Compliance and Enforcement Approach to Natural Health Products

Regulatory Operations and Regions Branch

CHFA West
May 12-13, 2016
Overview

- Regulatory Operations and Regions Branch (RORB)
- NHP Regulatory Requirements
- NHP tracking and trending
- Compliance Monitoring Projects – Marketed NHPs
- Topics of Interest: sampling, personal importation
- Regulatory Openness and Transparency Framework - Advertising

Looking forward

- Regulatory Openness and Transparency Framework - Compliance Narrative
Regulatory Operations and Regions Branch  
*Launched April 4, 2016*

- The Regulatory Operations and Regions Branch (RORB) brings together the former Health Products and Food Branch Inspectorate and the Regions and Programs Bureau.

- RORB - Anne Lamar, Assistant Deputy Minister
  - The Health Product Compliance Directorate - Steven Schwendt, A/Director General
    - Health Product Inspection and Licensing - Etienne Ouimette, Director
    - Health Product Compliance and Risk Management - Ken Moore, A/Director

- RORB was created to strengthen the delivery of the Department’s compliance and enforcement programs for drugs, natural health products, consumer products, tobacco, pesticides, medical devices, blood, donor semen, and cells, tissues and organs.

- Uniting regional frontline Inspectors with support staff in one branch allows for greater efficiency, consistency and coordination of national compliance and enforcement activities. It also strengthens accountability and simplifies the delivery of health product compliance and enforcement programs.
Shared Responsibility for Health and Safety

- The health and safety of Canadians is a shared responsibility between:
  - Product licence holders
  - Companies that manufacture, package, label or import NHPs
  - Retailers
  - Federal Government

*Product licence holders* are responsible for:
- ensuring that they are complying with Canada’s regulatory requirements
- applying for and receiving a product licence before a product can be legally sold in Canada
- keeping their product licences up to date
Shared Responsibility for Health and Safety

**Companies** that manufacture, package, label or import NHPs must:

- follow the requirements for good manufacturing practices, which are described in the Natural Health Products Regulations
- ensure their products follow all other requirements set out in the regulations, including those about product quality

**Retailers** are responsible for:

- making sure the NHPs they sell have a valid product licence number (NPN or DIN-HM).

**Federal Government** is responsible for regulating the safety, effectiveness and quality of health products. This includes drugs, NHPs and medical devices.

- examining products at the border
- responding to complaints
- conducting planned reviews
- monitoring international information
NHP Regulatory Requirements

• 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 Food and Drugs Act (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.
Compliance & Enforcement Approach

_Risk to health continues to drive C&E priorities and actions._

**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.
Central Triage & Intake

• The Central Triage Unit is responsible for the intake, screening, information gathering, prioritization and assignment of complaints related to drugs, nhps, biologics, and APIs.

• All complaints are received centrally and triaged within a one-business day service standard.

• Recalls and issues self-identified by regulated parties are out of scope and continue to be routed to the appropriate regional office.
Tracking and Trending

A critical component of effective risk-based prioritization is to make greater use of all available and relevant sources of data, evidence and information to set, support and track risk-based compliance and enforcement priorities and actions in a proactive, predictable and transparent manner.

• All incidents regardless of risk-type are subject to trending and analysis to inform appropriate compliance and enforcement decisions and actions.
• Higher risk incidents are a higher priority for C&E action.
• Collective action (e.g., compliance promotion) to be used along with proactive compliance monitoring (e.g., market surveys) to improve how lower priority incidents are addressed.
RORB is making better use of the data and information that we are collecting to inform C&E decision-making and appropriate actions to help protect the health of Canadians

- Transitioned to a new database in October 2014 which provides enhanced ability to track and trend C&E data.

- 459 cases opened between April 1st, 2015 and March 31, 2016th relating to NHPs:
  - 59% of cases were from consumer and trade complaints.
  - 40% of total cases were due to illegal sale (e.g., sale without a license)
  - Other issues related to advertising (9%) and quality issues/GMP (11%)
  - 15 recalls: missing labels, incorrect dosage, no market authorisation, unauthorized claims, adulteration or contamination.
NHP Cases Received by Month and Type
Cases opened from Apr 1, 2015 – March 31, 2016

Cases Received by Month and Type

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<tr>
<td>Mar</td>
<td>70</td>
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</table>

Case Priority

- Complaint (272 cases)
- Referral (91 cases)
- Internal (71 cases)
- Recall (15 cases)
- Company Notification (10 cases)
NHP Incident Nature Distribution
Cases opened from Apr 1, 2015 – March 31, 2016

- Illegal Sale (239 instances)
- Not Specified (108 instances)
- No establishment license (64 instances)
- Advertising (52 instances)
- GMP (39 instances)
- Prohibited ingredient (28 instances)
- Product Quality (27 instances)
- Adverse Drug Reaction (16 instances)
- Health Hazard (16 instances)
- Suspected counterfeit or tampering (4 instances)
- Distribution of samples (1 instance)
Compliance Monitoring Project (CMP) – Marketed NHPs

- A review to proactively assess compliance of regulated parties and products with the FDA and its Regulations
- A review of marketed NHPs was conducted from September-November 2015
- 24 samples were purchased from 19 unique retailers
- The review focused on products meant for vulnerable people (children, pregnant women) spanning 4 product types:
  - melatonin supplements
  - folic acid supplements
  - cough and cold syrups for children
  - liquid vitamin D for infants and children

We examined each product with the following questions in mind:
  - Is the product licensed?
  - Is it labelled and packaged appropriately?
  - Does it contain ingredients that it should or should not contain?
Health Canada Laboratories tested liquid products for:

- microbiological contamination
- a general drug screening
- identity and assay (vitamin D, melatonin and folic acid products)

What we found:

- 1 unlicensed folic acid product
- 2 minor labelling violations (1 folic acid product, 1 cough and cold syrup)
- 1 low assay for a melatonin product
- No risk communications (advisories) were warranted
- Inspectors worked with companies to address the non-compliances identified
Distribution of NHP and OTC samples to the general public is currently prohibited under the FDA 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.

- The department's current approach is risk-based and sampling activities are considered on a case-by-case basis.
- Health Canada is developing an interim policy to clarify its compliance and enforcement approach as it relates to the distribution of samples to the general public.
- The scope of the interim policy will be limited to non-prescription drugs and NHPs and will not include products that require oversight by a health care professional.
- We will continue to engage CHFA and others as we continue to advance our work in this area.
Openness and Transparency

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 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.

- 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.
Health Product Advertising Complaints

A table of health product advertising complaints is posted online quarterly.

Scope: Currently limited to complaints related to the following types of health products - pharmaceuticals, biologics (including vaccines), medical devices, and NHPs.

C&E actions:

- **Low Risk** - the company is informed of the non-compliance and asked to take the appropriate corrective measures.
- **High Risk** – Inspectors follow up as needed to verify that the requested action has been completed to Health Canada’s satisfaction.
- In addition, Health Canada may consider stronger action for advertising activities determined to pose a high health risk. These actions could include seizing the non-compliant advertising materials, site visits, issuing a public communication, or initiating enforcement proceedings (e.g., seeking an injunction or fines where a court order has been breached), to minimize the potential health risk to Canadians.
- For complaints that involve the advertising of an unauthorized health product, Health Canada takes action to confirm that the company stops both the advertising and sale of the non-compliant health product in Canada, as the sale of unauthorized health products is not permitted in Canada.
# Health Product Advertising Complaints


<table>
<thead>
<tr>
<th>Date received</th>
<th>Company/Organization</th>
<th>Product(s)</th>
<th>Product Licence Status</th>
<th>Product type</th>
<th>Complaint source</th>
<th>Advertising medium</th>
<th>Complaint detail</th>
<th>Relevant Regulatory provision</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-12-26</td>
<td>Young Living - Independent Distributor</td>
<td>Various products</td>
<td>Various NPNs and Unlicensed</td>
<td>Natural Health Product</td>
<td>Trade</td>
<td>Website</td>
<td>Complaint regarding the advertising of unauthorized products and unauthorized claims including claims for serious disease</td>
<td>Prohibited advertising to the general public as treatment or cure for any Schedule A disease (Section 3, Food and Drugs Act) and False, misleading or deceptive advertising (Section 9, Food and Drugs Act)</td>
<td>Compliance letter sent to request correction of non-compliance; Ongoing follow-up to confirm the non-compliant materials are modified/removed/discontinued.</td>
</tr>
<tr>
<td>2015-12-17</td>
<td>SCM Products Inc.</td>
<td>Revivogen MD</td>
<td>Unlicensed</td>
<td>Natural Health Product</td>
<td>Consumer</td>
<td>Website</td>
<td>Complaint regarding the advertising of therapeutic claims in a cosmetic-like product</td>
<td>False, misleading or deceptive advertising (Section 9, Food and Drugs Act)</td>
<td>Compliance letter sent to request correction of non-compliance; Ongoing follow-up to confirm the non-compliant materials are modified/removed/discontinued.</td>
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<tr>
<td>2015-12-11</td>
<td>Botox by MD - Dr. Charles Solnik</td>
<td>Botox Cosmetic (Onabotulinum Toxin A)</td>
<td>DIN: 02243721</td>
<td>Prescription Drug</td>
<td>Health Canada</td>
<td>Website</td>
<td>Complaint regarding the direct-to-consumer advertising of Botox</td>
<td>Advertising of a prescription drug beyond brand name, price and quantity (Section C.01.044, Food and Drug Regulations)</td>
<td>Compliance letter sent to request correction of non-compliance; Ongoing follow-up to confirm the non-compliant materials are modified/removed/discontinued.</td>
</tr>
</tbody>
</table>
Compliance Narrative – Looking Forward

• Working to make more health and safety information available online to help Canadians make informed decisions about the health products that they use and help industry be better positioned to comply with regulatory requirements.

• Annual summary of compliance and enforcement statistics (drugs, NHPs, medical devices). This will describe the role that we play both at the Canadian border and in-country and explain to Canadians what we are seeing through our compliance verification activities.

• Reporting on the findings of CMPs.
For More Information

• Visit Health Canada’s website:
  www.health.gc.ca
  http://healthycanadians.gc.ca/index-eng.php

• Visit Health Canada’s Regulatory Openness and Transparency Framework:

• Health Product Advertising Complaints:

• Health Product Complaint Form: