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Communicating Health Product Risk to Health Professionals and the Public

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Canada 

Purpose

- **Provide an overview of the Health Products and Food Branch (HPFB) health product risk communication program.**
- **Present key challenges and considerations faced by Health Canada in the translation of new knowledge pertaining to the risk of health products.**
- **Propose a new KT framework for communicating health product risk information for consideration.**



Health Product Risk Communication in Context (Health Canada's Role)

- Health Canada's mandate is to help Canadians maintain and improve their health.
- The translation of timely & effective health product risk information factors into this mandate by:
 - ensuring that new safety / risk information can be considered when weighing the benefits of a health product against its risks (by both HPs and public),
 - facilitating appropriate therapeutic prescribing and choices by Canadians,
 - helping to mitigate newly identified risks, without jeopardizing the benefit of product availability.



Health Products and Food Branch Health Product Risk Communication Program



Health Canada Issued / Posted Risk Communication Tools

- Risk Communications targeting the public include:
 - Public Advisories
 - Public Warnings
- Risk Communications targeting health professionals include:
 - Dear Health Care Professional Letters (DHCPL)
 - Notice to Hospitals (NtoH)
 - Canadian Adverse Reaction Newsletter (CARN)
- Risk Communications targeting both include:
 - Health Product Recall Notice
 - Information Updates
 - Foreign Product Alerts
 - It's Your Health
 - Fact Sheets and Backgrounders



MAH Issued Risk Communication Tools

- **Health Professional Communication (HPC)**
A risk communication tool used to communicate new information about safety and therapeutic effectiveness of marketed health products to health care professionals in a timely manner. HPCs include, for example, DHCPLs (Dear Healthcare Professional Letters) and NtoHs (Notice to Hospitals)
- **Public Communication (PC)**
A risk communication tool used to communicate new health safety information to consumers, patients and the general public regarding marketed health products. A PC is the plain language version of a health professional communication on the same issue.



Public Advisories and Warnings

- **Public Advisory:**
 - Notice to consumers/public issued by Health Canada
 - Informs of possible serious health hazard to enable public to make informed decisions concerning their continued use of the product.
- **Public Warning:**
 - Notice to consumers/public issued by Health Canada
 - Informs public that there is a high probability that the use of, or exposure to a product will cause serious adverse health effects or death such that the public should stop using the product immediately.



Canadian Adverse Reaction Newsletter (CARN)

- Published quarterly in the CMAJ (sent to 67,000 physicians).
- Articles are written by HC scientists and are based on Canadian adverse reaction reports.
- useful mechanism to disseminate adverse reaction information before comprehensive risk/benefit evaluations are completed.
- Raises awareness / stimulate adverse reaction reporting
- Posted on MedEffect website (Public can subscribe via list-serve).
- Distributed through a hard copy mailing list to pharmacists and other stakeholders (26,000).
- Summaries published in Canadian Pharmacists Journal, Canadian Family Physicians Journal and Canadian Association of Naturopathic Doctors (1000).



It's Your Health (IYH)

- IYH is a single or *series* of articles or fact sheets issued by HC that cover a wide range of health topics and issues.
- An IYH article is written in consultation with Health Canada or the Public Health Agency's scientists and experts, and may also be reviewed by national experts outside the department.
- These articles also include Internet links and references to more information about the health issue.



Information Updates (IUs) and Foreign Product Alerts (FPAs)

- **IU's**: are issued by HC when the risk of a product is not considered high or where the product involved does not generally affect a large number of people. Can update on the progress of HC's review or reinforce safety recommendations previously issued.
- **FPA's** are issued by HC and provide standard warnings about products which are not authorised for sale or not found on the Canadian marketplace but may have entered via personal importation or purchase over the internet. The alert provides details on identified foreign products in a table format.



Issuance of Risk Communication

Tools

		Target Audience	
		Public	Health Professionals / Hospitals
Responsibility for Issuance	HC	<ul style="list-style-type: none"> • Public Warning (PW) • Public Advisory (PA) • Health Product Recall Notice • It's Your Health (IYH) • Fact Sheets and Backgrounders • Foreign Product Alert (FPA) • Information Update (IU) 	<ul style="list-style-type: none"> • Dear Health Care Professional Letter (HPC_DHCPL) • Notice to Hospitals (HPC-NtoH) • Canadian Adverse Reaction Newsletter (CARN)
	MAH with HC	<ul style="list-style-type: none"> • Industry Issued Public Communication (MAH-PC) 	<ul style="list-style-type: none"> • Dear Health Professional Letter (HPC-DHPL) • Notice to Hospitals (HPC-NtoH)



Methods of Disseminating Risk Info

- **HC website posting**
 - **links to health professional association websites**
- **HC media e-mail list /Canada Newswire Service**
- **MedEffect e-Notice**
- **Mail out/fax out**
 - **industry issued HPCs**
 - **Health Canada issued NtoHs**
- **Health Professional Association website postings**
- **Industry website postings ¹**
- **Patient/Consumer Association website postings ¹**

¹ for selected HPCs and PCs



Guidance For Health Product Risk Communication

Guidance for Industry*:

Issuance of Health Professional Communications and Public Communications by Market Authorization Holders provides the following guidance:

- DHCPL, NtoH (HPCs) and public communications (PC) templates
- type of information that should be included in the risk comm document (as well as what should not be included)
- how to select the target audience and considerations for disseminating the information in a timely manner
- steps to be followed and the time lines to be adhered to in developing HPCs and PCs
- requirements for translation.

• [*http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/guide-ld/index_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/guide-ld/index_e.html)



Guidance For Health Product Risk Communication

Draft Guidance for HC and Industry*:

- ***Triggers for Issuance of Risk Communication Documents for Marketed Health Products for Human Use:***
 - describes each risk communication tool, its intended use and target audience
 - provides information on the triggers for the issuance of each type of risk communication tool
 - provides guidance for a consistent and comprehensive strategy for how to target the right audience for each communication tool.

* http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/guide/triggers-elements_consultation_e.html



Key Areas of Challenge in the Translation of New Knowledge Pertaining to the Risk of Health Products



Health Professional and General Public Surveys

- Focus of the 4 Surveys:
 - Familiarity with HC sources of health product risk information
 - Use of HC sources of risk information
 - Satisfaction with HC sources of risk information
- Two Health Professional Surveys done:
 - Baseline: **2003 n=551**
 - Follow-up: **2007 n=1108**
- Two General Public Surveys done:
 - Baseline: **2003 n=1500**
 - Follow-up: **2006 n=1500**



Challenge 1: Regulatory Authority

- **Current legislation does not provide Health Canada with the authority to:**
 - **require Marketed Authorization Holder (MAH) to issue a risk communication**
 - **require prior approval of content of risk communications before issuance**
 - **require MAH to update the labelling (product monograph) of a product to include new risk information.**



Considerations: Regulatory Authority

- Health Canada currently has a Legislative Renewal Project (LRP) underway to revise and update the legislation that provides its regulatory authority.
- MHPD is working with the LRP to ensure that appropriate regulatory authority is sought to allow Health Canada to require that new risk information be communicated should the MAH deem that it is not necessary or appropriate.



Challenge 2: Context and Evidence Base for Risk Information

- **Identified by Marketed Authorization Holders:**
 - Risk(s) identified in risk communication tools are not put in context for the reader (especially the public)
 - Information is often not sufficiently evidence based
 - Sources of evidence considered are not provided in the risk communication.



Considerations: Context and Evidence Base for Risk Information

- Ensure that HPCs include relevant evidence sources evaluated in the determination of new risks
- Evaluating possible usage of level of evidence statements in HPCs
- Evaluating how statements of relative risk might be used in PCs to aid the public in understanding the risk



Challenge 3a: Content/Useability

Identified in Health Professional Survey Results

2003 *n*=551 & **2007** *n*=1108

- *HPs that said they were familiar with HC Sources of Risk Information: 2003 70%; 2007 68%.*
- **Areas of HP satisfaction with Health Canada risk information sources (*unprompted responses*):**
 - relevancy of information (**51%, 52%**)
 - currency of information (**37%, 28% & 42%***)
 - importance of information (**27%, 26%**)

*** specifically asked about currency of information**



Challenge 3b: Content/Useability

Identified in Health Professional Survey Results
2003 *n*=551 & **2007** *n*=1108

- Areas of HP dissatisfaction with Health Canada risk information sources (*unprompted responses*):
 - confidence/trust in HC (20%, 0%*)
 - message felt to be clear & concise (6%, 18%)
 - Information comprehensive (12%, 9%)
 - information timely (10%, 6%)
- * in 2007 none of the HPs surveyed voluntarily stated they were dissatisfied with or lacked trust in HC



Challenge 3c: Content/Useability

Indicated in General Public Survey Results
(2003 n=1500, 2006 n=1500)

- Public's satisfaction 2003 n=113 (8%), 2006 n=132 (10%) with HC website:
 - good source of info (30%, 43%)
 - get information wanted (34%, 32%)
 - current (5%, 13%)
 - easy to understand (2%, 7%).
- Those that indicated dissatisfaction with HC website centred on site & information being hard to find.



Considerations: Content / Useability

- information communicated must be important to the reader.
- information provided must be evidence based.
- source of information must be seen as credible.
- only important/essential information should be included.
- clarity of message is important and concise information on what action the reader should take must be included.
- meaningful comparative risk statements should be included where appropriate.



Challenge 4: Uptake of Risk Information by the Media

Identified by the General Public Surveys
(2003, 2006)

- Majority of public (62%, 62%) identified their awareness of PA&W as due to the media coverage they receive:
 - does content change when issuing new risk information through the media?
 - is there an interpretation of the risk information by the media?



Considerations: Uptake of Risk Information by Media

- Evaluate how media uses the risk information provided by HC in their media stories.
- Evaluate how the power of the media can be harnessed to further disseminate health product risk information.
- Evaluate how statements of relative risk might be used in information targeted to the public.



Challenge 5a: Dissemination and Sources of Risk Information (HPs)

Identified in the Health Professional Surveys

- New safety information is looked for in a variety of sources including (*unprompted responses*): :
 - medical/scientific journals (34%, 28%)
 - CPS (18%, 25%)
 - drug manufacturers (33%, 21%)
 - on-line sources (27%, 30%)
 - Health Canada (*includes HC website at 9% & 12%**)
- Dissatisfaction with risk information sources includes not being able to find the information (8%, 17%).

**HC website/MedEffect*



Challenge 5b: Dissemination and Sources of Risk Information (Public)

Identified in the Public Surveys

- Consumers said they consult the following sources for health product risk information:
 - their pharmacists (54%, 36%)
 - doctors (29%, 32%)
 - the Internet (32%, 47%)
 - of those who consulted the Internet only 8 % & 10% (MedEffect) consulted HC's website.



Challenge 5c: Dissemination and Sources of Risk Information (HPs)

Identified in the Health Professional Surveys

No single dissemination method appears to be preferred by Health Professionals:

- mail (56%, 29%)
- e-mail (53%, 38%)
- fax (36%, 18%)
- Internet (29%, 6%)
- software updates via computer or hand-held devices (25%, 8%).



Challenge 5d: Dissemination and Sources of Risk Information (Public)

Identified in the Public Surveys:

- Awareness of HC sources of risk information:
 - PA&W issued through the media (62%, 62%)
 - HC website (31%, 36%).¹
- More than half of Canadians in both the 2003 & 2006 surveys felt that dissemination via the media is the preferred way to receive health product risk information.

¹ remains relatively unchanged despite the introduction of MedEffect in 2005



Considerations: Dissemination and Sources of Risk Information (1)

- Offer multiple methods for disseminating risk information to HPs.
- Target the 'right' audience (i.e those who need to know most).
- Ensure that pharmacists receive risk information in a timely manner.
- Partner with professional associations to improve dissemination of post-market safety information via web & point-of-care.
 - link HC/MedEffect risk information with professional association websites.



Considerations: Dissemination and Sources of Risk Information (2)

- Increased diffusion on internet using Websites of choice for the intended audience.
- Ensure timely delivery (as seen by intended recipients).
- Make information accessible when needed (time of prescribing/point-of-sale).
- Develop relevant partnerships to disseminate information to targeted audiences.
- Investigate software updates via computer or PDA devices.



Challenge 6: Uptake/Utilization

Identified in the Health Professional Surveys (2003, 2007)

- **HPs said they rely on a variety of different sources for new safety information:**
 - HC as a whole (23%, 20%) PA&W (2%, 1%)
 - HC Website (9%, 12% [MedEffect]) DHCPL (5%, 3%)
 - CARN (2%, 1%) E-notice alerts (2%, 3%)
 - government publications (9%, 0%).
- **Impact of HC and MAH issued risk comm tools on professional practice behaviour (2003)**
 - Only 4% of HPs said they used the information in their practice; 2% adjusted prescribing patterns accordingly; 17% shared with other HPs; 16% notified patients of risk.



Considerations: Uptake/Utilization

- Ensure the source of information maintains its credibility and user confidence.
- Establish routine/multiple mechanisms to evaluate the effectiveness of risk communication tools.
- Must establish a balance between information overload and transparency.
- Promote a culture where awareness of a shared responsibility, confidence in and use of trusted sourced of new health product risk information becomes a standard of practice.
- Consider incentives to risk information uptake for

HRs.



Challenge 7a: Shared Responsibility

- **Health Canada and MAHs:**
 - conduct post market surveillance, evaluate the risks and benefits of health products and disseminate new risk information to health professionals and the public.
- **Healthcare Professionals:**
 - stay informed on new and emerging health risks associated with the health products they prescribe
 - report serious adverse reactions (ARs) to health products to Health Canada.
- **Patients:**
 - inform themselves about the potential risks associated with the health products consumed
 - report serious ARs experienced to either their physician or HC.



Challenge 8b: Shared Responsibility

- Identified in the Health Professional Survey and General Public Surveys (2003)
 - The majority of HPs and the public identified Health Canada as the *most* responsible for health product safety among all players
 - Less than 10% of both HPs and the public volunteered the response that health product safety was a *shared responsibility* between HPs, MAHs, the public and Health Canada.



Considerations: Shared Responsibility

- The public (in particular) and HPs (in general) need to be made more aware of the respective role they play in health product safety.
- A shift in paradigm is needed from one where responsibility for product safety is passed on to “someone else” to one where all parties understand, accept and play their part to ensure that the health products consumed by Canadians are both safe and effective.



A Proposed Knowledge Translation Framework for Communicating Health Product Risk Information



Knowledge Translation Framework

TRANSLATION ATTRIBUTES

- Temporality of information
- Context
- Clarity of message
- Credibility of source
- Evidence-based
- Importance of information
- Action oriented
- Currency of information
- Length of message
- Selectivity of information
- Accessibility
- Perception of risk issue
- Shared Responsibility

KNOWLEDGE TRANSLATION NEEDS High-----Effectiveness-----Low

- Just in time ----- Too late
- Relevant ----- Not relevant
- Clear & concise----- Not clear or concise
- Credible----- Not credible
- Based on strong evidence ----- Anecdotal
- Important ----- Not important
- Action to take described-----No action info
- Current ----- Out of date
- Just right ----- Too long or short
- Selective ----- Too general
- Very accessible----- Inaccessible
- High risk ----- Low risk
- Acceptance high -----Acceptance low



Questions / Comments...

