Amendments that the Ontario government introduced to Ontario’s $3.4 billion a year drug benefit programs came into force on October 1, 2006. The amendments are to the *Ontario Drug Benefit Act* (ODBA) and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA).

The ODBA regulates Ontario’s publicly funded drug benefit programs. The programs cover the cost of various drug products for certain groups of Ontario residents, including seniors, recipients of social assistance, residents of long-term care facilities, people enrolled in the province’s home care program and Trillium Drug Program recipients. The government reimburses pharmacists who dispense brand name and generic drug products to these individuals in amounts listed on the Ontario Drug Benefit Formulary. DIDFA regulates the designation of generic drug products as interchangeable with brand name drug products. This designation affects not only the province’s drug benefit programs but also private payers of prescription drugs, including private health insurance companies, since pharmacists are permitted to substitute an interchangeable generic product for a brand name product.

### Expanded Definition of Interchangeability

The amendments to DIDFA expand the meaning of “interchangeability” by including products that have the same or similar active ingredients in the same or similar dosage form. Previously, drugs needed to have the same active ingredients in the same dosage form in order to be interchangeable. The term “similar active ingredients” is defined to mean “different salts, esters, complexes or solvates of the same therapeutic moiety”. The term “similar dosage form” is not defined.

### New Governance

The governance of Ontario’s drug benefit programs will now be the responsibility of an “executive officer” instead of the Minister of Health and Long-Term Care and the Cabinet. The executive officer has an expansive list of responsibilities, including maintaining the Formulary, assigning and removing the designation of products as interchangeable with other products and negotiating volume discounts with drug manufacturers.

### Method for Listing Pre-NOC Drugs in the Formulary

Under the amendments to the ODBA, drug manufacturers may submit their drug products for listing on the Formulary even though Health Canada has not yet approved the product for sale in Canada (i.e., the drug has not obtained a Notice of Compliance (NOC) from Health Canada). Under the previous regime, pre-NOC drugs could not be listed on the Formulary. The details of the procedure for this type of listing have not yet been developed.

To qualify for this new early review, an application must have been made to Health Canada to approve the product for sale in Canada and the drug must either (i) offer treatment for life-threatening or serious diseases; (ii) offer substantial improvements on significant outcomes; or (iii) offer savings or create efficiencies for the Ontario government.
Method for Providing Off-Formulary Interchangeability

Generic drug manufacturers will be able to seek an interchangeable designation for a drug without seeking listing on the Formulary. This designation can be sought whether or not the brand name drug is listed on the Formulary. Amendments relating to this off-Formulary interchangeability will come into force on April 1, 2007.

Restrictions on Drug Prices

The amended legislation makes it an offence for drug manufacturers to sell a listed product at a price higher than the price listed on the Formulary if sold for the purpose of supplying a drug under the ODBA. Failing to comply with this new rule is an offence punishable by fine or imprisonment. Non-compliance can also result in a delisting of the drug or a refusal to list additional drugs made by that drug manufacturer. In addition, the executive officer can make an order requiring that the drug manufacturer repay the government the price difference.

Lower Formulary Prices for Generic Drugs

All generic drug manufacturers will now have their drugs listed on the Formulary at 50% of the comparative drug’s price, typically the brand name price. Under the former regime, the first generic drug was listed at 70% of the brand name price, and each subsequent generic drug was listed at 90% of the previous generic drug price (i.e., the second generic drug was listed at 63% of the brand name price, assuming listing of the first generic drug at 70%).

Possibility of Reference-based Pricing

Amendments to the ODBA have introduced the possibility of reference-based pricing. Reference-based pricing would enable the government to examine all the prescription drugs in a therapeutic category and determine, on the basis of such factors as safety, efficacy and cost, which drug is the preferred drug. The cost of the preferred drug will then be the price of the “reference drug” for the level of coverage that the province will establish for any medication in that class used to treat that condition. Patients eligible for drug benefits will receive coverage only up to the amount of the reference drug. If patients choose a more expensive drug, they will have to pay the difference in price. British Columbia’s publicly funded drug program, PharmaCare, already employs referenced-based pricing for various classes of drugs.

Elimination of Rebates to Pharmacies in Favour of “Professional Allowances” and the Establishment of a Code of Conduct

Pharmacies are now prohibited from receiving rebates from drug manufacturers but are allowed to receive “professional allowances” whose uses are restricted to educational purposes or counselling services. This move is intended to eliminate practices whereby drug manufacturers sell their products to pharmacies at a price lower than the price listed on the Formulary, sometimes giving rebates of 60% of

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1 An individual is liable to a maximum fine of $25,000 and/or 12-month imprisonment for a first offence and a maximum fine of $50,000 and/or 12-month imprisonment for a subsequent offence. A corporation is liable to a maximum fine of $50,000 for a first offence and $200,000 for a subsequent offence.

2 British Columbia PharmaCare, “Reference Based Program.” Available at <www.health.gov.bc.ca/pharme/rdp/rdpindex.html> (last accessed October 23, 2006).
Regulating Drug Costs in Ontario: Amendments to Ontario’s Drug Benefit Programs and Generic Drug Interchangeability Designation Are Now in Force

the dollar value of the drugs they sold. Professional allowances are limited to 20% of the listed drug cost for supplies under the ODBA. A code of conduct has also been created to provide guidance about the appropriate use of professional allowances.

New Procedure for Obtaining Coverage for Unlisted Prescription Drugs

The amendments to the ODBA create a new mechanism for obtaining coverage of prescription drugs not listed on the Formulary. In 2004, doctors filled out 143,370 special application forms to obtain coverage for unlisted prescription drugs. Now, the executive officer is empowered to allow conditional and retroactive listing of drugs for the purpose of the patient obtaining coverage. The details of this process have not yet been developed.

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Conor McCourt (cmccourt@torys.com), a partner in the Toronto office of Torys LLP, practices in all areas of intellectual property, particularly in the chemical, biochemical and pharmaceutical patent, trademark and regulatory fields.

Eileen McMahon (emcmahon@torys.com), a partner in the Toronto office of Torys LLP, practices exclusively in the areas of intellectual property and food and drug regulatory law. She is one of a handful of Canadian lawyers who advise on regulatory clearance and intellectual property protection of products.

This article is a general discussion of certain legal and related developments and should not be relied upon as legal advice. If you require legal advice, we would be pleased to discuss with you the issues raised in this bulletin in the context of your particular circumstances.

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3 CMAJ, “Pharmacies receiving massive rebates from generic drug-makers”, quoting committee hearings on Bill 102. Available at <www.cmaj.ca/cgi/content/full/175/4/342> (last accessed October 23, 2006) [CMAJ].

4 CMAJ.