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Pharma in brief - Canada

Bill 92: An Act to extend the powers of the Régie de l'assurance maladie du Québec and to amend various legislative provisions

Summary

Bill 92 was introduced to the National Assembly of Quebec on April 27, 2016, by the Minister of Health and Services to amend various acts such as the Health Insurance Act, the Hospital Insurance Act, the Act respecting prescription drug insurance, the Act Respecting Administrative Justice, the Act respecting the Régie de l'assurance maladie du Québec and the Act Respecting Health Services and Social Services.

An Act respecting the Régie de l'assurance maladie du Québec

This act would be amended to grant the *Régie de l'assurance maladie du Québec* (**Board**) inspection powers to verify compliance with the *Act respecting the Régie de l'assurance maladie du Québec*, the *Health Insurance Act* and the *Act respecting prescription drug insurance* and the regulations.

The inspection powers granted would allow the Board to enter any place where a drug manufacturer or wholesaler accredited by the minister exercises functions or carries out activities, and obtain information and documents relating to the functions exercised or activities carried out by these drug manufacturers or wholesalers. The Board may also authorize any person to act as an inspector for the purpose of ensuring compliance with the law, and to undertake such inspection.

The health professional, dispenser or drug manufacturer or wholesaler would then have to make documents to which it has custody or control available to the inspector, and even to facilitate such examination. Furthermore, any person may be required to provide any information related to the functions exercised or activities carried out by a health professional, a dispenser, drug manufacturer or wholesaler accredited by the minister. Additionally, the inspector may, by registered mail or in person service, require from any person any information or documentation relating to the application of relevant laws.

Within the scope of these inspections or investigations, no person could refuse to communicate to the Board any financial information or document concerning the activities carried out by a drug manufacturer or wholesaler accredited by the minister. Anyone refusing to communicate such information or document would be guilty of an offence and thus liable for a fine of \$5,000 to \$50,000. The Board would even have the right to apply to the Superior Court to obtain an injunction in respect of any matter relating to an act under the Board's administration.

An Act respecting prescription drug insurance

This act would be amended to allow the Board to recover from a drug manufacturer or wholesaler an amount corresponding to 15% of the non-authorized rebates, gratuities or other benefits extended by the manufacturer or wholesaler. Monetary administrative penalties (e.g. \$2,500 to \$12,500) and penal offences would thereby be prescribed for cases where: (i) a manufacturer or wholesaler extends such benefits, or (ii) a pharmacist receives such benefits. Furthermore, the minister would be entitled to prescribe, by regulation, the monetary administrative penalties (up to \$2,500) applicable by the Board for any other failure by a manufacturer or wholesaler to comply with a condition or commitment prescribed by regulation.

It is also worth mentioning that if after an investigation the Board believes that rebates, gratuities or other benefits were granted contrary to the conditions or commitments prescribed, then the manufacturer may have to pay back these amounts (in addition to the administrative penalty).

Other acts

Additional inspection powers would be granted by the Board under other acts to recover any amounts obtained in contravention to the law and to prosecute healthcare professionals and third parties who committed such violations.

Bill 92 has not yet been adopted by the National Assembly and therefore is not in force. Some consultations are taking place at the moment. Various organizations such as l'*Ordre des pharmaciens du Québec* (the **OPQ**) have submitted briefs in which they present their views on the subject examined during consultations held by the parliamentary committee. However, the National Assembly is not bound by these briefs. Until adopted, Bill 92 is still subject to being amended in light of the documents filed by any stakeholder (such as the brief prepared by the OPQ) or of the points raised by them during the special consultations and sittings, such as the one that took place on May 12 during which the OPQ made representations.

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