M.O., 2007

Order number 2007-016 of the Minister of Health and Social Services dated 5 October 2007

An Act respecting prescription drug insurance (R.S.Q., c. A-29.01)

MAKING the Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized

THE MINISTER OF HEALTH AND SOCIAL SERVICES,

CONSIDERING section 80 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01);

CONSIDERING that it is necessary to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by Minister's Order 92-06 dated 6 July 1992, to

— make the consequential amendments required by the coming into force of the Controlled Drugs and Substances Act (S.C., 1996, c. 19);

— specify, for the purposes of the basic prescription drug insurance plan (public plan and private plans), what benefits granted by a drug manufacturer to a pharmacist are authorized within the meaning of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01);

CONSIDERING the publication in Part 2 of the *Gazette officielle du Québec* of 20 June 2007, in accordance with sections 10 and 11 of the Regulations Act (R.S.Q., c. R-18.1), of a draft Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, with a notice that it could be made by the undersigned on the expiry of 45 days following that publication;

CONSIDERING that it is expedient to make such a regulation with amendments to follow up on the comments received;

ORDERS AS FOLLOWS:

The Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, the text of which appears as a Schedule, is hereby made.

Québec, 5 October 2007

PHILIPPE COUILLARD,
Minister of Health and Social Services

Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized [*]

An Act respecting prescription drug insurance (R.S.Q., c. A-29.01, s. 80)

1. Section 2 of the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized is amended by replacing paragraph 3 by the following:

"(3) he must hold a permit or licence issued under subsection 55(1) of the Controlled Drugs and Substances Act (S.C. 1996, c. 19) and be an authorized distributor holding a permit for the importation, production or sale of drugs and controlled substances issued under that subsection.".

2. Schedule I is amended in section 1 by replacing the third paragraph by the following:

"The guaranteed selling price is the price that a buyer must pay for a drug. It is reduced by the value of any reduction granted by the manufacturer as a rebate, discount or premium and by the value of any good or service provided without consideration to a buyer by the manufacturer, other than a benefit authorized under the Regulation respecting the benefits authorized for pharmacists [**].".

3. Schedule I is amended in section 2

(1) by replacing paragraph 2 by the following:

"(2) the manufacturer may grant a discount for a payment made within 30 days following the purchase, provided that the discount does not exceed 2% of the net price;";

(2) by replacing paragraph 4 by the following:

[*] The Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by Order 92 06 dated 6 July 1992 (1992, *G.O.* 2, 3263) of the Minister of Health and Social Services, was last amended by the regulation made by Minister's Order 1999 dated 28 April 1999 (1999, *G.O.* 2, 1289). For previous amendments, refer to the *Tableau des modifications et Index sommaire*, Québec Official Publisher, 2007, updated to 1 March 2007.

[**] The Regulation was published on page 2833A

"(4) no reduction in the price of a drug may be granted to a buyer or an intermediary, including a wholesaler, a commercial name or a chain of pharmacies for the attainment of a fixed purchase volume for a given period, and no good or service may be provided without consideration or reduction as a rebate, discount or premium, other than a benefit authorized within the meaning of the Regulation respecting the benefits authorized for pharmacists, or a professional allowance for an owner pharmacist who deals through a wholesaler, a commercial name or a chain of pharmacies that is paid in whole to the owner pharmacist, and other than a discount referred to in paragraph 2;";

(3) by striking out paragraph 5.

4. Schedule I is amended by inserting the following after section 2:

"2.1. The manufacturer undertakes to reimburse to the Board an amount corresponding to the value of any reduction as a rebate, discount or premium, of any good, service or gratuity or of any other benefit granted to an owner pharmacist that is not a benefit authorized within the meaning of the Regulation respecting the benefits authorized for pharmacists or a discount referred to in paragraph 2 of section 2. The manufacturer also undertakes to pay to the Board a sum corresponding to 20% of that amount as administrative expenses.

2.2. The generic drug manufacturer undertakes to send the Board an annual report on or before 1 March for the preceding calendar year giving the detail of the reductions as rebates, discounts or premiums, the gratuities, goods, services or any other benefit, other than the discount referred to in paragraph 2 of section 2, granted by the manufacturer to each owner pharmacist in Québec. The report must also state the value of all the sales of generic drugs on the list of medications that are sold directly to owner pharmacists or indirectly through wholesalers, a commercial name or a chain of pharmacies, under the basic prescription drug insurance plan. If a pharmacist owns more than one establishment, the data must be detailed by establishment. If a pharmacy is owned by a partnership of pharmacists or a joint-stock company, the data must be detailed by partnership or company and, where applicable, by establishment.

The manufacturer agrees to the Board sending the report to the Ministère de la Santé et des Services sociaux, the Conseil du médicament and the Ministère du Revenu du Québec. The manufacturer also undertakes to provide those departments and that body, on request, and the Board with all additional information they may require in relation to the content of the report.".

5. The English text of paragraph 5 of section 1 of Schedule II is replaced by the following:

"(5) no good may be provided without consideration and no reduction as a rebate, discount or premium may be granted to a buyer;".

6. The English text of the title of the Regulation is replaced by the following:

"Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications".

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

8357