15. The committee members are not remunerated. Each of the organizations represented on the committee defrays the costs related to the participation of its representative to the sittings of the committee.

CHAPTER III FINAL

16. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette* officielle du Québec.

102900

M.O., 2017

Order number 2017-003 of the Minister of Health and Social Services dated 23 March 2017

An Act respecting prescription drug insurance (chapter A-29.01)

MAKING the Regulation respecting calls for tenders for certain medications covered by the basic prescription drug insurance plan

THE MINISTER OF HEALTH AND SOCIAL SERVICES,

HAVING REGARD TO section 60.0.0.3 of the Act respecting prescription drug insurance (chapter A-29.01) pursuant to which the Minister determines by regulation the conditions and mechanics applicable to calls for tenders concerning accredited drug manufacturers and wholesalers as well as those applicable to supply contracts concluded following calls for tenders with accredited drug manufacturers and wholesalers;

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1) a draft of the Regulation respecting calls for tenders for certain medications covered by the basic prescription drug insurance plan was published in Part 2 of the *Gazette officielle du Québec* on 24 August 2016, with notice that it could be made by the undersigned upon the expiry of the 45 days following that publication;

WHEREAS the 45 days have expired;

WHEREAS it is expedient to make that regulation without amendment;

CONSEQUENTLY, the Minister of Health and Social Services hereby makes, without amendment, the Regulation respecting calls for tenders for certain medications covered by the basic prescription drug insurance plan, the text of which is attached hereto.

GAÉTAN BARRETTE, Minister of Health and Social Services

Regulation respecting calls for tenders for certain medications covered by the basic prescription drug insurance plan

An Act respecting prescription drug insurance (chapter A-29.01, s. 60.0.0.3; 2016, c. 16, s. 1)

DIVISION I SCOPE

- **1.** This Regulation applies to
- (1) contracts entered into with a manufacturer of medications accredited by the Minister of Health and Social Services to establish the price of a medication or supply and the conditions for its entry on the List of medications drawn up by the Minister under section 60 of the Act respecting prescription drug insurance (chapter A-29.01);
- (2) contracts entered into with a wholesaler of medications accredited by the Minister to establish the supply conditions of owner pharmacists and the profit margin.

DIVISION II

CONDITIONS AND MECHANICS APPLICABLE TO CONTRACTS ENTERED INTO WITH A MANUFACTURER

- **2.** With respect to contracts entered into with a manufacturer, the call for tenders is carried out in accordance with this Division.
- §1. General call for tenders
- **3.** A general call for tenders is made, with the necessary modifications, in accordance with Divisions I to IV.1 of Chapter II of the Regulation respecting certain supply contracts of public bodies (chapter C-65.1, r. 2).

"General call for tenders" means the awarding process through which the Minister invites all accredited manufacturers of medications to submit a price for the purchase of a medication or supply for the purpose of concluding a contract. **4.** The Minister may enter into a contract with a maximum of 3 manufacturers per medication of the same form and strength or per supply.

The Minister indicates in the tender documents, for each medication of the same form and strength or each supply,

- (1) the number of manufacturers likely to be selected; and
- (2) the shares of the market allocated to the manufacturers likely to be selected.
- §2. Fixed-price call for tenders
- **5.** The Minister may also make a fixed-price call for tenders to award a contract to one or more manufacturers. In that case, the Minister fixes the price for each medication of the same form and strength or for each supply. The price is indicated in the tender documents.
- **6.** A fixed-price call for tenders is made by publishing a notice on the electronic tendering system approved by the Government.
- **7.** In a fixed-price call for tenders, the instructions to the manufacturers include, in particular,
- (1) the eligibility requirements required of manufacturers and the compliance requirements for tenders;
- (2) a list of the documents or other items required from manufacturers;
 - (3) the period of validity of tenders;
 - (4) the tender opening procedure; and
- (5) an indication that the Minister does not undertake to accept any of the tenders received.
- **8.** In order to submit a tender, a manufacturer must meet the following eligibility requirements:
- (1) have all the necessary qualifications, authorizations, permits, licences, registrations, certificates, accreditations and attestations:
- (2) have in Québec or in a territory covered by an applicable intergovernmental agreement an establishment where activities are carried on on a permanent basis, clearly identified under the manufacturer's name and accessible during regular business hours;

(3) meet any other eligibility requirement specified in the tender documents.

Despite subparagraph 2 of the first paragraph, if competition is insufficient, the Minister may make eligible any manufacturer that has an establishment in a territory not covered by an applicable intergovernmental agreement, provided that the Minister so specifies in the tender documents.

A manufacturer that fails to comply with any of those requirements is ineligible.

- **9.** Compliance requirements must specify the cases that will entail automatic rejection of a tender, namely,
- (1) the place or the closing date or time has not been complied with;
 - (2) a required document is missing;
- (3) the required signature of an authorized person is missing;
 - (4) the tender is conditional or restrictive; or
- (5) any other compliance requirement stated in the tender documents as entailing automatic rejection of a tender has not been complied with.
- **10.** The Minister may refuse to consider any manufacturer that, in the 2 years preceding the tender opening date, failed to follow up on a tender or contract or had a contract cancelled because of failure to comply with the contract conditions.
- **11.** The Minister may amend the tender documents by means of an addendum sent to the manufacturers concerned.
- **12.** Tenders are opened by the Minister at a public opening in the presence of a witness at the designated place and on the date and time fixed in the tender documents.
- **13.** The Minister evaluates the tenders received, ensuring that the manufacturers are eligible and the tenders are compliant.

If the Minister rejects a tender because the manufacturer is ineligible or the tender is non-compliant, the Minister so informs the manufacturer and gives the reason for the rejection not later than 15 days after awarding the contract.

14. The award is made to all eligible manufacturers whose tender is compliant.

DIVISION III

CONDITIONS AND MECHANICS APPLICABLE TO CONTRACTS ENTERED INTO WITH A WHOLESALER

- **15.** With respect to contracts entered into with an accredited wholesaler, the call for tenders is carried out, with the necessary modifications, in accordance with Divisions I to III and IV.1 of Chapter II of the Regulation respecting certain service contracts of public bodies (chapter C-65.1, r. 4).
- **16.** A wholesaler may not be eligible to submit a tender as part of the call for tenders where
- (1) the enterprise has, in the preceding 5 years, been found guilty of an offence listed in Schedule I to the Act respecting contracting by public bodies (chapter C-65.1);
- (2) any of the wholesaler's shareholders is a natural person who holds 50% or more of the voting rights attached to the shares that may be exercised under any circumstances and who has, in the preceding 5 years, been found guilty of an offence listed in Schedule I to the Act respecting contracting by public bodies (chapter C-65.1);
- (3) any of the wholesaler's directors or officers has, in the preceding 5 years, been found guilty of an offence listed in Schedule I of the Act respecting contracting by public bodies (chapter C-65.1).

A finding of guilty must be disregarded if a pardon has been obtained.

For the purpose of this division, the term "enterprise" designates a private corporation, a general partnership, a limited partnership, a joint venture (undeclared partnership) or a natural person who operates a sole proprietorship.

DIVISION IVMISCELLANEOUS

- **17.** The maximum term of a contract entered into with a manufacturer or a wholesaler following a call for tenders is 3 years, including any renewal.
- **18.** Every manufacturer selected following a call for tenders must with due diligence inform the Minister where the manufacturer anticipates the possibility of a disruption in the supply of a medication that is the subject of the contract resulting from the call for tenders.

DIVISION V

FINAL

19. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette* officielle du Québec.

102903

M.O., 2017-02

Order number V-1.1-2017-02 of the Minister of Finance dated 21 March 2017

Securities Act (chapter V-1.1, s. 331.1, subpars. 3, 32, 32.0.1 and 34)

CONCERNING the Regulation to amend Regulation 23-101 respecting trading rules

WHEREAS subparagraphs 3, 32, 32.0.1 and 34 of section 331.1 of the Securities Act (chapter V-1.1) stipulate that the *Autorité des marchés financiers* may make regulations concerning the matters referred to in those paragraphs;

WHEREAS the third and fourth paragraphs of section 331.2 of the said Act stipulate that a draft regulation shall be published in the Bulletin of the Authority, accompanied with the notice required under section 10 of the Regulations Act (chapter R-18.1) and may not be submitted for approval or be made before 30 days have elapsed since its publication;

WHEREAS the first and fifth paragraphs of the said section stipulate that every regulation made under section 331.1 must be approved, with or without amendment, by the Minister of Finance and comes into force on the date of its publication in the *Gazette officielle du Québec* or any later date specified in the regulation;

WHEREAS the Regulation 23-101 respecting trading rules was made by decision no. 2001-C-0411 dated August 28, 2001 (*Bulletin hebdomadaire*, vol. 32, no 35, dated August 31, 2001);

WHEREAS there is cause to amend this regulation;

WHEREAS the draft Regulation to amend Regulation 23-101 respecting trading rules was published in the *Bulletin de l'Autorité des marchés financiers*, vol. 13, no. 14 of April 7, 2016;