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Pharma in brief - Canada

Quebec's Bill 92, drug distribution models, and patient support programs

Summary

As previously reported <u>here</u>, Bill 92 proposed changes to a number of Quebec statutes. The bill has since passed and, with a few exceptions, is now in force.

Given the importance of the Quebec market, these changes may have a significant impact on drug manufacturers and wholesalers. In particular, they could affect programs that provide financial assistance to patients and impact certain distribution models for listed drugs.

Financial assistance

Bill 92 amends the *Act respecting prescription drug insurance* to prohibit manufacturers and wholesalers from reimbursing all or part of the price of a drug covered by the plan, except as provided for in the regulations. This provision is not yet in force and will not come into force until regulations are drafted defining exceptions to this prohibition. The government has not yet announced what those regulations will look like and how broad the exceptions will be. However, the language in Bill 92 suggests they will be focussed on defining so-called humanitarian exceptions.

It appears this restriction on providing financial assistance was added as a result of lobbying by the *Ordre des pharmaciens du Québec* (Quebec order of pharmacists, the **Ordre**) whose submissions can be found <u>here</u>. The Ordre expressed concerns that such payments lead to medication selection not based on best medical practices and the use of more expensive medications, that they support the impression that generics are inferior to brand products, and that they may jeopardize the protection of personal information.

Of note, the Ordre also asked for restrictions on manufacturer contributions toward the cost of medications prior to their being covered by the plan, sometimes known as "bridging" programs. However, given that the restrictions included in Bill 92 relate only to medications covered by the plan without reference to a retroactive effect, it is possible these programs may still be permissible under the new provisions.

Distribution model

Other provisions already in force restrict the ability of manufacturers and wholesalers to enter into exclusive or preferential distribution agreements. If a manufacturer or wholesaler is contemplating a distribution model with a degree of preference or exclusivity in the context of a patient support program or otherwise, the new provisions should be considered to ensure the model is not prohibited by law.

The prohibition of exclusivity agreements with pharmacies also largely stems from concerns expressed by the Ordre. The Ordre argued that exclusivity or preferential supply agreements can impact patients' ability to choose their pharmacy, may require patients to travel long distances to obtain medication, and may result in fragmentation of

patients' records and care. Unfortunately it appears the Quebec legislature may not have considered that alternative distribution models may be good for some patients, particularly those receiving specialty medications, and that a consequence of Bill 92 may be reduced support for patients.

The prohibition of exclusivity agreements with wholesalers seems to have stemmed from concerns about pharmacy chains insisting that their franchisee pharmacies purchase product exclusively from them or their preferred wholesaler. The provisions, however, have been drafted more broadly than that and capture other exclusive wholesaler situations. On their face, they would seem to prevent a manufacturer from electing to distribute a product through an exclusive wholesaler, which may have been an unintended consequence. It remains to be seen how the minister will interpret and apply this prohibition.

As with most new legislation, the devil will be in the details. In the case of Bill 92 these details will come in the form of regulations relating to financial assistance and in the form of interpretation by government agencies for distribution models. We are continuing to monitor how the bill is changing the landscape in Quebec and will keep you posted.

Link:

Bill 92

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