
**ONTARIO TAKES LEGAL ACTION AGAINST PHARMACIES,
GENERIC DRUG COMPANIES AND WHOLESALERS**

April 27, 2009

Background

Through changes made by Bill 102 to the legislation that governs Ontario's publicly funded drug programs, the government is improving patient access to prescription drugs, ensuring better value for money spent on prescription drugs, strengthening the accountability within the drug system, and ensuring that pharmacists are valued and compensated for the important services they provide. This legislation, the *Transparent Drug System for Patients Act, 2006*, made changes to the *Ontario Drug Benefit Act (ODBA)* and the *Drug Interchangeability and Dispensing Fee Act (DIDFA)*.

Professional Allowances

Prior to Bill 102, generic drug companies used to pay rebates to pharmacies that carried their products. These rebates were reportedly between \$600 million to \$800 million.

Bill 102 created Professional Allowances as follows:

- Under the ODBA and DIDFA, drug manufacturers (including distributors and suppliers) are allowed to provide professional allowances and pharmacies are allowed to receive professional allowances as follows
 - For the Ontario Drug Benefit (ODB) market, manufacturers may provide and pharmacies may receive up to 20% of generic drug product sales (per pharmacy) in professional allowances. Furthermore, these allowances must be used for activities outlined in the regulations. That is, activities focused on patient care that benefits customers, such as flu clinic days and high blood pressure clinics as examples.
 - For the private market (Ontarians without insurance coverage, employee benefit plans and the insurance companies who provide these plans) there is no limit on the amount of professional allowance paid or received. However, as with the ODB market, these allowances must be used for activities outlined in the regulations.

Drug manufacturers are required to report to the Ministry of Health and Long-Term Care the amount of professional allowances paid, and pharmacies are required to report to the Ministry the amount of professional allowances received. In addition, pharmacies are required to report on how professional allowances are spent. Ministry staff have the right to conduct audits and inspections and review any records pertaining to professional allowances. Any professional allowance payment not meeting the regulated requirements is a "rebate" and is prohibited.

Enforcement of Professional Allowance Regulations

The Ministry reviewed the reports provided by drug manufacturers and pharmacies and found major discrepancies. For instance, the Ministry found discrepancies between the amounts that manufacturers reported having paid, and the amounts that pharmacies reported having received. Based on the discrepancies, the Ministry conducted audits of companies across the supply chain – including generic drug companies, wholesalers, and pharmacies. The audits were conducted at 14 locations, including three generic drug companies, five wholesalers, and six pharmacies.

Through the audits, the Ministry uncovered drug purchasing schemes whereby pharmacies purchase a greater quantity of generic drugs than they require, collect the professional allowance on the greater quantity, and then return what they don't need to the wholesaler. The wholesaler then re-sells the product, again triggering a second professional allowance payment. This scheme enables alleged professional allowances to be collected multiple times. Not only is this practice illegal, it also raises serious safety concerns. For example, in the case of a recall, it would be very difficult to track the original source of the drug or to be able to track it throughout the distribution system.

Results

The audits revealed improper activities across the supply chain. As a result, the Ministry is taking the following enforcement actions:

- Rebate penalty orders have been issued in the amount of \$33.8 million against 7 generic drug companies, 4 wholesalers and 1 pharmacy – these orders are penalties for paying or receiving excessive professional allowances (rebates)
- 20 provincial offence charges have been laid for providing false and/or misleading information, or obstructing an inspection against a generic manufacturer, wholesaler, pharmacy and 3 individuals
- 3 pharmacies have been put on notice that their Pharmacy Subscription Agreements may be terminated and Suspension orders issued. The agreements in effect provide a license for pharmacies to work within the Ontario Public Drug Programs structure
- Demand letters have been issued that require 51 pharmacies, one generic manufacturer and one wholesaler to provide information on professional allowances; these may be followed by full-scale audits
- Complaints have been filed with the Ontario College of Pharmacists against one pharmacist, one wholesaling business and 3 pharmacies so that the College may investigate their conduct
- Complaints have been filed with Health Canada against 5 wholesalers regarding suspected violations under the *Food and Drug Act* as it relates to public safety issues