

Votre santé et votre sécurité...notre priorité.

Transparency of Drug Safety Reviews

CAPRA Education Day 2014

Canada

Matt Bown Therapeutic Effectiveness and Policy Bureau Marketed Health Products Directorate



Together we can improve health product safety

MedEffet Canada

Ensemble nous pouvons améliorer l'innocuité des produits de santé

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.

- **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.

 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



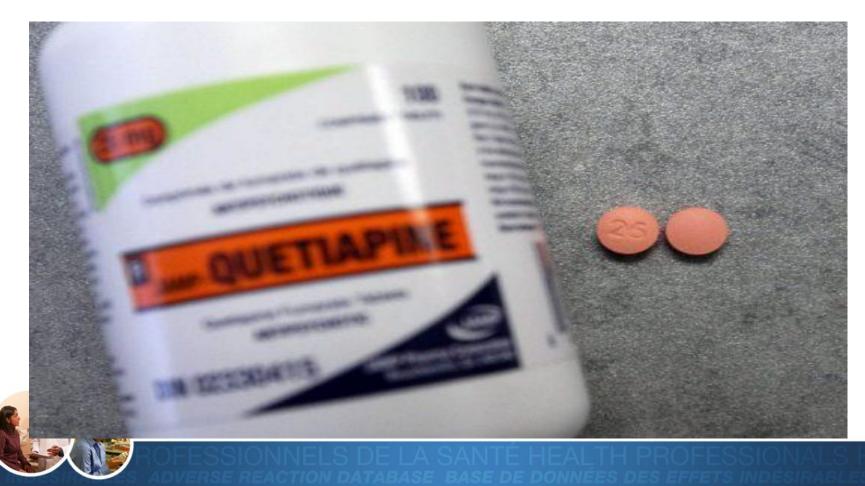
SIONNELS DE LA SANTE HEALTH PROFESSIONALS le reaction database base de données des effets indésirable

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?

