



FACT SHEET - COMPLIANCE INSPECTIONS OF CANADIAN PHARMACY SITES SELLING PRESCRIPTION DRUGS VIA THE INTERNET OR OTHER FORMS OF DISTANCE DISPENSING

With the growing business of prescription drug sales over the internet, Health Canada is working with a number of its partners to protect the health and safety of Canadians. These partners include the provincial and territorial regulatory authorities which govern the practice of medicine and pharmacy as well as health care professionals, industry and consumers. This collaborative approach allows Health Canada and its partners to benefit from their respective areas of expertise and knowledge, in working to protect Canadians.

In keeping with this approach, in October 2003, Health Canada sent a letter to provincial pharmacy and medical associations, regulatory authorities and provincial and territorial ministries of health to clarify regulatory responsibilities for Canadian pharmacies selling prescription drugs via the Internet and advise them that inspections may be conducted by Health Canada.

Once this letter was sent, a decision was made to conduct a number of compliance inspections. In preparation for these compliance inspections, Health Canada developed an Inspection Plan that outlined the process to be used to verify the compliance of Canadian pharmacies selling prescription drugs via the Internet and other forms of distance dispensing with the *Food and Drugs Act and Regulations*. Under this federal legislation, Health Canada is responsible for evaluating and monitoring the safety, quality and effectiveness of health products. The department is also responsible for compliance and enforcement activities, including compliance inspections of Canadian pharmacy sites.

Of the over 7,000 pharmacies in Canada, approximately 270 operate either strictly over the Internet or through a combination of traditional methods and Internet pharmacy and/or distance-dispensing, such as mail order.

In 2004 a first round of one-day compliance inspections was completed that focussed on 11 pharmacy sites involved in the sale of prescription drugs via the Internet or other forms of distance dispensing. In early 2005, another round of compliance inspections will be conducted of a similar number and type Canadian pharmacy sites.

Highlights

Overall, Health Canada found that pharmacy activities were in compliance with the *Food and Drugs Act and Regulations* and that products being sold by the pharmacies were approved for sale in Canada.

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During these compliance inspections, a few areas of non-compliance were observed and Health Canada took immediate steps to have the pharmacists implement corrective actions. The actions taken, outlined below, were based on the **precautionary principle** as Health Canada does not have any evidence of harm to any individual receiving drugs through distance dispensing.

As a result of the compliance inspections, Health Canada has reminded all pharmacists in Canada of their responsibilities and obligations under the *Food and Drugs Act and Regulations*.

Health Canada's Observations of Sites Inspected & Corrective Actions Taken

Observation: Some pharmacies packaged and shipped temperature-sensitive products in a way that could risk exposure to temperatures potentially impacting the product's safety and effectiveness.

Health Canada's Action: Health Canada issued a regulatory letter to these pharmacies advising them that packaging and shipping of temperature sensitive drugs should not be continued until they could provide evidence that the shipping conditions do not risk exposure of the drugs to conditions that may impact safety and effectiveness.

Observation: Certain pharmacies were supplying some of the inspected pharmacies with prescription drugs without the required Establishment Licence to wholesale these drugs. An Establishment Licence is required for all Canadian businesses involved in the fabrication, packaging/labelling, importation, distribution, wholesaling, and testing of drugs in Canada. Unlicensed wholesaling activity could pose a potential health risk, for instance, in the event of a recall. In such a case, the tracking of the drug supply through the supply and distribution chain would be more difficult.

Health Canada's Action: Health Canada issued a regulatory letter to these pharmacies to notify them of the licensing requirements and requested the suspension of wholesale activity of scheduled drug products.

Observation: Some pharmacies were selling prescription drugs based on prescriptions signed using rubber stamps or electronic prescriptions signed with electronic signatures. Such prescriptions are not considered to be valid written prescriptions as required by the Regulations.

Health Canada's Action: Health Canada issued a regulatory letter to these pharmacies, outlining their obligations under the *Food and Drugs Act and Food and Drug Regulations*.

Pharmacist's Actions

Health Canada has received written confirmation that the pharmacies inspected have either stopped activities found to be non-compliant with the *Food and Drugs Act and Regulations* or have taken immediate steps to come into compliance. Pharmacists are licensed professionals required to act according to their Codes of Conduct; they are regulated by their provincial regulatory authorities who are responsible for ensuring that pharmacists act in the best interest of their patients.

Additional Inspections

Health Canada will conduct another round of compliance inspections of Canadian pharmacies selling prescription drugs over the Internet and other forms of distance dispensing, such as mail order, in early 2005 in order to verify that Canadian pharmacies are complying with the *Food and Drugs Act and Regulations*.

Related Resources

To see a copy of the summary report by the Health Products and Food Branch Inspectorate, please click on the following link:

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/sale_presc_drug_internet_tc_e.html

To see a copy of the Dear Pharmacist Letter please click on the following link:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/obligations_of_pharmacists_ltp_e.html

To see a copy of Frequently Asked Questions, please click on the following link:

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/sale_presc_drug_internet_faqs_e.html