

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

Audit Uncovers "Drug Purchasing" Scheme

NEWS

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Ontario is taking legal action against a number of pharmacies, generic drug manufacturers and wholesalers after the discovery of their involvement in a scheme where drug products were being sold several times.

The Ministry of Health and Long-Term Care's Ontario Public Drug Programs conducted audits at pharmacies, generic manufacturers and wholesalers after finding discrepancies in the reporting of professional allowances paid and received. Further audits are ongoing. Professional allowances are monies generic drug manufacturers pay pharmacies for buying their prescription drug products.

The audits found that some pharmacies have been purchasing a greater amount of generic drugs than they require, collect professional allowances on the full amount, and then return what they don't need to the wholesaler. The wholesaler then re-sells the product, triggering a second professional allowance payment. This scheme enables professional allowances to be collected multiple times.

This practice raises serious safety concerns since it would be very difficult to track the original source of the drug or to be able to track it throughout the distribution system.

As a result of the audit findings, the following enforcement actions have been taken by the Ontario government:

- 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, a wholesaler, a 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, 1 generic manufacturer and 1 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

QUICK FACTS

- Under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*, on a biannual basis, drug manufacturers are required to report to the government the amount of professional allowances paid out to pharmacies.
 - Pharmacies are required to report the amount of professional allowances they have received.
 - Pharmacies are required to report on how professional allowances are spent, with the requirement that they must be used for direct patient care.
 - Professional allowances are capped at 20% for the Ontario Drug Benefit plan (ODB) market.
 - There is no cap for the private market, however, as with the ODB market, these allowances must be used for activities outlined in the regulations.
- Generic companies reported providing \$680 million in professional allowances to pharmacies in 2008 (based on reporting from January to June 2008, on an annualized basis).
- Rebates are illegal under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*. A payment of more than 20% on the ODB side is considered a rebate as well as any payment that is not for direct patient care.

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