

PRODUCT NAME:

APPLICATION FOR EVALUATION OF A NON-PHARMACEUTICAL INNOVATION

Initial Request:

or

New Indication

Each of the required documents must be included in the application on the date of submission for it to be considered for evaluation. A written justification is required for each missing document. Refer to the section titled "[Submit an application for evaluation](#)" under the topic "Non-pharmaceutical innovations" of the INESSS website and the **Guide to Submitting an Application to INESSS for Innovative Non-Pharmaceutical Technologies**.

	REQUIRED	COMPLETE	COMING SOON	N/A
ADMINISTRATIVE SECTION				
1. Cover Letter	R	☐		
2. "Application for Evaluation of a Non-Pharmaceutical Innovation" Form	R	☐		
3. Licence issued by Health Canada	R	☐		
4. Authorization to Share Information	R	☐		
5. "Summary Description of the Application" Form	R	☐		
POPULATIONAL DIMENSION				
1. Populational Analysis Document	R	☐		
CLINICAL DIMENSION				
1. Published clinical studies or manuscripts submitted for publication	R	☐		
a. Complete clinical study report from the pivotal study	R	☐		
b. Indirect comparison (if applicable)	R	☐		☐
2. Appendices, supplements, <i>errata</i> , or editorials (if applicable)	R	☐		☐
3. Posters, abstracts, or oral presentations related to the main studies submitted (if applicable)	R	☐		☐
4. List of published and unpublished clinical studies, including those currently in progress	R	☐		
5. Health Canada Summary Basis of Decision (class III and IV only)	RD	☐	☐	
6. User Guide	R	☐		
7. Data on the Precision and Accuracy of Results	R	☐		☐
ORGANIZATIONAL DIMENSION				
1. Organizational Dimension document	R	☐		
ETHICAL AND ENVIRONMENTAL ASPECTS (optional)				
1. Ethical and Environmental aspects document		☐		☐
ECONOMIC DIMENSION				
1. Cost Justification	R	☐		
2. Economic Analysis	R	☐		
3. Budget Impact analysis	R	☐		

LEGEND: N/A = not applicable
R = Required as of the date the evaluation request was filed
RD = Required as soon as possible