Healthy Environments and Consumer Safety Branch

Direction générale, Santé environnementale et sécurité des consommateurs

Frequently Asked Questions
Prescription Drug Abuse (PDA) Inspections

1. Why conduct PDA inspections?

The PDA inspections aim to promote to improve compliance through greater communication between federal regulators and retail pharmacy operators with the *Controlled Drugs and Substances Act* (CDSA) and its relevant regulations. Working with pharmacies across the country, these inspections will help to ensure the safe handling, storage and security of prescription drugs in Canada, and reduce opportunities for the diversion of prescription drugs for illegal sale and use.

2. What is Health Canada's authority when going in to the pharmacies?

Health Canada inspectors are designated under the *Controlled Drugs and Substances Act* (CDSA) and have specific authorities regarding enforcement and compliance of the CDSA and its associated regulations. Under Section 31 of the CDSA, inspectors may enter a pharmacy or professional practice for the purpose of an inspection to ensure compliance with the regulations at any reasonable time. Throughout the inspection, inspectors may open and examine any receptacle that may contain a controlled substance, use any computer system to examine electronic data, reproduce any documents found, examine or take labels or advertising materials, examine any substance found, take samples, and seize unauthorized controlled substances.

3. Do pharmacies get notified of the inspection or is the inspection unannounced?

As discussed in the Health Canada and National Association of Pharmacy Regulatory Authorities meeting held on June 25, 2015, 100 inspections will be carried out during the 2015-2016 fiscal year, beginning in November 2015. The Colleges will be notified of all 100 pharmacies slated for inspection, but a random selection of 50 of these 100 will be notified by Health Canada in advance.

4. What are the procedures followed throughout an inspection?

The inspections planned over the next four years are not punitive in nature; rather, they aim to improve compliance through greater communication between federal regulators and retail pharmacy operators. A typical inspection would involve the following steps:

- Upon arrival at the pharmacy, the Health Canada inspector will introduce themselves with the appropriate documentation, then request to meet with the pharmacist on duty.
- The inspector will include the pharmacist on duty on all his/her observations throughout the inspection and discuss any potential deficiencies that may be observed (to ensure understanding of the regulations).
- *Inspections will focus on the verification of purchase and prescription records as well as the review of electronic transaction records, loss and theft reports, inventory reconciliation and any other information relevant to the act of dispensing controlled substances.*
- The inspection will finish with an exit interview where the inspector will inform the pharmacist on duty that a copy of the Inspection Report will be issued to the pharmacy within approximately 14 calendar days.
- The inspector will also provide the pharmacist with documents such as a Fact Sheet, Circular Letter, and relevant forms (ie. Destruction Authorizations and Loss-Theft Forms, Frequently Asked Questions).

5. Will there be a priority or emergency contact person within the Office of Controlled Substances (OCS) concerning these inspections?

Any correspondence or enquiries can be sent directly to OCS at compliance-conformite@hc-sc.gc.ca.

6. Will follow-up inspections within the same pharmacy occur and how will matters of misconduct be referred to the respective Colleges?

As per the standard processes currently being practiced within the Controlled Substances Program, follow-up inspections can occur, and would be subject to the same authorities, privacy, and processes as the initial inspection. Similarly, the standards currently in practice when reporting misconduct under the *Controlled Drugs and Substances Act* will continue to be followed.

7. Will the increased number of inspections create an administrative burden for pharmacies?

The Government of Canada has developed an inspections plan that minimizes unnecessary burden on pharmacies and supports better surveillance and compliance with the *Controlled Drugs and Substances Act*. The Canadian pharmacy industry is supportive of these new measures.

In creating the inspections plan, the Government of Canada attempted to minimize the inspections' impact on day to day business and client care within pharmacies. Inspections will be carried out with as little interference with pharmacy operations as possible, and the process will allow for pharmacists and inspectors to discuss issues that may arise during the course of the inspection.