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Gouvernement du Québec

O.C. 861-2018, 20 June 2018

Financial Administration Act
(chapter A-6.001)

Institut national d'excellence en santé et en services sociaux — Fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product

Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product

WHEREAS, under subparagraph (1) of section 5 of the Act respecting the Institut national d'excellence en santé et en services *sociaux* (chapter I-13.03), the mission of the institute consists more particularly in assessing the clinical advantages and the costs of the technologies, medications and interventions used in health care and personal social services;

WHEREAS, under subparagraph (8) of section 5 of the Act, the mission of the institute consists more particularly in making recommendations to the Minister of Health and Social Services with a view to updating the list of medications referred to in section 60 of the Act respecting prescription drug insurance (chapter A-29.01);

WHEREAS, under subparagraph (9) of section 5 of the Act respecting the Institut national d'excellence en santé et en services sociaux, the mission of the institute consists more particularly in making recommendations to the Minister of Health and Social Services for the purpose of updating the lists of medications provided for in section 116 of the Act respecting health services and social services (chapter S-4.2) and section 150 of the Act respecting health services and social services for Cree Native persons (chapter S-5);

WHEREAS, under subparagraph (11) of section 5 of the Act respecting the Institut national d'excellence en santé et en services sociaux, the mission of the institute consists more particularly in carrying out any other mandate entrusted to it by the Minister of Health and Social Services;

WHEREAS the Minister has entrusted to the Institut national d'excellence en santé et en services sociaux the mandate of evaluating stable blood products;

WHEREAS, under the first paragraph of section 83.8 of the Financial Administration Act (chapter A-6.001), a fee may be set under that Act to fund a particular public service or a set of public services delivered by a body or an institution, provided the law does not otherwise confer the power to set that fee;

WHEREAS, under the second paragraph of that section, in the case of a department or an institution, the fee must be determined by government regulation; in the case of another body, the fee is set by a regulation of that body, approved by the Government with or without amendment;

WHEREAS the scientific evaluation of a drug or a stable blood product is a service for which the fee is not otherwise set under the Act respecting the Institut national d'excellence en santé et en services sociaux;

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1), the draft Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product was published in Part 2 of the *Gazette officielle du Québec* of 21 February 2018, with a notice that it could be submitted to the Government for approval on the expiry of 45 days following that publication;

WHEREAS the Institut national d'excellence en santé et en services sociaux adopted, on 19 April 2018, by Resolution No. 2018-55-01, the Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product;

WHEREAS it is expedient to approve the Regulation without amendment;

IT IS ORDERED, therefore, on the recommendation of the Minister of Health and Social Services and the Minister of Finance:

THAT the Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product, attached to this Order in Council, be approved.

ANDRÉ FORTIER,
Clerk of the Conseil exécutif

Regulation respecting the fees payable to the Institut national d'excellence en santé et en services sociaux for the scientific evaluation of a drug or a stable blood product

Financial Administration Act
(chapter A-6.001, s. 83.8)

1. A manufacturer who asks the Institut national d'excellence en santé et en services sociaux to conduct a scientific evaluation of a drug or a stable blood product shall pay the fees set out in Schedule 1.

These fees vary according to the scientific evaluation that the Institut decides to conduct after receiving the request from the manufacturer.

2. As used in this regulation:

"scientific evaluation": means a structured evaluation, the objective of which is to guide decision-making, of a health technology that can concern both the direct impact of that technology and its indirect and unintentional consequences;

"manufacturer: means a person or group of persons who manufacture, produce, import or sell, under their name or a brand name, drugs or stable blood products;

"indication": means the indication for use requested by a manufacturer;

"drug": means a product that can be entered on the list of medications referred to in section 60 of An Act respecting prescription drug insurance (chapter A-29.01) or on the lists of medications referred to in section 116 of An Act respecting health services and social services (chapter S-4.2) or in section 150 of An Act respecting health services and social services for Cree Native persons (chapter S-5);

"stable blood product": means an acellular component of blood with the storage characteristics of drugs and that is used to treat certain disorders due to an imbalance in the circulatory system or certain specific diseases.

3. The fees stipulated in this regulation are non-refundable.

4. The fees stipulated in this regulation are indexed in the manner set out in chapter VIII.1 of the Financial Administration Act (chapter A-6.001).

The Minister of Health and Social Services shall publish the result of the indexation in Part 1 of the *Gazette officielle du Québec*.

5. This regulation shall come into force on the fifteenth day following its publication in the *Gazette officielle du Québec* and applies only to scientific evaluation requests received by the Institut national d'excellence en santé et en services sociaux on or after that date.

SCHEDULE I
(Section 1)

FEES PAYABLE FOR THE DIFFERENT SCIENTIFIC EVALUATIONS

Scientific Evaluation		**Fee**
Health technology evaluated	**Type of evaluation**	
New drug or new indication for a currently listed drug	First evaluation	$38,921 per indication
	Reevaluation	$19,460 per indication
Biosimilar	First evaluation	$7,784 per submission
	Subsequent evaluation (i.e., addition of an indication)	$7,784 per submission
	Reevaluation	$3,892 per submission

Scientific Evaluation		Fee
Health technology evaluated	**Type of evaluation**	
Subsequent entry non-biological complex drug	First evaluation	$7,784 per submission
	Subsequent evaluation (i.e., addition of an indication)	$7,784 per submission
	Reevaluation	$3,892 per submission
New strength(s) or new form(s) of a currently listed drug	First evaluation	$3,892 per submission
	Reevaluation	$1,946 per submission
New nutritional formula, new dressing or new combination of currently listed drugs	First evaluation	$5,189 per submission
	Reevaluation	$2,595 per submission
Diagnostic agent of a currently listed non-proprietary name	First evaluation	$2,595 per submission
	Reevaluation	$1,297 per submission
Exemption from the application of the lowest price	Any exemption request	$6,487 per submission
New stable blood product	First evaluation	$32,744 per submission
	Reevaluation	$16,372 per submission

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M.O., 2018

Order of the Minister of Municipal Affairs and Land Occupancy dated 19 June 2018

An Act respecting land use planning and development (chapter A-19.1)

Regulation respecting public participation in matters of land use planning and development

CONSIDERING section 80.3 of the Act respecting land use planning and development (chapter A-19.1), which allows the Minister of Municipal Affairs and Land Occupancy to set any requirement relating to public participation for the purposes of the Act and to the content of a public participation policy;

CONSIDERING the publication in Part 2 of the *Gazette officielle du Québec* of 15 November 2017, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1), of a draft Regulation respecting public participation in matters of land use planning and development with a notice that it could be made by the Minister on the expiry of 45 days following that publication;

CONSIDERING that it is expedient to make the Regulation with amendments;

THE MINISTER OF MUNICIPAL AFFAIRS AND LAND OCCUPANCY ORDERS AS FOLLOWS:

The Regulation respecting public participation in matters of land use planning and development, attached to this Order, is hereby made.

Québec, 19 June 2018

MARTIN COITEUX,
Minister of Municipal Affairs and Land Occupancy

Regulation respecting public participation in matters of land use planning and development

An Act respecting land use planning and development (chapter A-19.1, s. 80.3)

DIVISION 1
PRELIMINARY

1. This Regulation regulates public participation in matters of land use planning and development, and sets requirements relating to the content of a public participation policy adopted under section 80.1 of the Act respecting land use planning and development (chapter A-19.1).