



FREQUENTLY ASKED QUESTIONS - COMPLIANCE INSPECTIONS

Q1. What is Health Canada's role in protecting health?

A1. Protecting the health and safety of Canadians is a shared responsibility between the federal, provincial and territorial governments, health care professionals, industry, consumers and other stakeholders. Health Canada is working with the appropriate health care professionals to help ensure Canadians have access to safe, effective, high quality prescription drugs.

Q2. What were Health Canada's impressions from the inspections?

A2. Overall, the compliance inspections showed that pharmacist activities were in compliance with the *Food and Drugs Act and Regulations* and that the products sold were approved in Canada. Health Canada does not have any evidence of harm to any individual receiving drugs through distance dispensing. The compliance inspections did bring to light a few areas of non-compliance that required Health Canada to remind pharmacists of their responsibilities and obligations under the *Food and Drugs Act and Regulations*.

It is important to note that any violations of the *Food and Drugs Act and Regulations* noted during compliance inspections are addressed in accordance with the Health Canada's Health Product and Food Branch Inspectorate's Compliance and Enforcement Policy.

Q3. How did Health Canada prioritize compliance actions and follow-up activities?

A3. Health Canada's first priority was to communicate to those pharmacies that had violations that included a potential risk to health. The key objective was to bring them into compliance on the specific practices observed. Health Canada's next priority was to provide a compliance report to all inspected pharmacies to inform them of the results of the inspections. The next key communications was to all pharmacists in Canada, the various Colleges of Pharmacists and the Colleges of Physicians and Surgeons to ensure they were aware of the findings of the inspections and their respective responsibilities under the *Food and Drugs Act & Regulations*.

Health Canada assessed potential risks associated with the observations. Health Canada does not have any evidence of harm to any individual receiving drugs through distance dispensing. The Department determined that the potential risk did not warrant immediate warning to the public, but that a letter to pharmacists reminding them of their obligations would be an appropriate next step.

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Q4. What are Health Canada's next actions?

A4. Health Canada will conduct another round of similar inspections early in 2005 in order to ensure compliance with the *Food and Drugs Act* and *Food and Drug Regulations*.

Q5. Is this the first time that Health Canada has conducted this type of inspection, looking at Internet or other forms of distance dispensing?

A5. As part of its regulatory responsibilities, Health Canada has conducted various types of inspections of pharmacy sites over the years. This is the first round of compliance inspections that has focussed primarily on Internet or other forms of distance dispensing. In early 2005, another round of similar compliance inspections will be conducted.

Q6. Does HC usually report on compliance inspections?

A6. The Health Products and Food Branch Inspectorate has posted summary reports on clinical trial compliance inspections, as well as inspections of facilities processing cells, tissues and organs. Health Canada's priority is ensuring health and safety of Canadians, and the department acts on this by addressing areas of concern immediately and then reporting to the public.

Q7. Why have these inspections been conducted now?

A7. With the growing business of prescription drug sales over the internet, Health Canada decided to inspect pharmacies engaging in Internet pharmacy or other forms of distance dispensing to ensure that these operations were complying with the applicable requirements under the *Food and Drugs Act and Regulations*.

Q8. How long have Internet pharmacies been in existence?

A8. Internet pharmacies have been operating, in any sort of significant manner, since 1999.

Q9. What is the role of Health Canada with respect to regulating pharmacies?

A9. Protecting the health and safety of Canadians is a responsibility that is shared between health care professionals, industry, consumers, government and other stakeholders. Health Canada's Inspectorate has the regulatory authority to conduct compliance and enforcement activities in accordance with the *Food and Drugs Act and Regulations*. The Inspectorate's actions are guided by Health Canada's Health Products and Food Branch Compliance and Enforcement Policy. The provincial and territorial governments are responsible for regulating the practice of medicine and pharmacy, often through their Colleges or Registrars of Physicians and/or Pharmacists.

Q10. How were the pharmacies selected?

A10. The selection of pharmacies was based on established criteria such as distance-dispensing and the sale of drugs requiring controlled storage conditions.

Q11. Can you provide the names of the pharmacies inspected?

A11. The public interest would not be served by providing the names of pharmacies, all of whom took immediate steps to comply with the *Food and Drugs Act and its Regulations* where non-compliant activities were found.

Q12. How many pharmacies of this type are there?

A12. Of the over 7,000 pharmacies in Canada, approximately 270 operate either strictly via the Internet or a combination of traditional methods and Internet pharmacy and/or distance-dispensing.

Q13. What did Health Canada find?

A13. Overall, the compliance inspections showed that pharmacist activities were in compliance with the *Food and Drugs Act and Regulations* and that the products sold were approved in Canada. Health Canada does not have any evidence of harm to any individual receiving drugs through distance dispensing. However, the recently completed inspections did bring to light a few areas of non-compliance that required Health Canada to remind pharmacists of their responsibilities and obligations under the *Food and Drugs Act and Regulations*.

Health Canada has sent a letter to pharmacists and their licensing authorities providing information on the types of observations of activities that were considered violations of the *Food and Drug Act and Regulations*. Health Canada also issued regulatory letters regarding the specific observations made by Inspectors to the pharmacies that were visited.

Q14. What are these specific violations and do they affect the safety of the product?

A14. The inspections found that in some cases some temperature-sensitive products were packaged and shipped in a manner that could risk exposure of the drugs to temperatures potentially impacting the safety and effectiveness of the drug product. The pharmacies involved have either ceased the practice or have taken immediate action to come into compliance. Health Canada has advised all pharmacists in Canada that they must package and ship temperature-sensitive drugs in a manner that does not risk exposure of drugs to conditions that may impact the safety and effectiveness of the drug product.

As well, the inspections found evidence of wholesale activity of prescription drugs by some pharmacies supplying some of the inspected pharmacies. Under the *Food and Drugs Act and Regulations*, wholesaling of prescription drugs can only be conducted by a company holding a drug establishment licence. Without an establishment licence, the tracking of the drug supply through the supply and distribution chain would be more difficult in the event of a recall. Health Canada has issued a regulatory letter to these specific pharmacies engaged in wholesaling prescription drugs to notify them of the licensing requirements and requested the suspension of wholesale activity of scheduled drug products until they receive the required Establishment Licence.

Finally, Health Canada found some pharmacies were selling prescription drugs based on prescriptions signed with electronic signatures and/or rubber-stamp signatures. The use of rubber stamps, electronic signatures, or other means of signature which is not distinct for each transaction is not a valid signature and does not fulfil federal requirements for prescriptions. Health Canada issued a regulatory letter to these pharmacies, outlining their obligations under the *Food and Drugs Act and Food and Drug Regulations*.

Q15. Do you have any confirmation that the pharmacies in question have corrected these violations?

A15. Health Canada has received written confirmation that the pharmacies have either ceased activities found to be in violation of the *Food and Drugs Act and Regulations* or have taken immediate steps to come into compliance. Pharmacists are licenced professionals required to act according to their Codes of Conduct; they are regulated by their provincial regulatory authorities who are tasked to ensure that pharmacists act in the best interest of their patients.

Temperature-Sensitive Drugs

Q16. What types of drugs are temperature-sensitive drugs?

A16. These include drugs that require refrigeration. These types of drugs can range from treatments for diabetes to HIV.

Q17. Roughly, what percentage of drugs are temperature sensitive?

A17. All drug products are technically temperature sensitive in that they have a temperature range specified as a condition of approval by Health Canada. Specific to these compliance inspections, from a priority and safety perspective, Health Canada considered “temperature sensitive” drug products to be those that required refrigeration (between 2 and 8 degrees) and concentrated on these products.

Q18. What is the risk to health if these types of drugs are not shipped within the recommended temperature range?

A18. Given the large number of products on the market, it is not possible to generalize what would happen to a product if it remained outside of optimal temperature conditions for an extended period of time. In some cases, the drug could lose its potency or become ineffective.

Q19. What is the potential impact on the drug of such mistreatment -- does it become more powerful, or lose potency?

A 19. Given the large number of products on the market, it is not possible to generalize what would happen to a product if it remained outside of optimal temperature conditions for an extended period of time. In some cases, the drug could lose its potency or become ineffective.

Q20. How does Health Canada evaluate risk?

A20. Health Canada uses a tool called the Decision Making Framework to identifying, assessing, and managing health risks. A copy of this framework can be found at http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_tc_e.html

Q21. What should Canadians do if they have taken drugs shipped over long distances?

A21. Health Canada does not have any evidence of harm to any individual receiving drugs through distance dispensing. We are, therefore, recommending that Canadians not take any steps at this time other than to continue using the drugs as they have been prescribed. Health Canada has sent a letter to all pharmacists in Canada reminding them that they must package and ship temperature sensitive drugs in a manner that does not risk exposure of drugs to conditions that may affect the safety and effectiveness of the drug product. If you have any concerns, you are encouraged to contact your pharmacist.

Q22. Why do Canadians use distance dispensing?

A22. Canadians may use distance dispensing if they are in remote locations.

Q23. What can Canadians do if they live in a remote location where their only option is to have their drug shipped?

A23. Health Canada does not have any evidence of harm to any individual receiving drugs through distance dispensing. We are, therefore, recommending that Canadians not take any steps at this time other than to continue using the drugs as they have been prescribed. Health Canada has sent a letter to all pharmacists in Canada reminding them that they must package and ship temperature sensitive drugs in a manner that does not risk exposure of drugs to conditions that may impact the safety and effectiveness of the drug product. If you have any concerns, you are encouraged to contact your pharmacist.

Wholesaling

Q24. What is wholesaling/why would it be a problem?

A24. According to the *Food and Drugs Act and Regulations*, wholesaling is the activity of selling any prescription drug other than at retail sale, where the seller's name does not appear on the label on the drug. While none of the pharmacies inspected were observed to be engaging in wholesaling, Inspectors did find certain pharmacies were supplying some of the inspected pharmacies with wholesale prescription drugs without the required Establishment Licence. This activity could pose a potential health risk because, in the event of a drug recall, the tracking of the drug supply through the supply and distribution chain would be more difficult. This is why Health Canada asked the pharmacies who have been supplying other pharmacies in this way to stop this activity until they receive the required Establishment License.

Q25. What is an Establishment Licence?

A25. An Establishment Licence is required by any site involved in manufacturing, importing, wholesaling, distributing, packaging/labelling or testing of drug products. It is issued after a firm has been inspected by Health Canada and the firm has demonstrated that it has fulfilled the applicable requirements of the *Food and Drug Regulations*.

Q26. Why is an Establishment Licence necessary?

A26. An Establishment Licence is necessary to ensure that products entering the drug distribution chain are adequately stored, transported and that records are maintained that permit products to be effectively recalled from the market.

Q27. What is the risk that the compliance inspections identified?

A27. The inspections found that none of the inspected pharmacies were engaging in wholesale activity. However, some of the pharmacies visited were being supplied prescription drugs by pharmacies that did not have the required Establishment Licence. This activity could pose a potential health risk because, in the event of a drug recall, the tracking of the drug supply through the supply and distribution chain would be more difficult. As a result, Health Canada has asked pharmacies engaged in wholesaling without an Establishment Licence to cease this activity until they receive the required Establishment Licence.

Q28. The summary report identifies significant wholesale activity. What does 'significant' mean?

A28. In this situation, the term 'significant' refers to the fact that quantities of drugs were routinely being wholesaled as opposed to just one pharmacist responding to another's request for a small quantity of a drug in an exceptional or urgent circumstance.

Q29. If a pharmacy transfers a drug from one store to another, is this a violation?

A29. This is not a violation as long as the pharmacy has the required Establishment Licence to wholesale.

Rubber stamping

Q30. Is filling a rubber-stamped prescription a violation of the Food and Drugs Act?

A30. Yes. Pharmacists must obtain a written prescription from a physician registered to practice in Canada to fulfill requirements under the *Food and Drugs Act and its Regulations*. Health Canada reminded pharmacies of their obligations for obtaining valid written prescriptions under the *Food and Drugs Act and its Regulations*. This was done through a regulatory letter to the two pharmacies where non-compliance with this part of the Regulations was observed.