3. The Regulation respecting the application of the Building Act (chapter B-1.1, r. 1) is amended by revoking out section 3.3.5.

4. This Regulation comes into force on (*insert the date occurring 45 days following the date of publication of this Regulation in the Gazette officielle du Québec*), except section 74.2, made by section 1 of this Regulation, which comes into force on *(insert the date occurring 1 year after the coming into force of this Regulation)*.

For the purposes of section 74.2, where an owner has more than 6 existing installations concerned, the risk assessment reports do not all have to be obtained by (*insert the date occurring 1 year after the coming into force of this Regulation*). However, at least 6 installations per year must have been the subject of such a report and all the owner's installations must have been the subject of a report not later than (*insert the date occurring 5 years after the coming into force of this Regulation*).

103352

Draft Regulation

Financial Administration Act
(chapter A-6.001)

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

Notice is hereby given, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1), 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, pass by the Institut national d'excellence en santé et en services sociaux and the text of which appears below, may be submitted to the government for approval at the expiry of the period of 45 days following the publication of this notice.

The draft regulation sets out the fees that a manufacturer will have to pay to the Institut national d'excellence en santé et en services sociaux when the manufacturer asks it to conduct a scientific evaluation of a drug or a stable blood product.

This draft regulation will therefore have an impact on manufacturers, who, once the regulation comes into force, will have to pay the Institut national d'excellence en santé et en services sociaux the fees set out therein for the Institut to conduct the said scientific evaluations.

For additional information, please contact:
Hélène Beaulieu, Senior Advisor
Institut national d'excellence
en santé et en services sociaux
2535, boulevard Laurier, 5e étage
Québec (Québec)
G1V 4M3
Telephone: 418-643-1339, ext. 12549
Fax: 418-646-8349
E-mail: helene.beaulieu@inesss.qc.ca

Any interested person who wishes to submit comments about this draft regulation is asked to send them in writing, before the expiry of the above-mentioned 45-day period, to the Minister of Health and Social Services, 1075, chemin Sainte-Foy, 15e étage, Québec (Québec) G1S 2M1.

GAÉTAN BARRETTE,
Minister of Health and Social Services

CARLOS J. LEITÃO,
Minister of Finances,

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 the 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 nonrefundable.

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*.

This regulation does not apply to scientific evaluations in progress on the date it comes into force, regardless of the date of receipt of the requests for these evaluations. It does, however, apply to scientific evaluations to be conducted, regardless of the date of receipt of the requests for these evaluations.

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	$38,921 per indication
Biosimilar	First evaluation	$19,460 per submission
	Subsequent evaluation (i.e., addition of an indication)	$14,595 per submission
	Reevaluation	$14,595 per submission
Subsequent entry non-biological complex drug	First evaluation	$19,460 per submission
	Subsequent evaluation (i.e., addition of an indication)	$14,595 per submission
	Reevaluation	$14,595 per submission
New strength(s) or new form (s) of a currently listed drug	First evaluation	$3,892 per submission
	Reevaluation	$3,892 per submission
New nutritional formula, new dressing or new combination of currently listed drugs	First evaluation	$5,189 per submission
	Reevaluation	$5,189 per submission
Diagnostic agent of a currently listed non-proprietary name	First evaluation	$2,595 per submission
	Reevaluation	$2,595 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	$32,744 per submission