3. This Regulation comes into force on the day of its publication in the *Gazette officielle du Québec*.

1113

O.M., 1996

Order of the Minister of Health and Social Services number 96-08 dated 9 December 1996

An Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32)

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

CONSIDERING section 80 of the Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32);

CONSIDERING the making, by Minister's Order 92-06 dated 6 July 1992 of the Minister of Health and Social Services, of the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized and its publication in the *Gazette officielle du Québec* of 15 July 1992;

CONSIDERING the necessity to amend that Regulation in order:

- to allow manufacturers of medications to submit different guaranteed selling prices for pharmacists and for wholesalers;
- to allow that the list of medications provide a maximum amount instead of a percentage as the profit margin of a recognized wholesaler for expensive drugs;
- to make concordance amendments now required by the coming into force of the Act respecting prescription drug insurance and amending various legislative provisions;

CONSIDERING sections 10, 12 and 13 of the Regulations Act (R.S.Q., c. R-18.1) and the publication of a Draft Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized in Part 2 of the *Gazette officielle du Québec* of 20 November 1996, on page 4713;

CONSIDERING section 18 of that Act;

CONSIDERING the urgency due to the following circumstances:

- the proposed measures must come into force on 1 January 1997, that is, on the same date as the list of medications drawn up under section 60 of the Act respecting prescription drug insurance and amending various legislative provisions and the basic prescription drug insurance plan;
- manufacturers of medications were informed of the proposed measures at the time of the publication of the Draft Regulation and some of them have already submitted, in respect of medications that will appear on the list, guaranteed selling prices that differ depending on whether the medications will be sold to wholesalers or to pharmacists;
- furthermore, the application of the proposed measures forces the Régie de l'assurance-maladie du Québec to prepare amendments respecting the reimbursement of the cost of medications to pharmacists, taking into account the implementation of an interactive system for the basic prescription drug insurance plan;

CONSIDERING that the Conseil consultatif de pharmacologie has been consulted about the Draft Regulation;

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

THEREFORE, the Minister of Health and Social Services makes the Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, attached to this Order.

Minister of Health and Social Services, JEAN ROCHON

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

An Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32, s. 80)

- **1.** The Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by Order of the Minister of Health and Social Services No. 92-06 dated 6 July 1992, is amended in section 2
- (1) by substituting "drawn up under section 60 of the Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32)" for "pro-

vided for in section 4 of the Health Insurance Act (R.S.Q., c. A-29)" in paragraph 1;

- (2) by substituting "drawn up under section 60 of that Act" for "provided for in section 4 of the Health Insurance Act" in paragraph 5; and
- (3) by substituting "drawn up under section 60 of that Act" for "provided for in section 4 of the Act" in paragraph 6.

2. Schedule I is amended

- (1) by substituting "list of medications drawn up under section 60 of the Act respecting prescription drug insurance and amending various legislative provisions" for "drug list provided for in section 4 of the Health Insurance Act (R.S.Q., c. A-29)" in section 1;
- (2) by substituting the following for subparagraph 2 of the second paragraph of section 1:
- "(2) it may differ for sales to pharmacists or to wholesalers, but such difference may not exceed 9 %;";
- (3) by striking out the word "insured" in subparagraph 3 of the second paragraph of section 1;
- (4) by substituting "by section 53 of the Act respecting prescription drug insurance and amending various legislative provisions" for "by section 39 of the Health Insurance Act" in section 3;
- (5) by substituting "in accordance with section 58 of that Act" for "under the second paragraph of section 40 of the Health Insurance Act (R.S.Q., c. A-29), enacted by section 572 of Chapter 42 of the Statutes of 1991" in paragraph 1 of section 4; and

(6) by substituting "section 58 of that Act" for "the second paragraph of section 40 of the Health Insurance Act" in section 6.

3. Schedule II is amended

(1) by adding the following paragraph at the end of section 2:

"The profit margin shall be limited to a maximum amount provided for in respect of certain medications entered on the list of medications drawn up under section 60 of the Act respecting prescription drug insurance and amending various legislative provisions."; and

- (2) by substituting "section 58 of the Act respecting prescription drug insurance and amending various legislative provisions" for "the second paragraph of section 40 of the Health Insurance Act (R.S.Q., c. A-29), enacted by section 572 of Chapter 42 of the Statutes of 1991" in section 4.
- **4.** Subparagraph 2 of the second paragraph of section 1 of Schedule I and the second paragraph of section 2 of Schedule II to the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by paragraph 2 of section 2 and by paragraph 1 of section 3 of this Regulation, respectively, apply to commitments made by manufacturers or wholesalers of medications before the date of coming into force of this Regulation.
- **5.** This Regulation comes into force on 1 January 1997.

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