

Québec government finalizes exceptions for patient support programs

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On March 31, the Québec government published the final version of the regulation respecting exceptions to the prohibition against paying or reimbursing the price of a medication or supply covered by the basic prescription drug insurance plan (Regulation)¹, made under the *Act respecting prescription drug insurance* (Act). This final Regulation will bring into force one of the key new prohibitions added to the Act as part of Bill 92 back in 2016².

What you need to know

- **Prohibition:** Section 80.2(1) of the Act will prohibit manufacturers, wholesalers and intermediaries from paying or reimbursing a medication or supply covered by the basic prescription drug insurance plan, except to the extent provided by the Regulation, in particular for "humanitarian reasons".
 - The final Regulation does not provide clarification on what the Act means by "humanitarian reasons". Instead the final version of the Regulation largely retains the exceptions included in the draft version of the Regulation, published in 2018³. A transitional measure has also been added to the final Regulation, which was not included in the draft Regulation.
- **Timing:** The Regulation will come into force on April 15, 2021. The prohibition in section 80.2(1) of the Act will come into force at the same time.
- **Impact:** After April 15, 2021 manufacturers, wholesalers and intermediaries will only be permitted to provide free or discounted medications that are covered by the basic plan to patients, in the following circumstances.
 - The medication is not subject to the lowest price method on the RAMQ List of Medications.
 - The medication does not have a generic or biosimilar version on the RAMQ List of Medications.
 - If the patient has already received payment or reimbursement for that same medication before April 15, 2021, that patient may continue to receive free or discounted medication.

Impact on manufacturers and patients

As one of the exceptions permits manufacturers to continue providing coverage for patients who have already received payment or reimbursement for that same medication before April 15, 2021, the Regulation will largely impact patients who are newly prescribed a medication on the RAMQ List of Medications after April 15 or who did not receive financial support prior to April 15. Notably, patients whose medication is reimbursed by RAMQ and those covered by a private insurance may both be affected by this restriction as the legislation is drafted such that it would apply to “all persons who are eligible for the basic plan”⁴.

For patients who did not receive financial support for a particular medication prior to April 15, manufacturers will only be able to pay or reimburse all or part of the price of the listed medication where the exceptions in section 1 of the Regulation are met. Specifically, for manufacturers to provide medication cost support to new patients, the listed medication must:

- a. not be subject to the lowest price method (LPM)⁵;
- b. not have a generic or biosimilar version on the RAMQ List of Medications.

There is some uncertainty regarding the exceptions. Until RAMQ provides further guidance it is unclear if the first point is a reference only to medications specifically listed in Annex V of the List (“List of drugs to which the lowest price method does not apply”) or to the broader class of drugs on the RAMQ List to which the LPM does not apply. For the second point, it is unclear how RAMQ will define “generic” or “biosimilar”, as these terms are not defined within the Québec legislation. For example, will RAMQ rely on the Health Canada approval process as determinative or could a broader definition (which might include therapeutic comparators) be used?

Ongoing transitional measures

The two key exceptions in the Regulation, a) non-application of the LPM and b) absence of generics/biosimilars, are not static factors. While a listed medication might meet the exceptions in 2022, and therefore the manufacturer could reimburse patients for their medication costs at that time, by 2023 the same medication may no longer meet the exceptions (e.g., if a generic comes to market and is added on the RAMQ List of medications).

Section 2 of the final Regulation allows manufacturers to continue paying or reimbursing patients’ medication costs for 30 days after conditions of the Regulation are triggered.

As a manufacturer’s ability to provide support can change at any time, to ensure transparency for patients newly supported after April 15, manufacturers should inform patients at the time they are enrolled in a program of the possibility that support may be terminated.

What’s next

While the text of the Regulation is short, there is much uncertainty regarding how RAMQ will interpret the exceptions set out in the Regulation. Guidance and clarification from RAMQ is anticipated. Until such guidance is published, manufacturers and wholesalers in Québec should exercise caution in their approach to patient support programs after April 15, 2021 as RAMQ has historically interpreted drug pricing and supply regulations broadly and is actively enforcing in this area⁶.

⁴ Regulation respecting exceptions to the prohibition against paying or reimbursing the price of a medication or supply covered by the basic prescription drug insurance plan, Gazette Officielle du Québec, March 31, 2021, Vol. 153, No. 13: <http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=1&file=104957.pdf>

² See Torys' prior [bulletin](#) on Bill 92.

³ See Torys' prior [bulletin](#) on the draft Regulation

⁴ Under the Act, every person who is resident in Québec and registered with RAMQ is eligible for the basic plan (with certain limited exceptions). Coverage under the basic plan is provided either by RAMQ or by group private insurance or employee benefit plans.

⁵ The LPM typically applies where a product with the same active ingredient, form and strength are already registered on the RAMQ List of Medications. The LPM also applies where an exceptional medication, prescribed for a therapeutic indication not set out in the RAMQ List of Medications with regard to this medication, is exceptionally covered under the basic plan pursuant to exceptional medication measure. Manufacturers can apply for exemptions to the LPM.

⁶ For example, the RAMQ's [List of control measures](#) (updated on January 21, 2021) states that in the 2019-2020 period, there were approximately 200 verifications involving manufacturers and wholesalers, 87 of which were retained for additional analysis. In the same period, there were 4 inspections involving manufacturers, all of which were retained for additional analysis.

To discuss these issues, please contact the author(s).

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