Ontario Seeks to Establish New Pricing Framework for Generic Drug Products

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On November 5, 2014, the Ontario Ministry of Health and Long-Term Care posted proposed amendments to O. Reg. 201/96 made under the Ontario Drug Benefit Act. If enacted, the proposed amendments will establish a new pricing framework for generic products listed on the Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index (the Formulary) on or after April 1, 2013 for which there are only one or two generic products available in Canada. In general, the proposed amendments are as follows:

- For a single source generic drug product, the maximum drug benefit price will be 75% of the drug benefit price of the brand manufacturer product or 85% if the brand manufacturer has not agreed to provide a volume discount to the Ontario Public Drug Programs.
- If there are two generic drugs available in Canada, the maximum drug benefit price will be 50% of the drug benefit price of the brand manufacturer product.
- If there are three or more generic drugs available in Canada, the current rules (generally 25% for solid dosage and 35% for non-solid dosage forms) apply.

For single source generic drug products (i.e., drug products where the price is set at 75% or 85% of the brand manufacturer product), the price may be reviewed by the Executive Officer of the Ontario Public Drug Programs 120 days before the second anniversary date of the listing. In conducting such review, the Executive Officer may request additional information to be provided by the manufacturer to support the price of the drug product including, but not limited to, raw material costs, manufacturing costs, cost of goods sold, price of the product in comparable jurisdictions outside of Canada, and specialized labour costs or unique market conditions that might result in significant patient safety or access concerns or significant cost increases to the Government of Ontario if the product is not continued to be listed at the same drug benefit price. If the information is not provided, the product will not continue to be designated as a listed drug product on the Formulary.

The legislation appears to be aimed at discouraging those generic manufacturers of limited source generic drug products (e.g., where the generic molecule is only available from two or three manufacturers) from only introducing these generic drug products in Ontario if the manufacturer can obtain single source status. As the amendments reference generic drugs available in Canada (not just on the Formulary), the introduction of an interchangeable generic drug in any jurisdiction in Canada will
result in a reduction in the drug benefit price of a single source generic drug listed on the Ontario Formulary. It is important to note that the amendments only apply to generic drugs listed on the Formulary on or after April 1, 2013.

Written comments on the proposed changes will be accepted by the Ministry of Health and Long-Term care until December 21, 2014 at 5:00 p.m. EST.

For more information regarding the proposed amendments and how to submit your comments, please see the Executive Officer Communication on the OPDP website or contact Michael Watts (Chair), Mark Austin or Jeff Murray of Osler’s Health Industry Group.

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