



May 26, 2021

Institut national d'excellence en santé et en services sociaux (INESSS)
Direction de l'évaluation des médicaments et des technologies à des fins de remboursement
2535, boulevard Laurier, 5^e étage
Québec (Québec) G1V 4M3

Subject: Mandatory advance notice

As expected at least 2 months ahead of time, this letter is to inform INESSS of our intention to submit an evaluation request to the Direction de l'évaluation des médicaments et des technologies à des fins de remboursement.

The required information is provided in the following table.

Information concerning the evaluation request

*Target submission date	2021/07/26
*Type of evaluation requested (enter the number of the checklist concerned)	Checklist No. 4 – First request: New pharmaceutical form or new strength of a listed drug
*Manufacturer's name	Knight Therapeutics Inc
*Brand name	IMVEXXY™ Indicate if confidential <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
*Generic name	Estradiol vaginal inserts
*Indications submitted for evaluation by INESSS	For the treatment of postmenopausal moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy.
FOR A DRUG WITH A HEALTH CANADA NOTICE OF COMPLIANCE	
Date of issuance of the notice of compliance	2020/08/17 <input type="checkbox"/> Conditional <input checked="" type="checkbox"/> Unconditional
Indications recognized by Health Canada	For the treatment of postmenopausal moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy.
Dosage forms	Vaginal inserts
Strengths	4 mcg and 10 mcg estradiol
Other characteristics	N/A
Companion test ^a Name of the analysis Objective(s) of the analysis	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Formulary for which the request will be made	<i>List of Medications (basic plan):</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>List of Medications – Institutions:</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No



Expedited request being considered ^b	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>a. By companion test, INESSS means a diagnostic test (or a pharmacogenetic test, or a test which allows therapeutic monitoring) enabling the selection, according to their status for a predictive marker identified by this test, of the patients for whom the treatment is likely to provide benefit among those diagnosed for a given disease. The test is considered a "companion" to the use of the treatment.</p> <p>b. The prioritization request will be assessed, according to the applicable administrative procedures, if a waiting list is required for the assessment requests.</p>	

It is understood that we will inform INESSS as soon as possible of any change to the target date for submitting our evaluation request.

We authorize INESSS to use the information in this advance notice to plan its work and to initiate a consultation process involving citizens, patients and their caregivers, health professionals, and related groups and associations. For this purpose, we authorize INESSS to publish on its website the asked information in the above table.

Comments: N/A



Signature

May 26, 2021

Date

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Title

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