Helping the people of Canada maintain and improve their health

Aider les Canadiens et les Canadiennes à maintenir et à améliorer leur état de santé

Compliance and Enforcement Approach to Natural Health Products

Health Products and Food Branch Inspectorate

CHFA West

April 9, 2015
Overview

Setting the Context

- Regulatory requirements
- Topics of interest: sampling, personal importation
- Post-transition update
- NHP C&E data

Looking forward

- Implementation of proactive compliance monitoring activities
- Regulatory Openness and Transparency Framework
• The *Natural Health Product Regulations (NHPR)* came into force in 2004 and prohibit the sale of NHPs for which a product licence has not been issued by Health Canada.

• Every person that conducts an activity subject to the FDA and/or the NHPR is expected to comply with the FDA and NHPR.
  
  • Products require a licence (NPN or DIN-HM) **before** being sold or imported into Canada.
  
  • A site license (SL) is required **before** conducting licensable activities (manufacturing, importing, labelling or packaging)

• Any person that conducts an activity or sells an NHP in contravention of the FDA and/or NHPR may be subject to compliance and enforcement action.
Personal Importation

Health Canada’s Import and Export Policy describes Health Canada’s approach to enforcing regulatory requirements related to imported health products...

• Factors which would deem a shipment to be commercial, including shipments of NHPs purchased online:
  ▪ A repeat pattern of personal importations of the same drug to the same importer which exceeds a quantity of 90 day supply within a 90 day period;
  ▪ A shipment destined to a retailer, distributor, or other commercial establishment;
  ▪ A shipment associated with advertising or promotional materials;
  ▪ A shipment from a single foreign supplier and its invoicing.

...including the requirements for appropriate product and site licensing for commercial shipments.
Sampling of NHPs and OTC drugs to the general public is currently prohibited...

- Examples of higher risk sampling activities include distribution of samples of unauthorized products or distribution to patient populations in which the product has not been authorized for use.
- Proposal under the CHP Framework is to introduce regulations that would allow the distribution of samples of authorized non-prescription drugs to any person.
- Health Canada is considering the comments received and will continue to engage with stakeholders on further policy development work based on the outcome of the consultations.

...and a risk based approach is employed on a case-by-case basis where higher risk sampling activities represent a higher priority for compliance and enforcement.
Sept 2014 - Posting of the NHP Compliance Policy (POL-0044)
• Introduction of a refined approach that makes better use of information to inform risk-based decisions that are proportionate to the risk to health.

Oct 2014 - Implementation of a new incident management system (RADAR)
• Better data integration, tracking, trending of incidents.

Nov 2014 - Commencement of a Central Intake and Triage Pilot Project
• Development of tools to increase consistency in risk-based prioritisation of incidents.
• Evaluation to be completed in Summer 2015.

Jan 2015 - Incidents are tracked and trended to inform risk-based compliance and enforcement actions, including proactive compliance monitoring and collective actions.
Moving towards a steady state...

**Compliance Generation**
HC supports industry compliance by providing information to regulated parties to clarify regulatory requirements as well as implementing transparency initiatives related to C&E activities.

**Compliance Monitoring**
Complement the complaint based model with proactive compliance activities, data analysis and trending to better detect and target higher risk.

**Risk Mitigation**
Actions to evaluate and mitigate the risks and achieve compliance with the regulations. Rapid response mechanism for the mitigation of higher risks and a systematic approach for addressing lower risk products.

...risk to health continues to drive compliance and enforcement priorities and actions.
C&E Approach - updates

Compliance Generation:
• Development of a post-transition fact sheet, brochures for industry and an information sheet on buying NHPs online.
• Posting and implementation of the C&E Policy for NHPs (POL-0044).

Compliance Monitoring:
• Enhanced ability to track and trend incidents to better inform proactive compliance monitoring activities, which will become a critical component of the C&E approach.
• Efficient incident case management and resulting risk-based C&E actions/decisions.

Risk Mitigation:
• Risk-based prioritisation of C&E actions and decisions according to a graduated and proportional C&E approach to risk mitigation and management.
A critical component of effective risk-based prioritization is to make greater use of all available and relevant sources of data, evidence and information...

- All incidents regardless of risk-type will be subject to trending and analysis to inform appropriate compliance and enforcement decisions and actions.
- Higher risk incidents will continue to be higher priority for C&E action.
- Collective action (e.g., compliance promotion) to be used along with proactive compliance monitoring (e.g., market surveys, product sampling) to improve how lower priority incidents are addressed.

...to set, support and track risk-based compliance and enforcement priorities and actions in a proactive, predictable and transparent manner.
The Inspectorate is making better use of the data and information that we are collecting...

- Transitioned to a new database in October 2014 that will provide enhanced ability to track and trend C&E data.
- 243 cases opened between October 2014 and March 31, 2015 relating to NHPs:
  - 70% of cases were from consumer and trade complaints.
  - 42% of total cases were due to illegal sale (e.g., sale without a license).
  - Other issues related to advertising (14%) and quality issues/GMP (6%).
  - 13 recalls: missing labels, incorrect dosage, no market authorisation, unauthorized claims, adulteration or contamination.

...to inform C&E decision-making and appropriate actions to help protect the health of Canadians.
243 NHP Cases Opened Between Oct 1, 2014 – March 31, 2015

Received by Month and Type

- **Complaint** (168 cases)
- **Referral** (43 cases)
- **Recall** (13 cases)
- **Other** (19 cases)

### Case Priority

- **A**
- **B**
- **C**
- **NA**

- **0%**
- **25%**
- **50%**
- **75%**
- **100%**

- **Oct**
- **Nov**
- **Dec**
- **Jan**
- **Feb**
- **Mar**

- **Q3**
- **Q4**

- **2014-2015**
NHP Incident Nature Distribution
Cases opened from Oct 1, 2014 – March 31, 2015

- Illegal Sale: 42%
- Not Specified: 18%
- Advertising: 14%
- GMP: 6%
- Prohibited Ingredient: 6%
- No Establishment License: 4%
- Health Hazard: 3%
- Adverse Drug Reaction: 3%
- Product Quality: 3%
- Other: 1%
- 10 Cases or Less: 14%
- Remaining 33 cases

Incident Natures by Case Type

- Illegal Sale (101 cases)
- Not Specified (45 cases)
- Advertising (34 cases)
- GMP (14 cases)
- Prohibited Ingredient (14 cases)
- Remaining 33 cases
As part of Health Canada’s Regulatory Transparency and Openness Framework, the Department has committed to providing Canadians with credible and timely information about regulatory decisions...

• Phased approach with three main goals:
  ▪ Making information easier to understand – presenting information in plain language in easy-to-navigate formats
  ▪ Making more information available - developing more health and safety information which can be shared proactively with the public
  ▪ Making the decision-making process more open – seeking opportunities to invite, hear and consider diverse points of views in the decision-making process.

...to provide a better understanding of how and why our decisions are made and so that Canadians can make well-informed decisions about their health and the health of their families.
As part of Health Canada’s Openness and Transparency Framework, the Inspectorate is making more data available online...

<table>
<thead>
<tr>
<th>Timing</th>
<th>Product types</th>
<th>Information</th>
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</thead>
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<tr>
<td>Winter 2015</td>
<td>Drugs</td>
<td>Non-Compliant Inspection Report Card; Domestic GMP Inspection List; Inspection Tracker</td>
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<tr>
<td>Spring 2015</td>
<td>Drugs, NHPs, Medical Devices</td>
<td>Advertising complaints; Report Card Summaries for all Drug GMP inspections; List of Foreign Sites</td>
</tr>
<tr>
<td>Summer/Fall 2015</td>
<td>Drugs, NHPs, Medical Devices</td>
<td>C&amp;E statistics; Inspection Report Card for other programs;</td>
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... to help Canadians make informed decisions about the health products they choose to use and help industry be better positioned to comply with regulatory requirements.
Looking forward

Continued dialogue with industry associations, stakeholders and regulatory partners ...

• Information on buying NHPs online, compliance and enforcement approach, and a brochure for retailers now available.

• As part of the shift to more pro-active C&E activities, compliance monitoring projects will be implemented to monitor the compliance of marketed NHPs with a focus on licensing, labelling, quality.

• Results of pro-active compliance monitoring activities to be posted online in line with Health Canada’s transparency initiative.

...to identify opportunities to promote, educate and generate compliance throughout the supply chain.
For more information...

- Visit Health Canada’s website:
  www.health.gc.ca
- Visit Health Canada’s Regulatory Openness and Transparency Framework webpage:

Thank you