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

NAME OF PRODUCT:

CHECKLIST A

REVALUATION REQUEST: New drug, new cell therapy, new gene therapy, new advanced therapeutic product or new radiopharmaceutical product already listed

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.

It should be noted that the clinical or economic data required differ according to the reasons for refusal of registration:

- **If the request for re-evaluation concerns a product that has been refused listing for therapeutic reasons**, provide new relevant clinical data and a rationale that addresses the reasons that led to the decision to refuse recognition of therapeutic value. It should be noted that clinical data previously provided and evaluated need not be resubmitted. The economic studies will have to be updated to include the new clinical data, as well as any other documents supporting the evaluation of the five aspects stipulated by INESSS law.
- **If the request for re-evaluation concerns a product that has been refused listing for all aspects**, the requirements of the clinical component are only required if new clinical data are used in the economic studies. The new data submitted must respond to the elements of uncertainty or concern raised when the previous evaluation was refused.
- **If the request for re-evaluation is made following a data monitoring process in a real care context (clinical monitoring condition; promising character/promise of therapeutic value),** provide new relevant clinical data and an update of the economic studies previously submitted, along with any other documents supporting the evaluation of the five aspects stipulated by INESSS law.

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 (if applicable)	R	☐		☐
4. Labels	R	☐		
5. Authorization to share information	R	☐		
6. Registration status in other provinces	R	☐		
7. Form entitled "Summary Submission Description"	R	☐		
CLINICAL SECTION				
1. Clinical studies published or submitted for publication	R	☐		☐
a. Clinical study report of the pivotal study (CSR)	R	☐		
b. Indirect comparison (if applicable)	R	☐		☐
2. Explanation of relevance: for an innovative drug that is a drug combination	R	☐		☐
3. Appendices, supplements, *erratum* or editorials (if applicable)	R	☐		☐
4. Poster, abstract or oral presentation concerning the main clinical studies submitted (if applicable)	R	☐		☐
5. List of published and unpublished clinical studies, including those in progress	R	☐		☐
6. Clinical executive summary	R	☐		☐
7. Comprehensive summary – Clinical Studies section (2.7.3)	R	☐		☐
8. Health Canada clinical reviewers' report	RP	☐	☐	☐
9. 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. Effects on population health	R	☐		
3. Effects on the health and social services system	R	☐		

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LEGEND : N/A = Not applicable
R = Required on the date that the assessment request it is filed
RP = Required as soon as possible

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