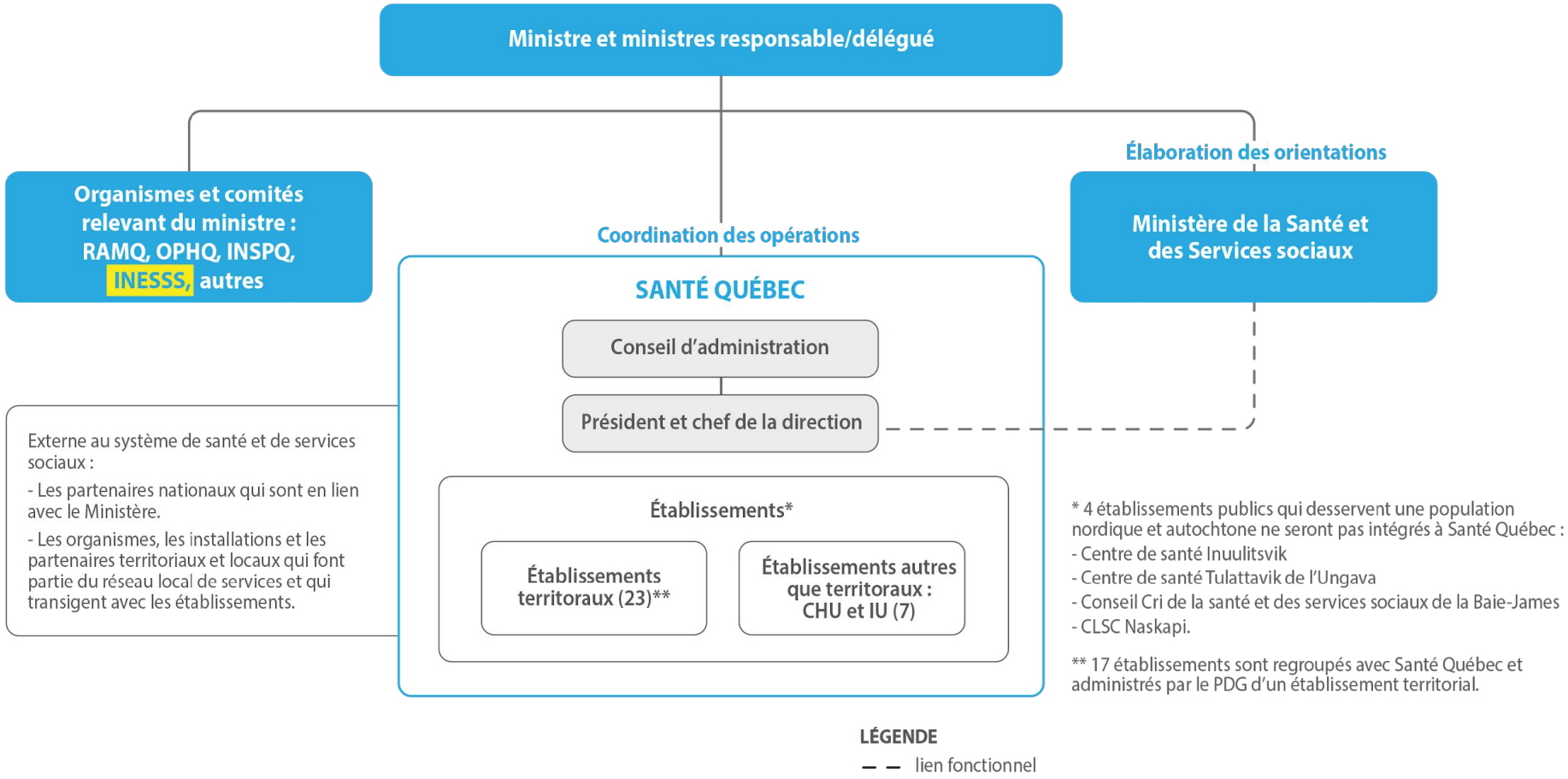
Market Access Summit

October 29 & 30, 2024
Hyatt Regency Toronto
Toronto, ON

Latest Developments at INESSS

Mélanie Caron, Director
Drug and Technology Evaluation for Reimbursement Purposes

What's new in Quebec?



INESSS Act

Projet de loi no 15 (2023, chapitre 34) Loi visant à rendre le système de santé et de services sociaux plus efficace

2 important changes

> **395** .. the establishment may only provide medications that have received a **Notice of Compliance from the federal government for therapeutic indications recognized by INESSS...**

399 …The anonymized decision of a pharmacology committee that grants an authorization referred to in Article 398 is sent to INESSS for the **purposes of the registry…**

I-13.03 - Act respecting the Institut national d'excellence en santé et en services sociaux

Nécessité Médicale Particulière (NMP)
A special program in hospitals to provide access to patients under specific conditions for particular last-resort treatments.

Strategic Plan 2024-2028

The consultation highlighted…

…the important balance between high and low value, and its implication for labour issues

…the importance of controlling costs and environmental aspects

Skills in line with rapidly evolving knowledge

…the professionnal satisfaction associated with the impact and influence of our work

…the importance of equity and inclusion for the health and well-being of the population

…the shared need to collaborate more and reduce duplication

The sustainability of the Health and Social services system under strain

…the key role of the 1st line in overall system performance…The importance of local services that mobilize local resources

…that the future lies in interprofessionalism, and that our tools should facilitate this by involving users in our work at an early stage

Strategic Plan 2024-2028

	Objectives
Guide	1.1 Prioritize the evaluation of health and social services innovations with high potential for value creation
	1.2 Stimulate the reduction of low-value interventions
	1.3 Support the economic and environmental sustainability of the health and social services network
Tools	2.1 Support optimal care and service pathways in 1st line and local services
	2.2 Increase the use of our knowledge products in collaboration with our target audiences
Mobilize	3.1 Evolve our methods and processes in an inclusive and concerted manner
	3.2 Promote the impact of our mission for the population

New Drug Submission Guidelines

Guide for Submitting a Request along with various forms, sheets, and letter templates to assist manufacturers in preparing their registration requests, has undergone significant updates.

Given the considerable changes made to the documents, you are encouraged to read them in their entirety: INESSS Drug Submission Guidelines (with changes - update june 2024)

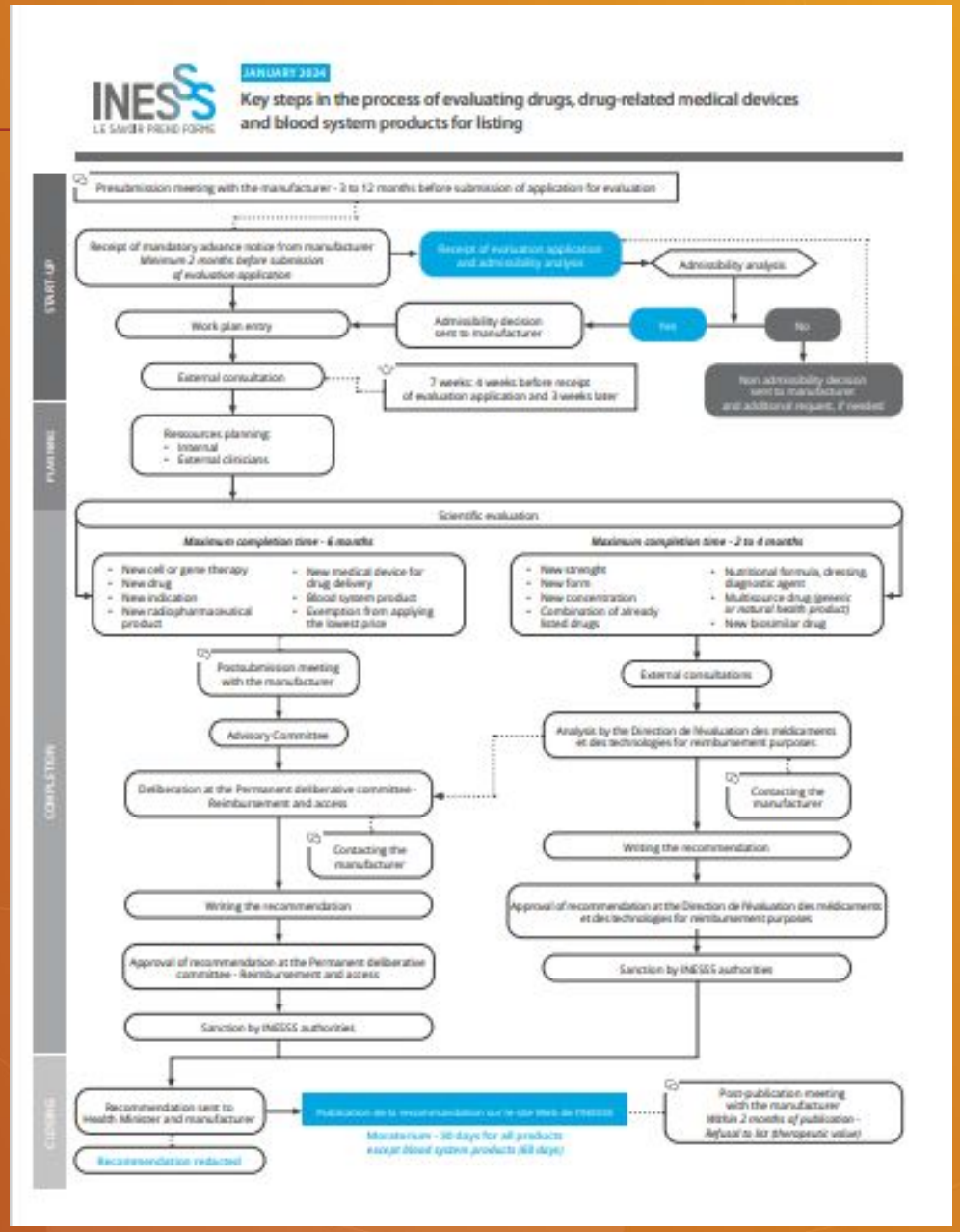
- Drugs,
- Blood System Products
- Medical Devices Related to the Administration of Drugs

- For non pharmaceutical innovation : INESSS: Faire une demande d'évaluation

Key steps

Dual-track process:
180-day standard review
120-day or 90-day expedited process.

The review process considers clinical effectiveness, safety, and economic impacts, aiming to support informed decisions on drug inclusion based on patient needs and public interest.



Admissibility

- **Weekly process**
- **Advance notice : mandatory for new drug, new indication and reevaluation**
- **Prioritized request** by Health Canada, including **ORBIS projects** and **Aligned** review between Health Canada, CDA-AMC, and INESSS
- **Activation of evaluations on a monthly basis** except for biosimilar and new form/streght activated directly
- Admissibility team is **available to answer** any questions before and during the process by email inscription@inesss.qc.ca (presubmission meeting offered)

Biosimilars and generics

Expedited process for indications already on the List

Individual process by indication for the new indications that had not been assessed previously

Possible to request a review of the reimbursement criteria

For the purpose of making its recommendations, INESSS has developed six criteria that enable it to take into account all the parameters specified in the Act:

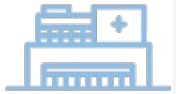
More specifically, the links between these six criteria and the five parameters specified in the Act are as follows:

CRITERIA	PARAMETER SPECIFIED IN THE ACT
1 The identification of the unmet health need in the intended patient population and the determination of the level of this need.	→ **Aspect 1 :** Therapeutic value
2 The drug's ability to confer a clinical benefit.	
3 The drug's efficiency.	→ **Aspect 2 :** Reasonableness of the price charged **Aspect 3 :** The drug's cost-effectiveness ratio
4 Level of impact of the medical condition and the drug on the health of the general population.	→ **Aspect 4 :** Impact of adding the medication on the list on the health of the population and on the other components of the health and social services system
5 The drug's level of burden on the system's budget.	
6 The system's organizational ability to offer the drug.	

MULTIDIMENSIONAL CONSIDERATIONS
Overall Value Assessment

CLINICAL Dimension
Does the intervention improve the health and well-being of users?

POPULATION Dimension
Does the intervention contribute to better health and well-being for the entire population in an equitable manner?



ORGANIZATIONAL Dimension
Does the intervention fit into the care and services setting in a way that contributes to strengthening the health and social services system?

SOCIOCULTURAL Dimension
Does the intervention fit into the reality of Québec society in a way that promotes its evolution towards the common good?

ECONOMIC Dimension
Does the intervention optimize the use of resources for their responsible and sustainable management?

Possible Recommendations for Listing

INESSS Recommendations	Applicability
Listing	Recommendation made when the assessment of all evaluation parameters specified in the Act favourable to listing the drug with no restriction
Conditional listing	Recommendation made when the assessment of all evaluation parameters specified in the Act favourable to listing the drug only if certain conditions are met. 3 possible conditions: Exception drug Monitoring Reduction of the economic burden
Refusal to list	Recommendation made in the following situations: - Drug's therapeutic value has not been demonstrated; - Patients' health need is almost nonexistent, that level of uncertainty regarding the drug's efficiency is too high and, when applicable, that it is not advisable to negotiate a listing agreement for the drug

Promise of therapeutic value (2018)

Counterpart of the TLR (CDA-AMC)

Conditional listing that may be dependent on clinical monitoring requirements if INESSS deems that the drug could offer a desired therapeutic value

Additional clinical data are required to do a re-evaluation or when there is a risk of non optimal use and RWD could support reassessments.

- Already used : Galafold, CAR-T, Spinraza, Carvikty, …
- Can lead or not to **pCPA Temporary Access Process (pTAP)**

NOC- C : Conditions Related to Listing

June 2024

Given that for certain health products, Health Canada issues market authorizations on the condition that the sponsor undertakes additional studies to verify clinical benefit, INESSS will now specify in its recommendations to the minister the possibility that the manufacturer may need to **collaborate** in the re-evaluation of data after the product's reimbursement.

The requirement for a follow-up means that the manufacturer may be called upon to provide relevant new **clinical data** (including real-world data) after a certain number of years or in accordance with commitments made to Health Canada, as well as an **update of previously submitted economic studies**, along with any other documentation supporting the evaluation of the five aspects stipulated by INESSS law.

INESSS may solicit the concerned manufacturers in a timely manner, as necessary.

Consultation – work in progress

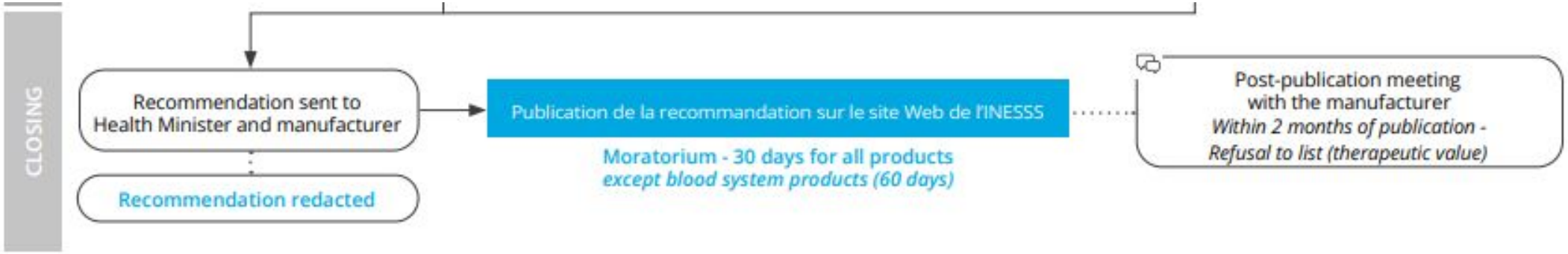
A-6.001, r. 6.1 - Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug, stable blood product or technology for listing purposes

New assessment lines & fees :

- new blood products with companions test
- therapeutic products approved in Canada and assessed for an indication not included in the Canadian product monograph
- new drug whose patent has expired and that has never been evaluated or listed for a given indication or review of listing required

Validity period of the evaluation

Consultation– work in progress



INESSS will receive ideas, comments, and arguments regarding the post-publication meeting. This repeated request from the industry will be discussed in the coming weeks now that the backlog and the management team have been completed.

- What we don't want :
  - Lose predictability in the timelines
  - Not receiving the right information the first time
  - Lose efficiency

Consultation – work in progress

DECEMBER 2018

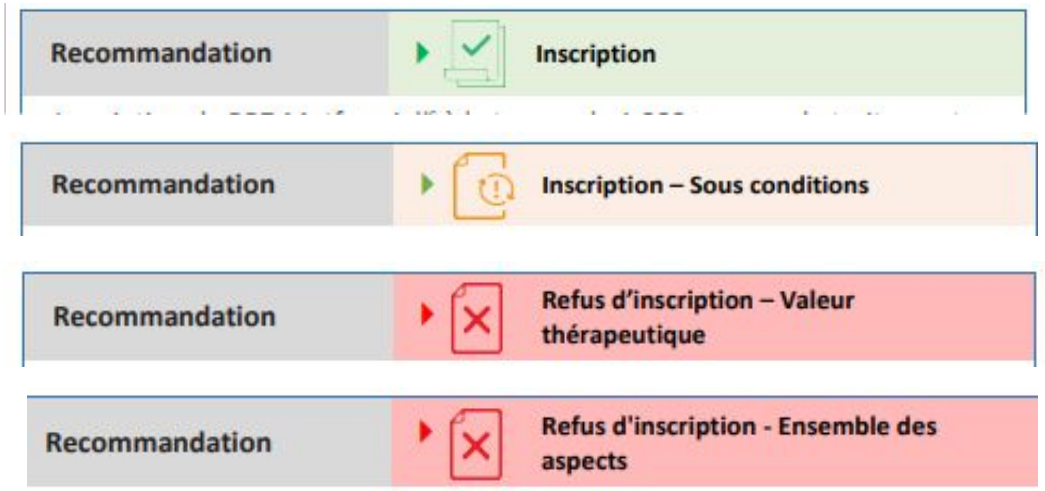
EVALUATION OF DRUGS FOR LISTING PURPOSES

A CHANGE OF APPROACH

The purpose of the exercise is to be more explicit about certain methods and conclusions, while adding specific details on :

- Promesse de la Valeur
- Refusal based on all criteria
- Clarifications regarding the prioritization of
  - evaluation for drugs whose patents have expired
  - evaluation of indication when not approved by Health Canada

INESSS is working on updating this framework in 2024-2025



Differences between CDA-AMC and INESSS

CDA-AMC	INESSS
Different committees for different drug class or processes.	1 committee
Time limited recommendations.	Promesse de valeur thérapeutique
Target Zéro	Pre-Noc & Aligned Review
Rolling Submission	Not in the usual process at the moment
Non-sponsored reimbursement review	INESSS initiative review or Sponsor review for a drug whose patent has expired and that has never been evaluated or listed for a given indication or review of listing required
Innovatives drugs	Innovatives, Companion test, Biosimilars, dressings, new forms, streghts, Nutritional formula and generic drugs
180 days	180, 120 or 90 days
pCPA-driven negotiation	pCPA or ministry driven negotiation

Anticipating Tomorrow

Overcoming Challenges Ahead

- **Budgetary context significantly different from the pandemic period**
- **Astronomic pricing of innovation**
- **Fairness in the treatment of different conditions**
- **EU joint clinical assessments**
- **Environmental considerations**