INESSS
LE SAVOIR PREND FORME

EVALUATION OF DRUGS FOR LISTING PURPOSES: A CHANGE OF APPROACH

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INESSS: THE HTA BODY IN QUEBEC

Created in 2011, following the fusion of 3 entities

- Conseil du Médicament (drugs)
- Agence d'évaluation des technologies et des modes d'intervention en santé (technologies)
- Social services

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INESSS: THE HTA BODY IN QUEBEC

Conseil du médicament

AETMIS

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MISSION

Social services

Promote clinical excellence and the efficient use of resources in the health and social services sector

VISION

Be the reference to inform decisions and practices

VALUES

Excellence
Independence
Openness
Scientific rigour
Transparency
Integrity
Equity

Direction du médicament

Direction des services de santé et de l'évaluation des technologies

Direction des services sociaux

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MANDATS

Evaluates

By legislation, INESSS assesses the clinical advantages and the costs of:

- technologies,
- medications,
- interventions used in health care and personal social services.

Recommends

It issues recommendations concerning their adoption, use and coverage by the Québec healthcare services.

Develops

It develops guides to clinical practices in order to ensure their optimal use in the Québec healthcare services.

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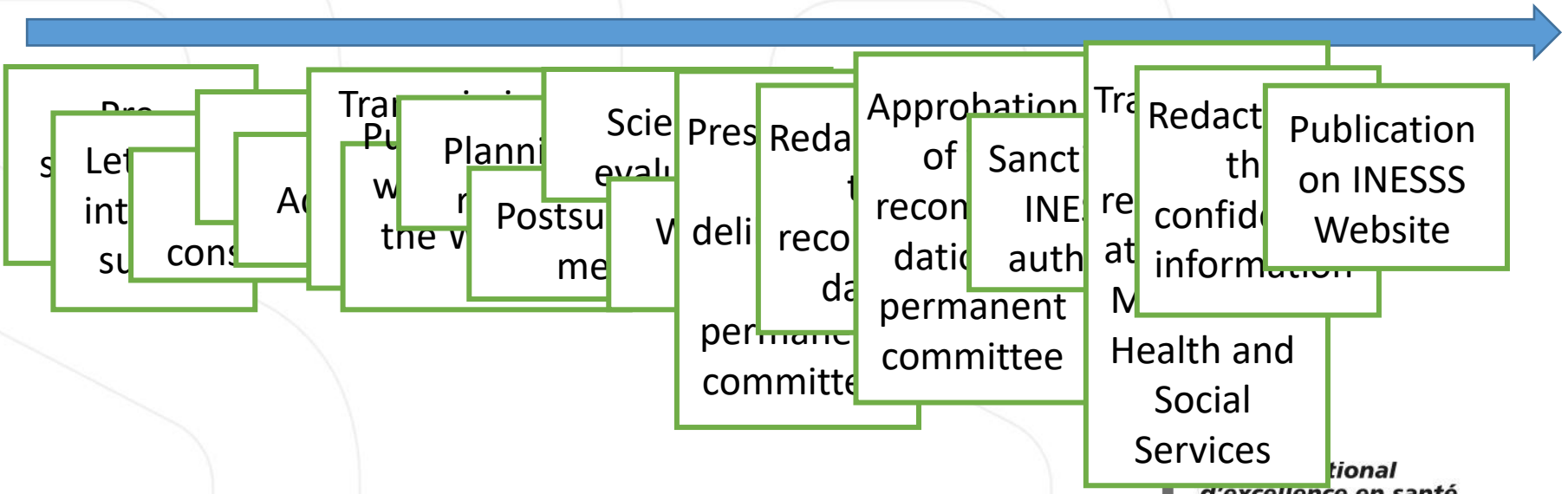
MAIN OBJECTIVES OF THE PRESENTATION

- Which changes ?
- Why were they brought?



CONTINUOUS MODE

Before: 3 dates per year

Main raison why : Faster access for patients

Persuasive factor for decision-making : Quebec life sciences strategy 2017-2027

Submission: post-NOC

Target :
Synchronize INESSS and CADTH recommendations so the mean delay between both is maximum 30 days

Now: No submission deadline

How beneficial this would be? : Chance of a faster listing in the event of a positive recommendation by INESSS

Submission: pré-NOC or post-NOC

But, the downside of it:

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PRESUBMISSION MEETING

- When: 3 to 12 months before submission

- Specific issues have to be identified by the manufacturer to justify the relevance, such as :

  - Clinical issues: uncertainty regarding clinical data (non comparative study, indirect comparison), the choice of the comparator, QoL, place of therapy, indication targeted for listing purposes, etc.

  - Economic issues: type of pharmacoeconomic analysis, budgetary impact approach, the choice of the comparator, uncertainty regarding clinical and cost inputs, data extrapolation technic, etc.

- Main objectives of the meeting:

- To broadly present to INESSS what is in the file, what are the main data concerning the therapeutic value of the drug and what are the significant issues identified by the manufacturer;
- To share information on the orientation they expect to take for the submission preparation;
- To allow, when appropriate, alignments from INESSS that do not require a deep knowledge of the file.

EXTERNAL CONSULTATION

Letter of intent by manufacturer: 2 months before submission

Allows us to start the external consultation earlier and hence, to make it last longer (7 weeks instead of the previous 4)

Picture of the symptoms of their medical condition

Quality of life

Expectations and hope towards a new treatment

Gives more time to patients, associations of patients, caregivers, citizens, health professionals, clinicians, etc. to answer questionnaires on our Websi

Daily living with the condition

Fears towards their conditions

In turn, the more information that patients, caregivers and understand the reality

Values and preferences

Resource utilization required by their condition

Benefit, risks and breaches of actual treatments

Experience with the drug evaluated or with current treatments

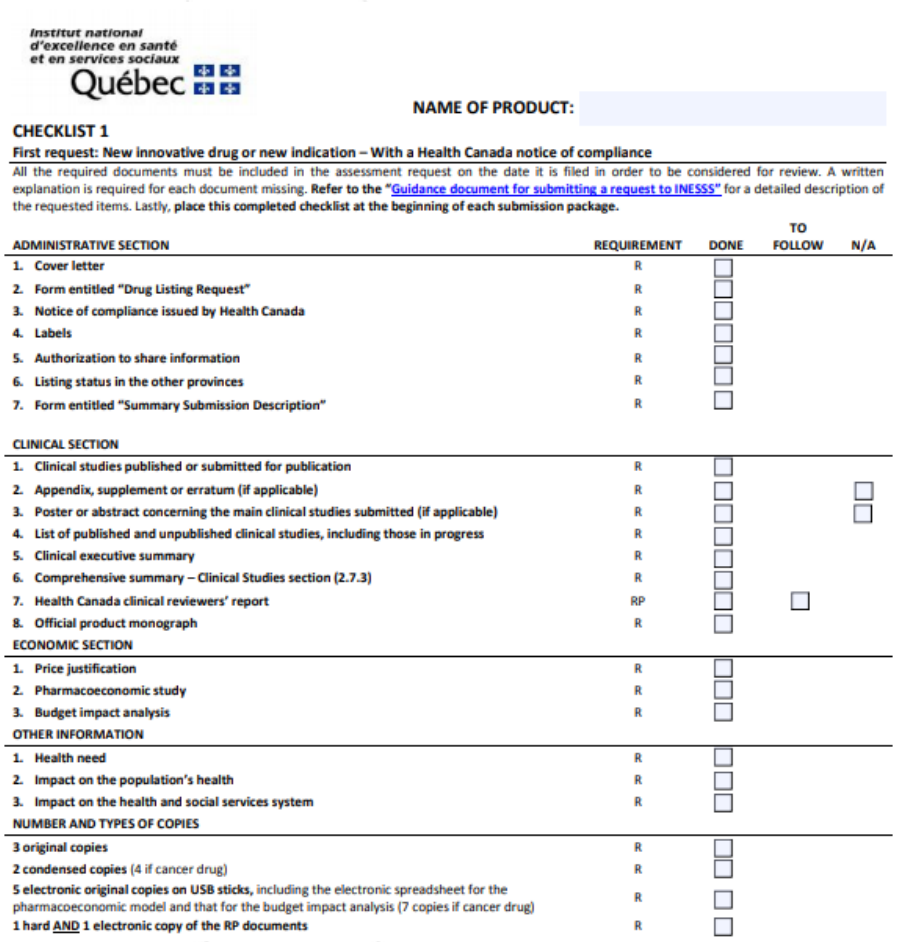
Unmet need

EXTERNAL CONSULTATION

In addition to this process (letters and questionnaires), the information may also be harvested through recognized consultation methods, such as focus group or semi-directed interviews.

- Recently participated in a rewarding consultation process, with patients suffering from spinal muscular atrophy, a rare disease, and with caregivers
- Context of the consultation : Evaluation of Spinraza® for listing purposes
- Phone interviews and in person meetings were conducted by GRIMN (Groupe de recherche interdisciplinaire sur les maladies neuromusculaires), affiliated to the rehabilitation school at Université de Sherbrooke
- Those activities consisted in collecting information namely regarding the experience of patients living with the disease and, for those who were treated with Spinraza®, regarding the advantages and disadvantages of the drug

ADMISSIBILITY PROCESS



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NAME OF PRODUCT:

CHECKLIST 1

First request: New innovative drug or new indication – With a Health Canada notice of compliance

All the required documents must be included in the assessment request on the date it is filed in order to be considered for review. A written explanation is required for each document missing. **Refer to the "Guidance document for submitting a request to INESSS"** for a detailed description of the requested items. Lastly, **place this completed checklist at the beginning of each submission package.**

ADMINISTRATIVE SECTION	REQUIREMENT	DONE	TO FOLLOW	N/A
1. Cover letter	R	☐		
2. Form entitled "Drug Listing Request"	R	☐		
3. Notice of compliance issued by Health Canada	R	☐		
4. Labels	R	☐		
5. Authorization to share information	R	☐		
6. Listing status in the other provinces	R	☐		
7. Form entitled "Summary Submission Description"	R	☐		
CLINICAL SECTION				
1. Clinical studies published or submitted for publication	R	☐		
2. Appendix, supplement or erratum (if applicable)	R	☐		☐
3. Poster or abstract concerning the main clinical studies submitted (if applicable)	R	☐		☐
4. List of published and unpublished clinical studies, including those in progress	R	☐		
5. Clinical executive summary	R	☐		
6. Comprehensive summary – Clinical Studies section (2.7.3)	R	☐		
7. Health Canada clinical reviewers' report	RP	☐	☐	
8. Official product monograph	R	☐		
ECONOMIC SECTION				
1. Price justification	R	☐		
2. Pharmacoeconomic study	R	☐		
3. Budget impact analysis	R	☐		
OTHER INFORMATION				
1. Health need	R	☐		
2. Impact on the population's health	R	☐		
3. Impact on the health and social services system	R	☐		
NUMBER AND TYPES OF COPIES				
3 original copies	R	☐		
2 condensed copies (4 if cancer drug)	R	☐		
5 electronic original copies on USB sticks, including the electronic spreadsheet for the pharmacoeconomic model and that for the budget impact analysis (7 copies if cancer drug)	R	☐		
1 hard AND 1 electronic copy of the RP documents	R	☐		

Beyond an administrative process…

To the best of our knowledge, without a scientific appreciation of the file, to ensure that all the relevant information is submitted

Examples of what:

- Service statement (180 days)
- Complete indirect comparison
- Clinical data and statistical analysis for a subgroup
- Workable Excel file

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SCIENTIFIC EVALUATION

Pre-submission meeting

Letter of intent to submit

Externa consultati

Postsubmission meeting

Working group

Transmissio

Presentation and deliberation by permanent committee

Redaction of the recommen-dation

on

Approbation of the recommen-dation by permanent committee

The main steps remain but few changes have been brought regarding how the evaluation is performed.

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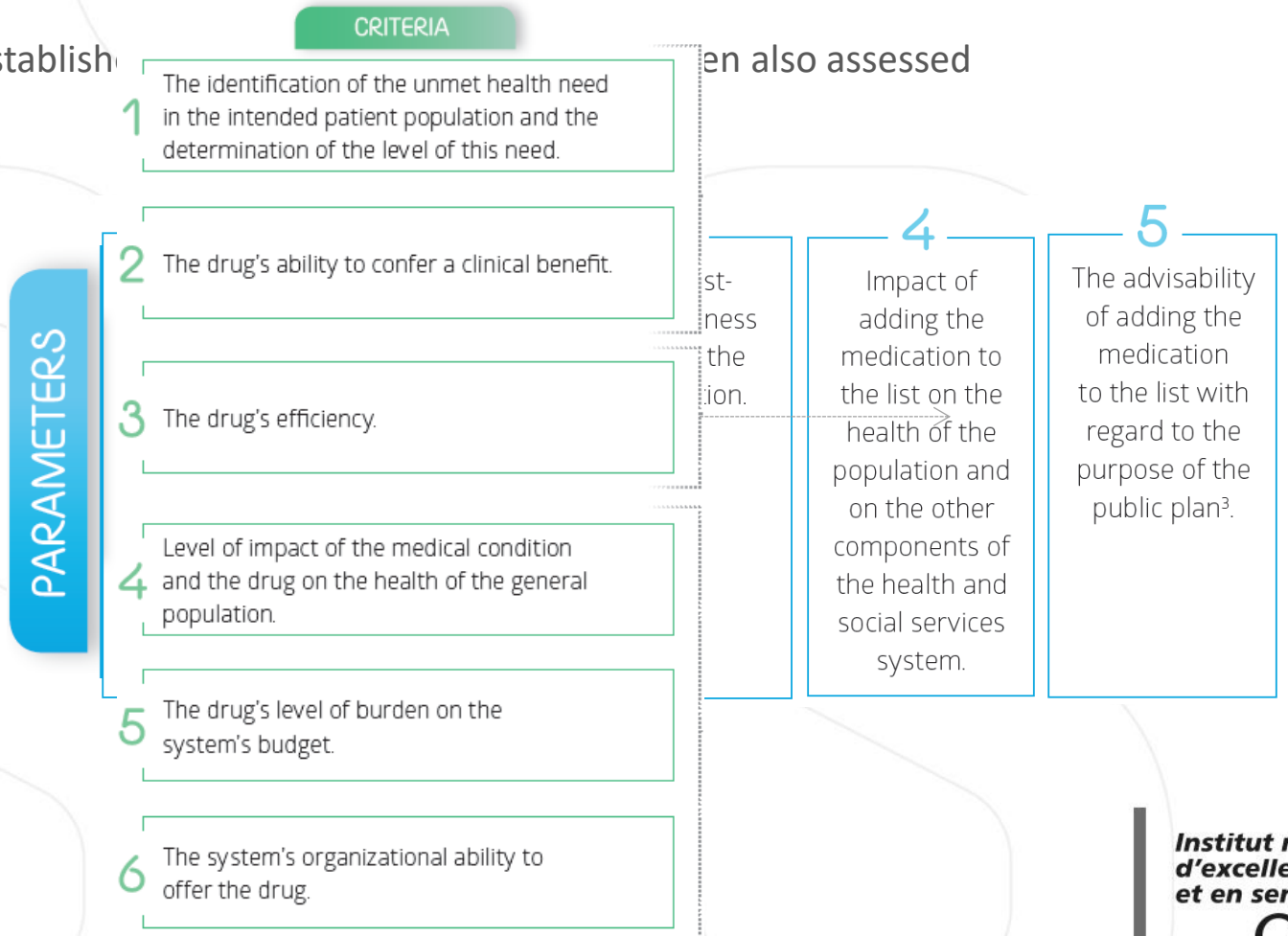
CRITERIA-BASED EVALUATIVE APPROACH

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:

In exercising ss the **therapeutic value** of a medication:

- If not estab that effect is transmitted to the Minister
- If establish en also assessed



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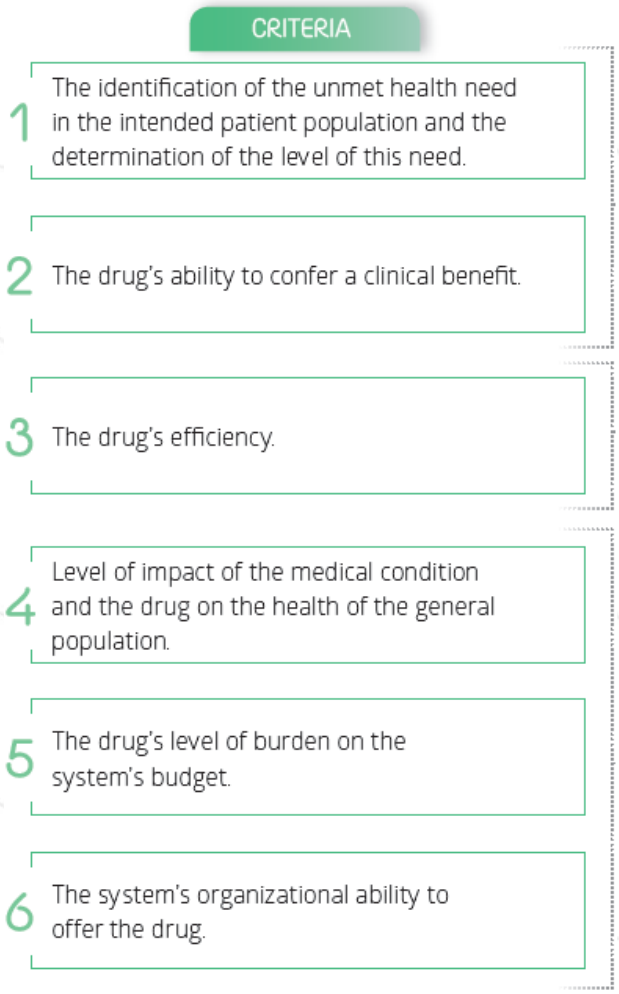

Objective:

Have a more structured evaluation process that will explicitly take into account these 6 complementary criteria

- to promote integration of the information for decision-making purposes by our permanent scientific committee
- to facilitate the presentation, and hence the comprehension, of the distinct reasons underlying the recommendation in our notices to the Minister

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CRITERIA-BASED EVALUATIVE APPROACH

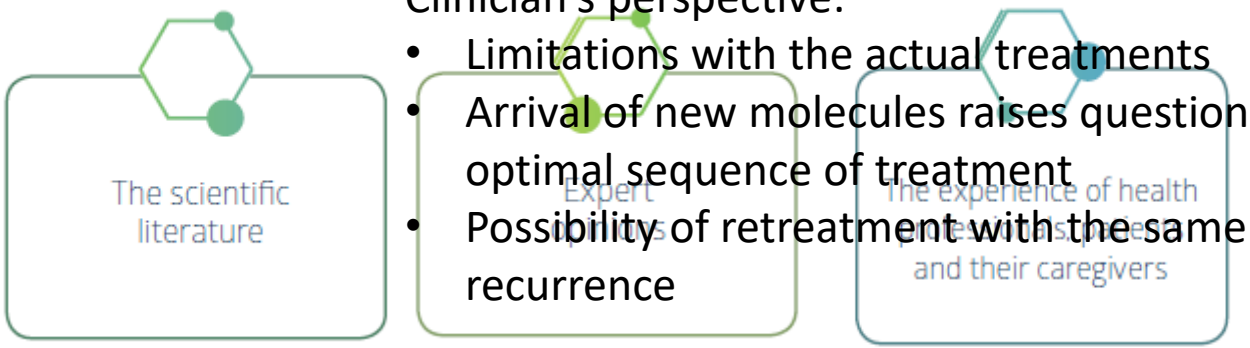
Before: patient's and clinician's perspective was presented in parameter 4 so, if the therapeutic value (parameter 1) was not established, both perspectives were not presented.

Patient's perspective: example of Radicava®
(amyotrophic lateral sclerosis)

- Experience with the drug (clinical benefits but difficulty of administration, end of dose symptoms)
- Expectations: reduce their symptoms, preserve their mobility

Clinician's perspective:

- Limitations with the actual treatments
- Arrival of new molecules raises questions regarding the optimal sequence of treatment
- Possibility of retreatment with the same molecule if recurrence



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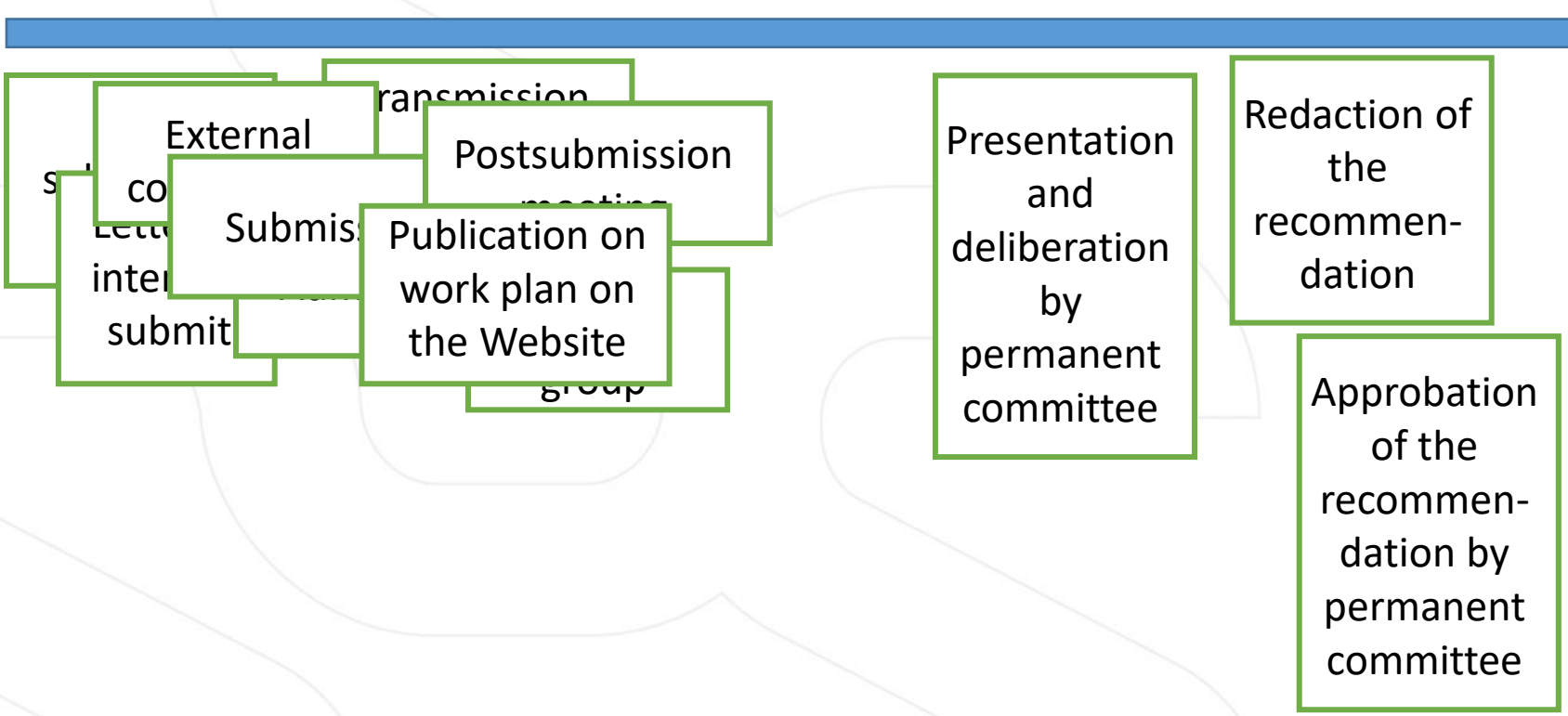
RECOMMENDATIONS CONCERNING THE FAIRNESS AND REASONABLENESS OF LISTING



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RECOMMENDATION CONCERNING THE FAIRNESS AND REASONABLENESS OF LISTING

Based on its overall evaluation, INESSS makes a recommendation to the Minister of Health and Social Services.

INESSS recommendation	Applicability
Listing	INESSS makes this recommendation when it considers the assessment of all the evaluation parameters specified in the Act favourable to listing the drug with no restrictions.
Refusal to list	INESSS makes this recommendation in the following situations: • When it considers that the drug's therapeutic value has not been demonstrated; • When it considers, in particular, that the level of the patients' health need is almost nonexistent, that the 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.

RECOMMENDATIONS CONCERNING THE FAIRNESS AND REASONABLENESS OF LISTING

Conditional listing	INESSS makes this recommendation when it considers the assessment of all the evaluation parameters specified in the Act favourable to listing the drug only if certain conditions are met. **POSSIBLE CONDITIONS:** **Exception drug** INESSS suggests this condition when it considers the assessment of all the evaluation parameters specified in the Act favourable to listing of the drug with specific utilization criteria. In such case, it proposes an indication recognized for payment or utilization criteria for the drug. **Monitoring** INESSS suggests this condition in the following situations: • When it considers that the drug offers a desired therapeutic value, but that additional clinical data is needed to do a re-evaluation (clinical monitoring); • When it considers that the drug is associated with a risk of nonoptimal use and that monitoring real world data is necessary in order to do a re-evaluation (monitoring optimal use). **Reduction of the economic burden** INESSS suggests this condition in the following situations: • When it considers that the drug's efficiency is unfavourable (not cost-effective); or • When it is unable to evaluate the drug's efficiency (efficiency not estimable); or • When it believes that listing the drug would have an unfavourable budgetary impact that could have repercussions on the health care system.

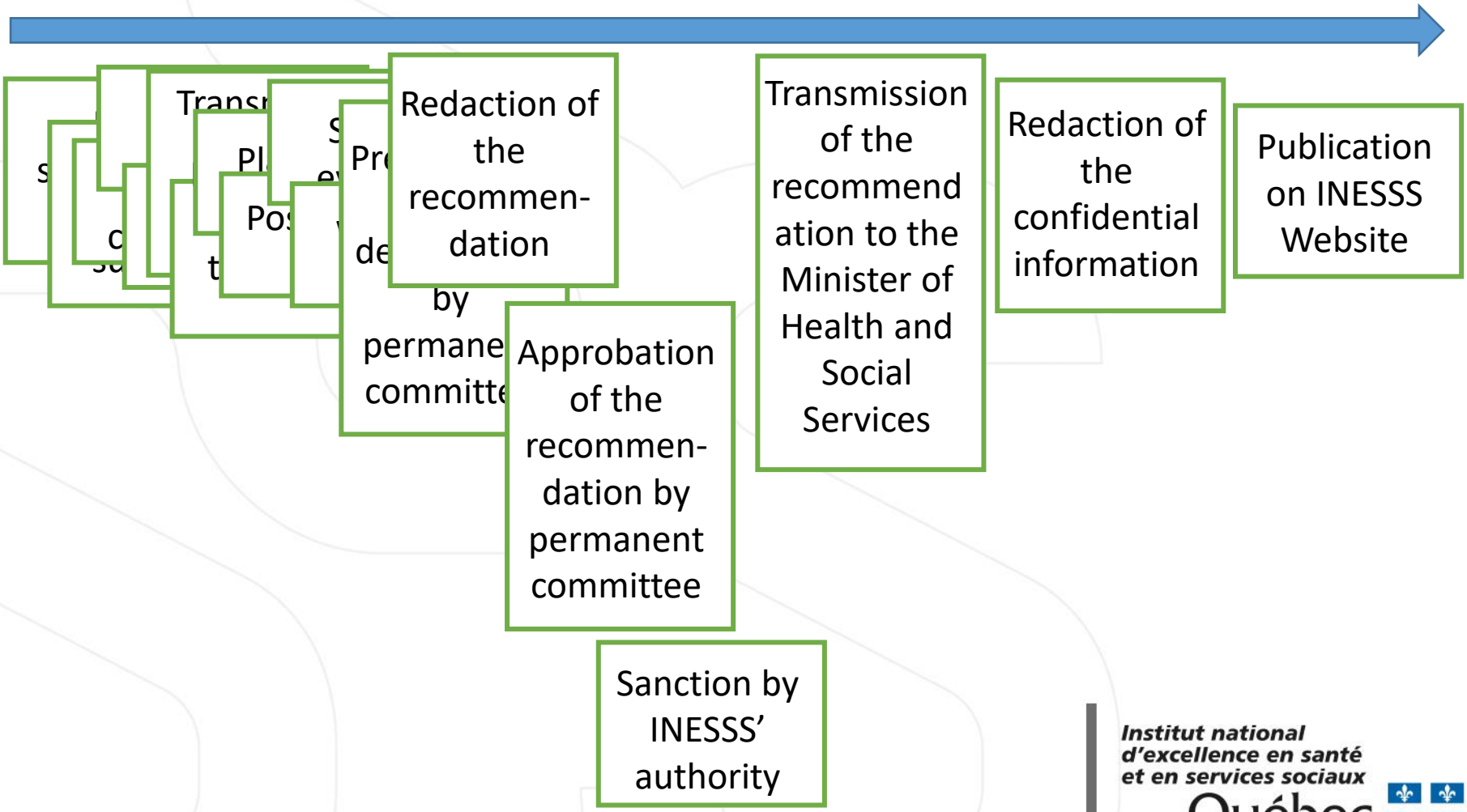
Spinraza (spinal muscular atrophy, INESSS 2019)

Galafold (Fabry disease, INESSS 2018)

Context :

- Rare or ultra-rare disease
- Poor vital and functional prognosis
- Limited clinical data and hard to obtain
- Significant unmet need

FINALISATION OF THE PROCESS



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THANK YOU

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