



Health  
Canada

Santé  
Canada

Your health and  
safety... our priority.

Votre santé et votre  
sécurité... notre priorité.



## REGULATORY

# TRANSPARENCY AND OPENNESS

## FRAMEWORK AND ACTION PLAN

2015-2018

*Contributing to the health and safety of Canadians and their confidence in the regulatory system through timely and open communication on issues important to their well-being*

### INFORM AND ENGAGE



Canadians have the latest information on important health and safety issues to support their decision-making and increase opportunities for engagement

### ENABLE



Industry and other stakeholders have the information they need to fulfill their responsibilities

### ENFORCE



Canadians can see how industry follows the rules that have been put in place to protect their health and safety

*The Regulatory Transparency and Openness Framework outlines concrete steps we are taking to improve access to timely, useful and relevant health and safety information, while still respecting privacy, confidentiality and security considerations.*

## THE FRAMEWORK WILL:

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- Help Canadians to better understand how and why our decisions are made. They can use this information to make well-informed decisions on their health and the health of their families.
- Assist industry to be better positioned to comply with current regulatory requirements and plan for upcoming regulatory changes.

## BUILDING ON OUR STRONG FOUNDATION

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We already make a lot of regulatory information publicly available and provide opportunities for public and stakeholder involvement in decision-making. This includes information related to the regulation of food, health and consumer products and pesticides, contributions to science and research, general health and safety advice and details regarding consultations and Departmental operations.

# INFORM AND ENGAGE

*Canadians have the latest information on important health and safety issues to support their decision-making and increase opportunities for engagement*

Canadians want to make informed decisions about their health and their families' health. We will support them by providing more access to plain language health, safety and scientific information; clearly describing Health Canada's job as a regulator; and providing more opportunities to engage in meaningful conversations on issues that impact them.

## OVER THE NEXT THREE YEARS WE WILL:

Clearly communicate our role as a regulator and our regulatory modernization agenda

Expand health, science and safety information for Canadians

Seek new ways to consistently give Canadians insight into our decision-making processes, and better communicate opportunities that they have to get involved

## BUILDING ON OUR STRONG FOUNDATION

- Recalls and safety alerts database
- Authorized products and businesses lists/databases
- Factsheets, tools, listservs and newsletters
- Drug and Health Product Register
- Summaries of safety reviews for pharmaceuticals, medical devices, etc.
- Clinical trial information
- Support industry information to Canadians on drug shortages
- Stakeholders Registry and Public engagement webpage
- Pesticide health and environmental reviews
- Incident and/or adverse reaction reports for products such as: pharmaceuticals, natural health products, vaccines, consumer products, cosmetics and pesticides



# ENABLE

*Industry and other stakeholders have the information they need to fulfill their responsibilities*

## BUILDING ON OUR STRONG FOUNDATION

- Forward regulatory plans
- Pre-approved information (monographs) for non-prescription drugs and natural health products
- Guidance documents to clarify industry responsibilities
- Compliance policies for pesticides
- Regulatory decision summaries for products approved or denied sale in Canada (pesticides, certain pharmaceuticals and medical devices)
- Scientific data and information on environmental indicators and novel foods

Industry is responsible for following the regulatory rules designed to provide Canadians with safe health and consumer products. Health Canada will help industry to fulfill this responsibility by updating and expanding our guidance about regulatory requirements. In addition, we will support scientists and experts by providing more data, documents and other information to enable independent research that benefits Canadians.

## OVER THE NEXT THREE YEARS WE WILL:

Enhance our early warning systems by telling industry how they must provide information about safety issues in other countries

Make coherent, targeted efforts to help industry fulfill their responsibilities to provide safe and effective products by providing up-to-date information and guidance

Communicate explanations for regulatory decisions

Support scientific research and development by sharing data and information



# ENFORCE

*Canadians can see how industry follows the rules that have been put in place to protect their health and safety*

The regulatory rules at Health Canada are designed to protect Canadians. Inspections are an important way that Health Canada enforces these rules. By seeing more inspection reports for more products, Canadians can better understand the systems we have in place to keep them safe.

## OVER THE NEXT THREE YEARS, WE WILL:

Expand inspection reporting for pharmaceuticals, medical devices, pesticides, tobacco, medical marijuana and other health product businesses that Health Canada regulates

Report on inspections and other compliance activities for all product lines, businesses and activities regulated by Health Canada

## BUILDING ON OUR STRONG FOUNDATION

- Annual inspection summary reports for health products
- Good Manufacturing Practices inspection list and summary report cards
- Emerging issues identified by our drug inspection program in the on-line Inspection Tracker
- Compliance and enforcement summary reports for consumer products and pesticides



# OUR COMMITMENT



**CLEARLY** communicate our role as a regulator and our regulatory modernization agenda



**EXPAND** health, science and safety information for Canadians



**SEEK** new ways to consistently give Canadians insight into our decision-making processes and better communicate opportunities that they have to get involved



**ENHANCE** our early warning systems by telling industry how they must provide information about safety issues in other countries



**MAKE** coherent, targeted efforts to help industry fulfill their responsibilities to provide safe and effective products by providing up-to-date information and guidance



**COMMUNICATE** explanations for regulatory decisions



**SUPPORT** scientific research and development by sharing data and information



**EXPAND** inspection reporting for pharmaceuticals, medical devices, pesticides, tobacco, medical marijuana and other health product businesses that Health Canada regulates



**REPORT** on inspections and other compliance activities for all product lines, businesses and activities regulated by Health Canada