



Health
Canada

Santé
Canada

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

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

Transparency of Drug Safety Reviews

CAPRA Education Day 2014

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MedEffect Canada

*Together we can improve
health product safety*

MedEffet Canada

*Ensemble nous pouvons améliorer
l'innocuité des produits de santé*

Canada 

Background

- On April 8th 2014, the Health Canada *Regulatory Transparency and Openness Framework and Action Plan* was announced.
- This *Framework* supports our commitment to the government's overall *Open Government* initiative.
- Health Canada is committed to transparency and openness. As a trusted source of credible and timely information, we can help Canadians take action on their health and safety.



What is transparency and openness?

- **Transparency** is making relevant, timely and useful information available to the public in easy to access formats.
- **Openness** is inviting, hearing, considering and sharing information with the public as Health Canada makes its regulatory decisions.



Improving

- Health Canada will take a step-by-step approach to making information and regulatory decision-making processes more transparent and open to Canadians.
- There are three main goals to be achieved moving forward:
 1. **Making information easier to understand**
 2. **Making more information available**
 3. **Making the decision-making process more open**



Summary Safety Reviews

- An initial commitment was made to begin publishing summaries of future drug safety reviews and to provide redacted full versions of reviews available upon request.
- Safety reviews are conducted when a safety issue is identified for a product on the Canadian market.
- The posting of Summary Safety Reviews (SSRs) will provide Canadians with plain-language descriptions of Health Canada's findings and decisions, so patients can make informed decisions and continue to have confidence in the health products they use.



Summary Safety Reviews

- Publication of the SSRs for *Diane-35* and *Serotonin Blocking Drugs* are the first steps in HPFB's planned transparency of drug safety reviews.
- Since the launch of these SSRs, Health Canada has received feedback from drug safety experts, media and Canadians who have encouraged even greater access to drug safety reviews.
- SSRs will complement other safety related information to help Canadians make informed decisions about medication choices.



Approach to Transparency of Safety Reviews

- Health Canada will respond to requests for more information by increasing the access to drug safety reviews immediately.

Health Canada will:

- Develop SSRs for all drug safety reviews (pharmaceuticals and biologics) completed after April 1st, 2014.
 - Redacted versions of the safety review will be available.
- Provide access to redacted versions of all safety reviews completed prior to April 1st, 2014, upon request.
- **HPFB will no longer direct requesters of drug safety reviews to use the Access to Information Process.**
 - Capacity created to provide timely redacted versions of drug safety reviews.
- Health Canada plans to hold stakeholder consultations in Fall 2014 on how we can expand our transparency even further.
 - e.g., Publishing a list of all ongoing reviews.



Links to drug risk communications:

- SSRs will be published shortly after any risk communication related to a drug safety review that meets the criteria.

SSRs will not be prepared for:

- Certain risk communications or label changes that do not have an accompanying safety review (e.g., foreign safety reviews, industry lead label changes).



Living in a Fishbowl



dreamstime.com



Does This Impact You?

Toronto Star obtains list of red-flagged drugs

Doctors and health experts alarmed that Health Canada won't make public its reviews of drug investigations in 2013.

www.thestar.com/news/canada/2014/04/12/star_obtains_list_of_redflagged_drugs.html



How Does This Impact You?

- More information, more questions.
 - HC is building a list of standard responses to support consistent messaging.
 - Available for contact on any questions you have regarding a particular safety review or SSR.
 - You may see an increase in media/public requests.
- Potential impacts on the health product supply chain.
 - Working on better contextualization of what a safety review is and what it means for patients, health professionals, etc.
 - Working to minimize fear-based decisions made by consumers on health products.
- Ensuring if its your product you will receive a heads-up prior to information being published.
- Posting a guidance document in the near future to be transparent regarding the process of releasing SSRs and redacted safety reviews.



Questions?

