



Health  
Canada Santé  
Canada

*Your health and  
safety... our priority.*

*Votre santé et votre  
sécurité... notre priorité.*

# Overview of Health Canada's Openness & Transparency Initiative of Posting Inspection Results

119<sup>th</sup> AFDO Annual Education Conference

June 21, 2015



Canada 

# Health Canada's Regulatory Transparency and Openness Framework

- The Government of Canada's Action Plan on *Open Government* is making more information available to Canadians than ever before
- In April 2014, Health Canada launched its *Regulatory Transparency and Openness Framework* (RTOF) to improve access to timely, useful and relevant health and safety information
- The Framework describes a long-term vision to make regulatory decisions and decision-making processes more transparent and open. The objectives of the RTOF are:
  - Help Canadians to better understand how and why our decisions are made and use this information to make well-informed decisions on their health and the health of their families
  - Assist industry to better positioned to comply with regulatory requirements and plan for upcoming regulatory changes



# Health Canada & Regulatory Transparency

“Patient safety is a priority to our Government. Greater access to easy to understand and credible information about the potential risks and appropriate use of health products is one of the most valuable safety tools we can provide Canadians and healthcare professionals.”

2014 News Release - Minister Ambrose announces a Transparency and Openness Framework

In addition, we will take steps to increase transparency and openness by communicating clearly with citizens, the private sector, and other partners and making *relevant, timely and useful* information available to the public. By integrating transparency and openness in Departmental regulatory decisions, Health Canada will remain a credible and reliable source of health information for Canadians.

2014-15 Report on Plans and Priorities (Minister’s Message)

“Canadians deserve to know that they can trust the health products they use. While Health Canada has always enforced internationally accepted manufacturing standards to help ensure the medicines we take are safe and of high quality, Canadians can now have a better understanding of exactly how Health Canada does this and how companies are measuring up.”

2015 News Release - Minister Ambrose Launches New Drug and Health Product Inspections Database, Underlines Commitment to Transparency

**We will also accelerate our commitment to openness and transparency. Health Canada will roll out new initiatives under the world-leading *Regulatory Transparency and Openness Framework and Action Plan*. As a result, Canadians will have access to more health and safety information than ever before about the products they use every day for themselves and their families.**

2015-16 Report on Plans and Priorities (Minister’s Message)



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# Highlights

## Health Canada's Transparency and Openness Framework Action Plan



# Canadians Given Opportunity to Engage in Decision-Making

- After the passing of *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* in November 2014, Health Canada invited Canadians to have their say:
  - Consultations via online questions:
    - Seeking feedback from Canadians on what they need when seeking information about drug safety
    - Using the feedback to develop tools and regulatory approaches that will effectively meet those needs
  - Stakeholders were invited to provide comments on the *Guide to New Authorities* developed to help Health Canada implement the new authorities now in force
- Launched the *Consultation and Stakeholder Information Management System*



# Canadians Have Access to More Easy-to-Understand Information

- Plain language information on health issues
  - Summaries of drug and health product safety reviews posted on Health Canada's Website
- Plain language information on health products
  - Consumer information on drug product use, safety and common and reported side effects are easier to find on the *Drug and Health Product Register*





# Drug Summary Safety Reviews

## Drug Summary Safety Reviews

Health Canada has posted over 25 reviews, starting with the safety review for acne medication Diane 35 which launched Health Canada's regulatory transparency activities.

### Drugs and Health Products

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### Summary Safety Review- DIANE 35 (Cyproterone Acetate and Ethinyl Estradiol) - Venous Thromboembolism (blood clot)

April 8, 2014

#### Issue

As part of Health Canada's efforts to minimize health risk factors to Canadians, a safety review was initiated to evaluate the currently available information regarding the potential risk of blood clots with DIANE-35. The review was prompted by a French medicines regulatory agency announcement on January 30th, 2013 indicating its intention to suspend the marketing authorizations for DIANE-35 and its generics for acne treatment in France within 3 months. The French decision was triggered by reports of deaths caused by blood clots associated with the use of DIANE-35 in France.<sup>1</sup> The Health Canada review includes the consideration of strategies that would minimize potential risks to Canadians with the use of DIANE-35.

#### Background

##### Approved use of DIANE-35 and its generics in Canada

DIANE-35 and its generics are approved in Canada for the treatment of severe acne with accompanying symptoms of androgenisation (male characteristics) including excessively oily skin as well as facial and body hair growth, after topical therapy or systemic antibiotic treatments have failed. It is to be used only after other acne treatments have not worked. In discussion with a woman's health care provider, the use of these medicines should be discontinued when signs of acne have cleared.

##### Blood clot-related side effects

Blood clots are a rare but well-known side effect associated with the use of DIANE-35 and



# Drug and Health Product Register

## Drug and Health Product Register

A new online tool designed to become the go-to resource for Canadians looking for quick access to information on hundreds of prescription drugs

[Search for Drug Products](#) [Report a Side Effect](#) [About](#) ▾

[Home](#) → [All Services](#) → [Health](#) → [Drugs, health & consumer products](#) → [Search](#) → [Results](#) → Details

### Details for: PROZAC

**Company: ELI LILLY CANADA INC**

DIN	Active Ingredient(s)	Strength	Dosage Form	Route of Administration
02018985	FLUOXETINE (FLUOXETINE HYDROCHLORIDE)	10 MG	CAPSULE	ORAL
00636622	FLUOXETINE (FLUOXETINE HYDROCHLORIDE)	20 MG	CAPSULE	ORAL

[View Reported Side Effects](#)      [Report a Side Effect](#)

#### Consumer Information

This information was provided by the drug's manufacturer when this drug product was approved for sale in Canada. It is designed for consumers and care givers. It is a summary of information about the drug and will not tell you everything about the drug. Contact your doctor or pharmacist if you have any questions about the drug.

- ▶ What The Medication Is Used For
- ▶ What It Does
- ▶ When It Should Not Be Used
- ▶ What The Medicinal Ingredient Is





# Canadians Have Access to Information on Key Regulatory Activities

- Public tracking of enforcement activities:
  - *Inspection Tracker* for drug manufacturing establishments launched in February 2015 to flag potential issues early to Canadians
  - *Drug and Health Product Inspections Database* launched in April 2015 to give Canadians access to searchable information on drug inspections conducted each year including:
    - Drug inspections conducted in Canada since 2012
    - Non-compliant drug inspections in Canada
    - Foreign site drug inspections



# Inspection Tracker

- Publishes information regarding emerging issues identified through Health Canada's drug inspection program
- Provides a snapshot of *potential* health and safety issues that Health Canada is tracking with drug companies
- Highlights actions Health Canada is taking such as:
  - requests for voluntary quarantine
  - stop sales
  - import restrictions
  - product recalls
- The tracker is updated regularly



# Inspection Tracker

## Inspection Tracker: Drug Manufacturing Establishments

Establishment	Status of Issue	Source of Information under review	Primary Reason for Action
<b>Agila Onco Therapeutics Ltd.</b> Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India	<ul style="list-style-type: none"> <li>• Voluntary recall in place</li> <li>• Voluntary quarantine in place</li> <li>• Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)</li> <li>• Facility has voluntarily ceased production</li> </ul> <p>Related recalls and alerts:</p> <p><a href="#">Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate Matter</a></p>	<ul style="list-style-type: none"> <li>• Canadian importer</li> <li>• Regulatory Partner</li> </ul>	<ul style="list-style-type: none"> <li>• General GMP observations</li> </ul>

## Online Inspection Tracker for drug manufacturing

Provides a snapshot of the potential health and safety issues Health Canada is tracking with drug companies. The risks are identified through Health Canada inspections, the companies, adverse reaction reports or from regulatory partners.



# Drug and Health Product Inspections Database

- A searchable database that brings together information, in plain language, about drug establishments and their inspection results:
  - Drug inspections conducted by Health Canada since 2012
  - Drug inspection ratings – Compliant or Non-Compliant
  - Terms and Conditions
  - Initial Inspection Deficiencies – posted within 3 days of an inspection
  - Inspection Report Cards – posted within 30 days of an inspection
  - List of Foreign Site inspections, including rating



# Searchable List of Drug Inspections

## Drug & health product inspections

### Drug inspections in Canada search results

Below are the results for drug inspections in Canada.

You can also learn about how [drug inspections](#) are conducted in Canada and [what inspectors look for](#).

Showing 1 to 10 of 1,355 entries | Show  entries

Lists inspections conducted by Health Canada from 2012 to present

Reference Number	Establishment Name	Site	Inspection Start Date	Rating	Currently Licensed	Terms and Conditions
102172	<a href="#">CCS Pharmaceuticals (Canada) Inc.</a>	A	2015-05-13	<a href="#">Inspection in progress</a>	No	No
100258	<a href="#">Associated National Brokerage Inc.</a>	A	2015-05-13	<a href="#">Inspection in progress</a>	Yes	<a href="#">Yes</a>
100542	<a href="#">Servier Canada Inc.</a>	A	2015-05-12	<a href="#">Inspection in progress</a>	Yes	No
100541	<a href="#">Proval Pharma, Division of Servier Canada Inc.</a>	A	2015-05-12	<a href="#">Inspection in progress</a>	Yes	No
101642	<a href="#">Linde Canada Limited</a>	E	2015-05-12	<a href="#">Inspection in progress</a>	Yes	No
101283	<a href="#">Alliance Wholesale Inc.</a>	A	2015-05-12	<a href="#">Inspection in progress</a>	Yes	No



# Posting of Inspection Results – Non Compliant

## Drug & health product inspections

### Non-compliant drug inspections in Canada search results

Below are the results for non-compliant drug inspections.

You can also learn about what [non-compliant drug inspections](#) involve.

Showing 1 to 10 of 55 entries | Show  entries

Preliminary Information  
Posted within 3 days of  
inspection

Reference Number	Establishment Name	Site	Inspection Start Date	Rating	Currently Licensed	Terms and Conditions
100820	<a href="#">Smiths Medical Canada Ltd.</a>	A	2015-03-04	<a href="#">Non-Compliant</a>	Yes	No
102166	<a href="#">Attix Corporation (dba Attix Pharmaceuticals)</a>	A	2015-02-02	<a href="#">Non-Compliant</a>	No	No
100785	<a href="#">Xenex Laboratories Inc.</a>	A	2014-12-17	<a href="#">Non-Compliant</a>	No	No
101734	<a href="#">Canadadrugs.Com LP</a>	A	2014-11-24	<a href="#">Non-Compliant</a>	No	No
102169	<a href="#">Corrid Air Inc.</a>	A	2014-11-06	<a href="#">Non-Compliant</a>	No	No
101076	<a href="#">McKesson Canada Corporation</a>	K	2014-10-29	<a href="#">Non-Compliant</a>	Yes	No
100681	<a href="#">Laboratoires K.A.B.S. Inc.</a>	A	2014-10-14	<a href="#">Non-Compliant</a>	Yes	No





# Posting of Inspection Report Card Summaries

Drugs and Health Products Print | Text Size: S M L XL Help | Share

**Health Canada Good Manufacturing Practices Inspection Report Card Summary - Laboratoires Matrix Inc. (2014-01-08)**

**Company Name**  
Laboratoires Matrix Inc.

**Establishment Licence**  
101254-A

**Start Date of Inspection**  
2014-01-08

**Type of Inspection**  
Good Manufacturing Practices (GMP)

**Inspection Rating**  
Non-Compliant (NC)

**Observations:**

**Critical observation (Risk 1)**  
A critical observation describes a situation that may produce an immediate or potential serious health risk to Canadians.

**Major observation (Risk 2)**

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**Health Canada Good Manufacturing Practices Inspection Report Card Summary - Tanta Pharmaceuticals Inc. (2013-12-17)**

**Company Name**  
Tanta Pharmaceuticals Inc.

**Establishment Licence**  
100673-A

**Start Date of Inspection**  
2013-12-17

**Type of Inspection**  
Good Manufacturing Practices (GMP)

**Inspection Rating**  
Non-Compliant (NC)

**Observations:**

**Critical observation (Risk 1)**  
A critical observation describes a situation that may produce an immediate or potential serious health risk to Canadians.

Report Cards for Non-Compliant Companies posted within 30 days of inspection



# Searchable List of Foreign Sites Drug Inspections

## Drug & health product inspections

### Foreign site drug inspections search results

Below are the results for foreign site drug inspections.

You can also learn about how the Government of Canada handles [drug inspections for foreign sites](#).

Showing 1 to 10 of 2,520 entries | Show  entries

Filter items

Reference Number <input type="text" value="↑↓"/>	Establishment Name <input type="text" value="↑↓"/>	Site <input type="text" value="↑↓"/>	Inspection Start Date <input type="text" value="↑↓"/>	Rating <input type="text" value="↑↓"/>	Currently Licensed <input type="text" value="↑↓"/>	Terms and Conditions <input type="text" value="↑↓"/>
4B40D610	<a href="#">Central Glass Germany GmbH</a>	Foreign Site	2015-02-16	Compliant	N/A	No
A16D5F91	<a href="#">Phast GmbH</a>	Foreign Site	2015-02-11	Compliant	N/A	No
2320F34A	<a href="#">Mylan Laboratories Limited</a>	Foreign Site	2015-02-04	Compliant	N/A	No
3A5843FB	<a href="#">PCAS Finland Oy</a>	Foreign Site	2015-02-03	Compliant	N/A	No
4211B7E0	<a href="#">Colep Laupheim GmbH &amp; Co. KG</a>	Foreign Site	2015-01-22	Compliant	N/A	No
18D040CC	<a href="#">Across Barriers GmbH</a>	Foreign Site	2015-01-20	Compliant	N/A	No
F62EA6A4	<a href="#">DSM Nutritional Products (UK) Ltd.</a>	Foreign Site	2015-01-13	Compliant	N/A	No
828C7254	<a href="#">Bial-Portela &amp; C, S.A.</a>	Foreign Site	2014-12-12	Compliant	N/A	No
6A124CB6	<a href="#">Heraeus Precious Metals GmbH &amp; Co. KG</a>	Foreign Site	2014-12-08	Compliant	N/A	No
786B52F7	<a href="#">GP Grenzach Produktions GmbH</a>	Foreign Site	2014-12-02	Compliant	N/A	No

1 2 3 4 5 ... 252 Next →

There are over 2,500 foreign site inspections to search



# Moving Forward with Transparency and Openness

- Expand the posting of inspection reports to include medical devices, good clinical practices and other health products
- Continue to implement initiatives that provides:
  - opportunities for Canadians to be engaged
  - industry with information and guidance to assist them in fulfilling their obligations
  - Canadians with information they want and need to make informed decisions on their health
- Continue to inform Canadians on the *Regulatory Transparency and Openness* initiatives that Health Canada will undertake each year and report on their progress:
  - 2014-15 Interim Report is available on the Health Canada website
  - The annual report to be posted soon
- Health Canada is currently finalizing the next phase of the RTOF



# For More Information ...

Health Canada's Regulatory Transparency and Openness Framework

<http://www.hc-sc.gc.ca/home-accueil/rto-tor/index-eng.php>



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**Regulatory transparency and openness**

The Government of Canada is making more data and information available to Canadians than ever before. Canadians are also being offered more opportunities to participate in discussions on government policies and priorities

As a regulator, Health Canada plays an important role in protecting the health and safety of Canadians. Greater transparency and openness with Canadians strengthens the trust in our regulatory decisions.



## Useful Links

- Drug Summary Safety Reviews  
<http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/ssr-rei-eng.php>
- Drug and Health Product Register  
<https://hpr-rps.hres.ca/search-recherche-eng.php>
- Inspection Tracker  
<http://www.hc-sc.gc.ca/dhp-mps/pubs/compli-conform/tracker-suivi-eng.php>
- Drug and Health Product Inspections Database  
<http://healthycanadians.gc.ca/apps/inspections/index-en.html>

