

Assessment of Health Canada's Communications to External Stakeholders on Marketed Health Products

QUALITATIVE RESEARCH

FINAL REPORT

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This public opinion research presents the results of a series of in-depth stakeholder interviews conducted by Pollara Strategic Research on behalf of Health Canada. This study consisted of 81 telephone interviews with Health Canada stakeholders from across the country. The purpose of the study was to understand current perceptions of stakeholders of various Health Canada communication tools related to Marketed Health Products.

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POLITICAL NEUTRALITY CERTIFICATION

I hereby certify as Senior Officer of Pollara Strategic Insights that the deliverables fully comply with the Government of Canada political neutrality requirements outlined in the Policy on Communication and Federal Identity and the Directive on the Management of Communications.

Specifically, the deliverables do not include information on electoral voting intentions, political party preferences, standings within the electorate or ratings of the performance of a political party or its leaders.

Signed:

A handwritten signature in black ink, appearing to read 'Richard Leigh-Bennett', written in a cursive style.

Richard Leigh-Bennett,

Vice President

Pollara Strategic Insights

EXECUTIVE SUMMARY

Pollara Strategic Insights (Pollara) is pleased to present this report to Health Canada summarizing the results of interviews with its stakeholders regarding the Marketed Health Products Directorate's external communications.

Feedback from this research will be used to inform the refinement of Health Canada's communications to key stakeholders to better meet their information needs related to health product safety and effectiveness.

The purpose and objectives of this research were as follows:

- To undertake an assessment of Health Canada's approach to external communication to key stakeholders on issues of health product safety (for all product lines, including natural health products, non-prescription drugs, cells/tissues/organs, prescription medications, medical devices), and to develop recommendations.
- To obtain feedback from stakeholders on the existing approach, including reach, uptake, and the extent to which tools meet identified stakeholder needs. The research will also be used as an opportunity to obtain more general feedback on the communications approach used by Health Canada for issues related to health product safety.
- To provide an assessment of existing tools, and recommendations for how to enhance the approach to external communications moving forward, including proposed formats, modes of distribution, timing of issuance, and type/level of information required.
- To meet the objectives of the research, a qualitative approach using in-depth interviews (IDIs) was used to obtain feedback from key stakeholders. A total of 81 interviews were undertaken with stakeholders identified by Health Canada. They represented the following sub-groups: Health care professionals (physicians, nurses and pharmacists), government, professional associations, non-governmental organizations, patient safety / advocacy groups, and industry.

It is important to note that qualitative research is designed to reveal a rich range of opinions and interpretations rather than to measure what percentage of the target population holds a given opinion. These results must not be used to estimate the numeric proportion or number of individuals in the population who hold a particular opinion because they are not statistically projectable.

Key findings were:

- Virtually all stakeholders used Health Canada sources for information on marketed health products. Many participants declared both receiving and looking for information themselves on the safety of marketed health products.
- Regardless of which set of communication tools respondents identified as the one with which they were the most familiar, many of the stakeholders interviewed were at least somewhat familiar with all four categories: Guidance and Regulations, Risk Communications, Health Product Safety Information, and Transparency Initiatives.
- Health Canada was generally considered the most important source, or certainly among the most important ones, for information related to the category of communication tools selected by the respondent.
- Other important sources of information included other regulatory agencies, professional and industry associations, colleagues, internal corporate networks, subscription and specialty services, scientific literature, and manuals and compendiums.
- With respect to information directly related to the safety of marketed health products in Canada, it was suggested that even if it was found elsewhere or obtained from another source, the information referred to ultimately came from or was developed by Health Canada.
- Health Canada's website was, for the most part, said to be much less user-friendly than those in other jurisdictions.
- The quality of information within Health Canada products was considered good to excellent and there were no issues with the language used. Health Canada was given the most positive assessment with regards to perceptions of trust and having public confidence. On the other hand, timeliness was a definite issue for many, saying that Health Canada tends to lag and not be proactive in sharing information.
- The majority of the stakeholders interviewed received information from Health Canada via email. Virtually all of them preferred this approach because emails arrive in their inbox where they can be filtered, managed, filed and transferred to others.
- Those who used tools that are not pushed but rather reside on the Health Canada website somewhere (such as product monographs, various databases, guidelines and regulations) were more likely to say that they were not easy to find/access.
- The information respondents received or found in databases and on the website tended to be "the right information." Everyone who received information reported looking at it immediately or at a designated point in time, as part of their routine, usually skimming through for relevance and reading in depth when it was warranted. Virtually everyone reported that they shared some of the information they received

at one time or another.

- There was an acknowledgement, by most who have been engaging regularly with Health Canada, that the Department has been improving in the past few years with respect to clarity of information, language used in communications, and overall transparency.
- It should be noted that given the number of front-line health care providers who were part of the study and the fact that many did not regularly look at, or receive information from Health Canada directly, there were generally not a lot of “behaviour changes” as a result of such communications.
- It was recommended for Health Canada to develop a simple, streamlined and comprehensive method for stakeholders to subscribe to communications and ascertain that they will receive all of the information that is relevant to their needs.

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BACKGROUND AND OBJECTIVES

Health product safety in Canada is a shared responsibility. Many different organizations and individuals, including Health Canada, health care professionals, manufacturers, consumers and others, have a role to play in the effective and timely communication of health product safety information.

As part of its role, Health Canada develops a wide range of products designed to communicate externally to key stakeholders (including the public) on issues related to health product safety, including, but not limited to:

- **Guidance Documents;**
- **Risk Communications;**
- **Health Product Safety Information; and,**
- **Communications around Transparency.**

Timely communication of important safety information allows health care professionals, patients, consumers, manufacturers, and other interested persons, access to the most current information concerning the potential risks and benefits of marketed health products.

The key responsibility for communicating externally regarding the safety of marketed health products rests with the Marketed Health Products Directorate (MHPD), situated within the Health Products and Food Branch (HPFB), which assesses and manages the safety of health products in the context of real-world use. MHPD oversees a wide range of products, regulated under various legal frameworks, including pharmaceuticals (prescription and non-prescription); biologics including biotechnology, radiopharmaceuticals and vaccines; natural health products; medical devices; and materials and therapeutic products of human origin (blood; cells, tissues and organs, and gametes for assisted human reproduction). Through the monitoring and assessment of new safety risk issues, the MHPD identifies risks that require communicating to health care professionals and/or the general public.

The Regulatory Operations and Enforcement Branch (ROEB), as well as the Communications and Public Affairs Branch (CPAB), also produce tools designed to communicate externally on topics related to health product safety.

In an effort to understand the effectiveness of its existing external communications approach and to inform its approach moving forward, Health Canada engaged Pollara to work with key stakeholders to assess uptake of its communications tools, obtain feedback on its current approach (including timing and utility of products), and provide recommendations on how Health Canada can improve its communication to key stakeholders and better meet their information needs related to health product safety and effectiveness.

Input from these key stakeholders is required in an effort to inform the approach moving forward. More specifically, feedback was sought to determine the effectiveness of Health Canada's existing communications, as well as what Health Canada needs to do to ensure its information is reaching key stakeholders with the information/content they need, in the formats they need it, through a mode that is easy and convenient, and in ways that maximize the likelihood that the information will be accessed and used.

The purpose and objectives of this research were as follows:

- To undertake an assessment of Health Canada's approach to external communication to key stakeholders on issues of health product safety (for all product lines, including natural health products, non-prescription drugs, cells/tissues/organs, prescription medications, medical devices), and to develop recommendations.
- To obtain feedback from stakeholders on the existing approach, including reach, uptake, and the extent to which tools meet identified stakeholder needs. The research will also be used as an opportunity to obtain more general feedback on the communications approach used by Health Canada for issues related to health product safety.
- To provide an assessment of existing tools, and recommendations for how to enhance the approach to external communications moving forward, including proposed formats, modes of distribution, timing of issuance, and type/level of information required.
- To meet the objectives of the research, a qualitative approach using in-depth interviews (IDIs) was used to obtain feedback from key stakeholders. A total of 81 interviews were undertaken with stakeholders identified by Health Canada. They represented the following sub-groups: Health care professionals (physicians, nurses and pharmacists), government, professional associations, non-governmental organizations, patient safety / advocacy groups, and industry.

Due to the qualitative nature of this study, results cannot be extrapolated to a broader audience and should be considered indicative, rather than definitive.

Contract Value for this research: \$84,805.05 + HST

RESEARCH APPROACH

A total of 81 confidential in-depth stakeholder interviews were conducted for this research. They were identified in the sample provided by Health Canada as belonging to or being representatives of one or more stakeholder subgroups, as follows:

Stakeholder Group(s)	# of interviews
Government	6
Pharmacists	9
Industry	21
Health care professionals (physicians, nurses)	16
Patient safety/Advocacy	11
Pharmacists + Industry	13
Pharmacists + Advocacy	1
Other	4
Total	81

Health Canada sent bilingual email invites to its stakeholders, explaining the background and objectives of the research, and introducing Pollara as the neutral third party conducting the research (See Appendix A).

Follow-up invites were then sent by Pollara and interviews were scheduled with interested stakeholders between July 22 and September 10, 2019. Upon scheduling of the interview, stakeholders were sent a background document containing a list of and links to the communications tools that would be discussed. Interviewees were asked to read the document in preparation for the interview (See Appendix D).

Interviews were conducted by telephone in the participants' official language of choice, resulting in 10 interviews conducted in French and 71 in English. Interviews lasted approximately 45-60 minutes and followed a pre-established interview guide (See Appendix B). The interview guide included an introduction section, reiterating the objectives of the research, and informing the interviewee of confidentiality and anonymity. It also allowed for confirmation of the stakeholder's organization or profession and stakeholder group, in order to ensure that the correct person was reached.

In order to offer interviewees optimal scheduling flexibility, a team of three senior qualitative research professionals conducted the interviews. Notes were captured and shared by the research team through a database. The team also met regularly to discuss findings and provide updates

throughout the interviewing period.

At the conclusion of all interviewing, a thank you note was sent to all participants (See Appendix C).

In addition to interviews, select web usage data from January 1 to June 30, 2019, were supplied by Health Canada. Data included metrics on visits, page views and bounce rates for five different website landing pages, as well as six sub-pages for one website. These numbers excluded internal government of Canada traffic.

A website is typically made up of web pages. A visit occurs when someone lands on a website; a visit can be divided into what the visitor does, including going to different web pages (called 'page views'). Page views are typically higher than visits, especially if there are many web pages on a website. If the visitor leaves without clicking on anything (or does nothing for 30 minutes or more) then it is considered a 'bounce.' Bounce rate is the percentage of visits that were bounces; the rate can be an indicator of a problem but if the website has little-to-no web pages then the bounce rate can also be high.

DETAILED FINDINGS

Except where specifically indicated, the findings represent the combined results across the various stakeholder groups and for both English and French respondents.

1. Information Sources

Virtually all stakeholders use Health Canada sources for information on marketed health products.

- This is consistent with the study sample having been drawn from specific Health Canada contact databases.
- By the same token, almost all respondents reported receiving information from Health Canada either via email or RSS feed or both.

Many participants declared both receiving and looking for information themselves on the safety of marketed health products.

- This often depends on which of the tools they were more familiar with and which tools were most relevant to them. For example, those who were more familiar with the various databases reported that they would go looking for that information on the Health Canada website where they are housed. On the other hand, those who subscribed to safety alerts or other notices, reported that they received information that was sent to them directly by Health Canada.

Among all of those interviewed, few reported either only having information sent to them or only searching for information themselves. Often, looking up information would be as a result of having received a communication. For example, stakeholders reported that they would sometimes follow a link to find out more information or follow up directly online or with a Health Canada contact to get more information about a topic of interest or importance to them that was first brought to their attention through an email.

Top-of-mind, a few issues were brought up about the communications in general:

- The responses obtained from those who receive information, either by email or RSS feed, reveal that many are uncertain of everything they have subscribed to. They gave a number of possible reasons for this, mainly related to the fact that in their eyes, subscribing to emails and RSS feeds from Health Canada, and from MHPD, is not streamlined. That is to say, it is not contained on one simple registration page or menu, where one can select what is of particular interest. Various pages on the Health Canada website and the MHPD section of the site allow for stakeholders to sign up for certain communications. Once one subscribes to a communication, there is no prompt to subscribe to other, similar communications. Stakeholders often say they “happen” upon something that is of interest but that they were not aware of other communications.

“It seems to be random what gets sent directly and what does not.”

- There is uncertainty about the frequency of certain communications. For example, it was mentioned often that there has not been another Annual Trends report. It was also mentioned that some communications come a few times a year, or consistently for a number of months, before either disappearing or arriving less frequently. This inconsistency results in stakeholders questioning whether they are still subscribed or whether they subscribed to the “right” communication.

“Be more transparent about how often communications are supposed to come out, what one is signed up for, how to sign up for other emails, or how they select who gets what - especially Letters to Professionals.”

- Communications do not consistently come from the same mailbox or person at Health Canada. This is particularly true about Guidance and Regulation notices. This, along with some other issues mentioned specifically about the communications on this topic, had quite a number of stakeholders in the regulatory sphere doubting whether they received all communications that were relevant to them.
- There is no periodic “check-in” to see whether stakeholders are getting the right communications or alerts, or to inform them that there is a new subscription available. It was mentioned quite frequently in one way or another that Health Canada is not very good at “communicating about their communications.”

As mentioned by many, there is a lingering concern that they may not be subscribed to all that is relevant to them. As one participant put it, *“you can’t know what you don’t know.”*

- Some believe that they are most likely “oversubscribed.” The result is that they receive too much, and all that seemingly irrelevant information ends up creating clutter.

This only serves to underscore the importance of finding a simple, streamlined and comprehensive method for stakeholders to subscribe to communications and ascertain that they will receive all of the information that is relevant to their needs.

“Would be nice not to have to sign up for everything separately.”

“would be nice if we could request summary of pediatrics topics, or check off some boxes for more narrower scope of topics to get emails about.”

A corollary to not having one single area for subscribing, is that it also causes stakeholders to not know what Health Canada has to offer them. A case in point is the list of communication tools that was forwarded to participants ahead of the interview.

- No one was aware of every single product or tool on the list, notwithstanding their specific area(s) of interest (except *Guidance and Regulations*, which had only one tool).

“I hadn’t seen all of this...I didn’t know some of these things existed.”

- A number of the participants stated, in an unprompted manner, that the list was extremely useful, and that if this would be posted or distributed, it would help many stakeholders get

a more complete picture of offerings.

"This document should be distributed, or put online as a one-stop resource. There should be a list, and a how-to use, or a quick reference list to everything that they may have instead of having to search for information."

"The PDF you sent me, it's great! They should send it out [to everyone]."

Given their responsibilities, a number of those interviewed reported concern about possibly missing something important.

Many of those interviewed, at some point or another, will search for information on the Health Canada website. The main feedback on the website revealed that:

- All but a few said it is difficult, time-consuming, and often frustrating to find the information they sought. In general, there was a sense that the website was not organized in a logical way and they often were not able to find the information they were looking for in the area of the site where it was most intuitive for them to find. Some heavier website users said it has become a bit easier to navigate for them over time, but then often quickly added that they have bookmarked the pages they most often visit in order to find what they are looking for quicker.

"It's not very intuitive, but to be expected for a government site."

- The built-in search engine was an issue for many. Documents and information are often described in very specific terms or with very specific titles. In turn, one has to search for those specific (often unknown) titles in order to find a document, and searching for general terms, which many stakeholders do, does not yield the right search results.
- Some mentioned that documents are also not organized in a logical or intuitive way, such as by date or alphabetically. They said it often felt random.

"Documents aren't always in the right date order."

- Without being prompted, some reported using Google and certain key words to conduct their search on the site.
- A number of stakeholders specifically noted that when they use the search engine on the Health Canada website, it searches throughout Canada.ca and, as such, provides numerous pages of often irrelevant information from other ministries.

"I'll consult the Health Canada site. I'll type in Google, for example, 'Health Canada, gentian violet' because I find the site difficult to navigate. "

("Je vais consulter le site de Santé Canada. Je vais taper dans Google, par exemple, 'Santé Canada, violet de gentiane' parce que je trouve le site difficile à naviguer.")

Many participants stated, at various points in the interview, that they rely on multiple sources of information, in addition to Health Canada:

- More formal networks (professional associations, advocacy groups, industry associations, internal communications channels within global organizations, etc.).
- Business relationships and services, such as industry reps, consulting services, third-party monitoring services.
- Other regulatory agencies, scientific literature and specialized resources (e.g. Merck Manuals, Compendium of Pharmaceuticals and Specialties (CPS), PubMed and MedLine).
- Informal groups (e.g., health care professionals who will consult each other, colleagues within an organization or an industry, etc.).

Multiple sources result in receiving the same or similar information multiple times.

- Most would rather have this occur than risk not receiving something in a consistent and timely manner.
 - A number of the stakeholders recounted having at times received information of importance to them from one of their other channels and not having received it from Health Canada at all.
 - Others reported having been alerted to information from other sources (e.g. advocacy groups, professional and industry associations, as well as reps), prior to being notified by Health Canada.

Virtually no one mentioned referring to social media for information on marketed health products, without being prompted.

- Some literally chuckled when asked if they used social media. It was only when examples were given, such as following a Twitter feed or subscribing to a Facebook page *hypothetically* belonging to Health Canada, did the participants see a certain usefulness.
 - However, they generally felt that this information would not be inclusive enough to provide them with everything they needed; instead, it could serve as complementary to their current communications.

With respect to the information stakeholders want to receive from Health Canada, regarding the safety of marketed health products, answers were quite disparate.

- The obvious common thread is that responses usually relate to the area of interest of the organization and/or that of the person being interviewed, and their professional roles and responsibilities.
- Among the more common and broader areas of interest were recall notices, adverse effects, notices regarding consultations or new guidelines and just following up on things Health Canada has communicated to stakeholders or that stakeholders have communicated to Health Canada.

2. Familiarity with Communication Tools

In preparation for the interview, a list with links to a multitude of communication tools from Health Canada's Marketed Health Products Directorate (MHPD) was sent to all stakeholders who agreed to participate in the study. The list (see Appendix D) was divided into four categories (each with multiple tools, except for *Guidance and Regulations*), as follows:

1. Guidance and Regulations (only one tool)
2. Risk Communications
3. Health Product Safety Information
4. Communications around Transparency/Transparency Initiatives for the Public

As part of the interview, participants were asked to identify the category they were most familiar with, as well as the other categories they had some degree of familiarity with.

- Guidance and Regulations
 - This was by far the category most referenced and used by the stakeholders interviewed.
 - No conclusion should be drawn from this, as it could be a function of the types of stakeholders invited to participate or their role/position within their organization. (The same caution should be used in interpreting the other three categories of communication tools).
- Risk Communications
 - A considerable number of participants singled-out this category as the one they were most familiar with (tools include Annual Trends Report and Health Product Infowatch).
- Transparency Communications/Initiatives
 - A relatively small proportion of stakeholders identified this specific category as the one they were most familiar with (tools include Canada Vigilance Adverse Reaction Online Database, New Safety and Effectiveness Reviews, and Reports and Publications - MedEffect Canada).
- Health Product Safety Information
 - Of the four, this category was the one selected the least and was the focus of very few interviews.

Regardless of which set of communication tools respondents identified as the one they were the most familiar, many of the stakeholders interviewed were at least somewhat familiar with all four categories.

- The degree of familiarity, however, varied considerably from one category to another.

- It is important to note that while many respondents were familiar with one or two of the tools within a given category, very few of those interviewed were familiar with all of them.
 - This is particularly true for tools under *Risk Communications* and *Transparency Communications/Initiatives*.

Multiple tools were listed in each of the *Risk Communications* and the *Transparency Initiatives* categories. Many respondents were at least familiar with one or two within each respective set.

- The number of tools, as well as the degree of familiarity with each of those, varied widely by individual stakeholder.
- Most importantly, the lack of familiarity is mostly due to a lack of awareness, as opposed to an absence of interest or a participant's field of responsibility.

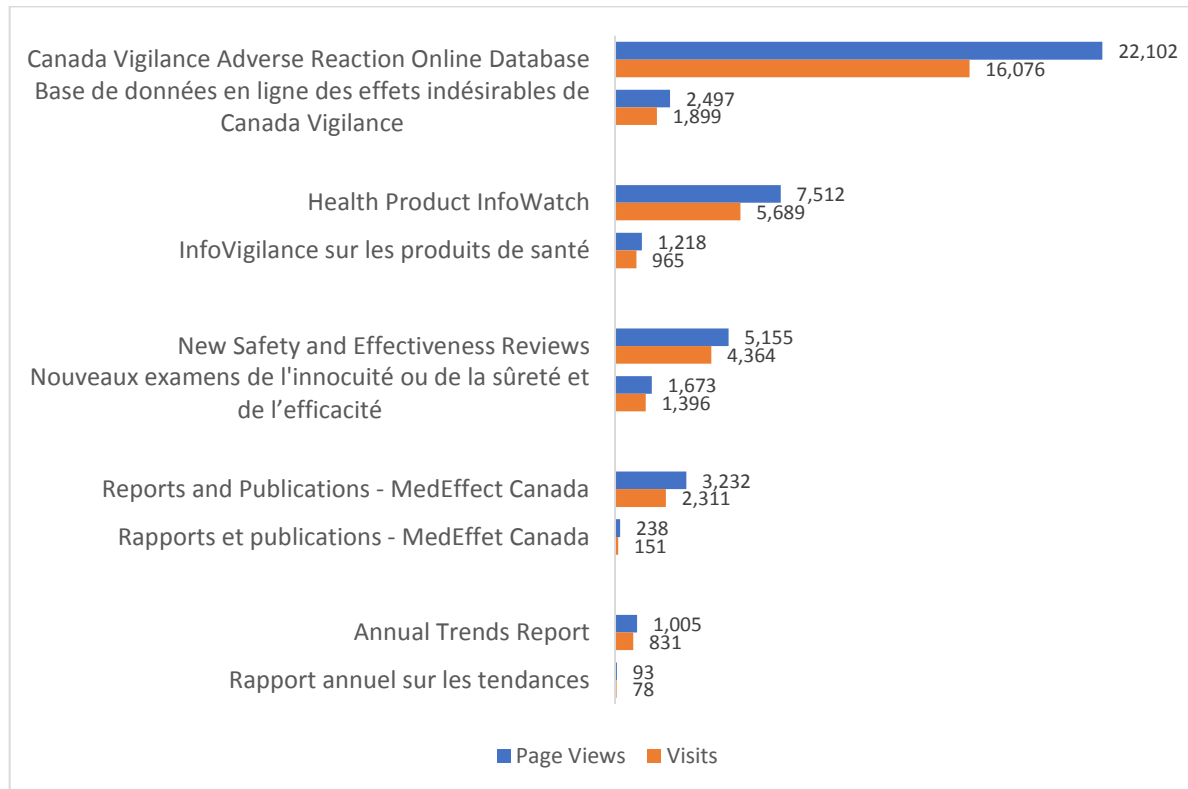
To put these findings in perspective, web analytics were provided for five tools in the *Risk Communications* (Annual Trends Report and Health Product Infowatch) and the *Transparency Initiatives* (Canada Vigilance Adverse Reaction Online Database, New Safety and Effectiveness Reviews, and Reports and Publications - MedEffect Canada) categories.

This analysis shows that the Canada Vigilance Adverse Reaction Online Database had the highest number of visits and page views of the five tools. A total of 22,102 page views for the English version and 2,497 for the French version were recorded. Health Product InfoWatch garnered the second most number of page views at 7,512 for the English site and 1,218 for the French site.

The Annual Trends Report recorded the fewest number of page views at just over one thousand (1,005) for the English site and just under one hundred (93) for the French site. See Figure 1.

There could be a range of reasons for the disparity between the tools most familiar to the interviewees and the web usage data. As stipulated in the qualitative disclaimer, qualitative data cannot be generalized to the whole population. Additionally, this study focussed on specific stakeholders (e.g., industry, health care professionals) while anyone can visit the websites.

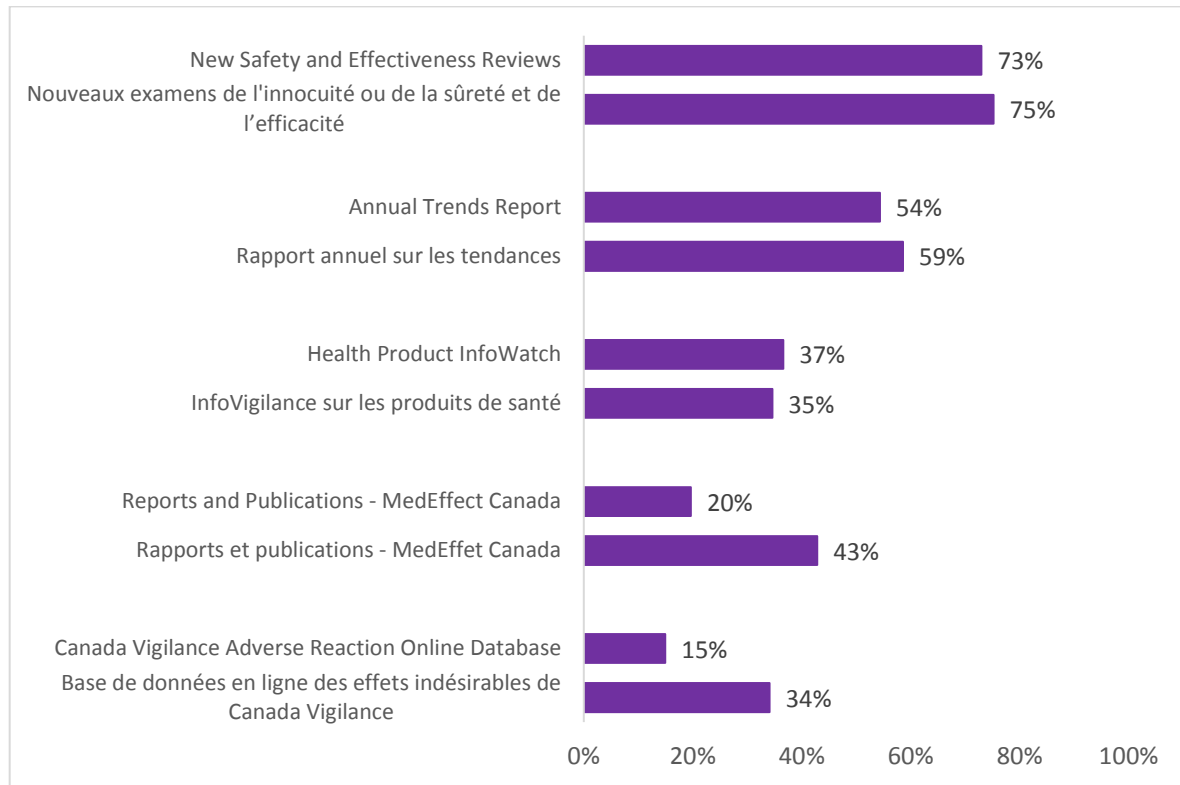
Figure 1. Page views and visits for select English and French tools from January 1 to June 30, 2019.



As indicated in Figure 2, Canada Vigilance Adverse Reaction Online Database had the lowest bounce rate among the four categories of communication tools at 15% for the English version and 34% for the French version, indicating that once at this site, more visitors viewed other pages within this site.

The highest bounce rate (i.e., visitors viewing the site then leaving) was for the New Safety and Effectiveness Reviews (73% for the English site and 75% for the French site). This particular site is a listing of Brand Name/Product Class/Medical Device(s), Medicinal Ingredient(s), and Potential Safety Issues with only two links to other pages so visitors can scroll through the one page and find most of the information they are looking for.

Figure 2. Bounce rate for select tools from January 1 to June 30, 2019.



Web page metrics for January to June 2019 InfoWatch monthly issues

Health Product InfoWatch also has monthly issues. Metrics for page views, visits, and bounce rates for January to June 2019 were collected.

The January issue page received the most number of page views and visits of the monthly issues pages for both languages, followed by the May version. See Figure 3. Bounce rates among the monthly updates range from just over 52% up to 68%. See Figure 4.

Figure 3. Page views and visits for January to June 2019 InfoWatch monthly issues.

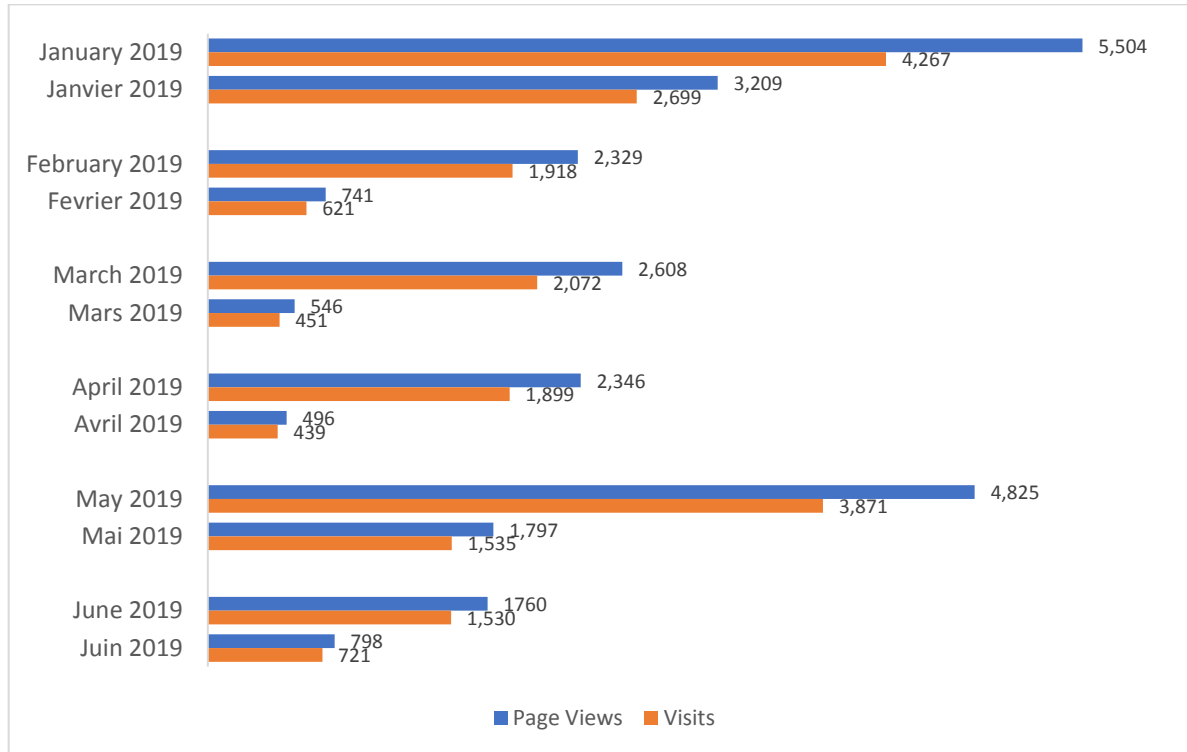
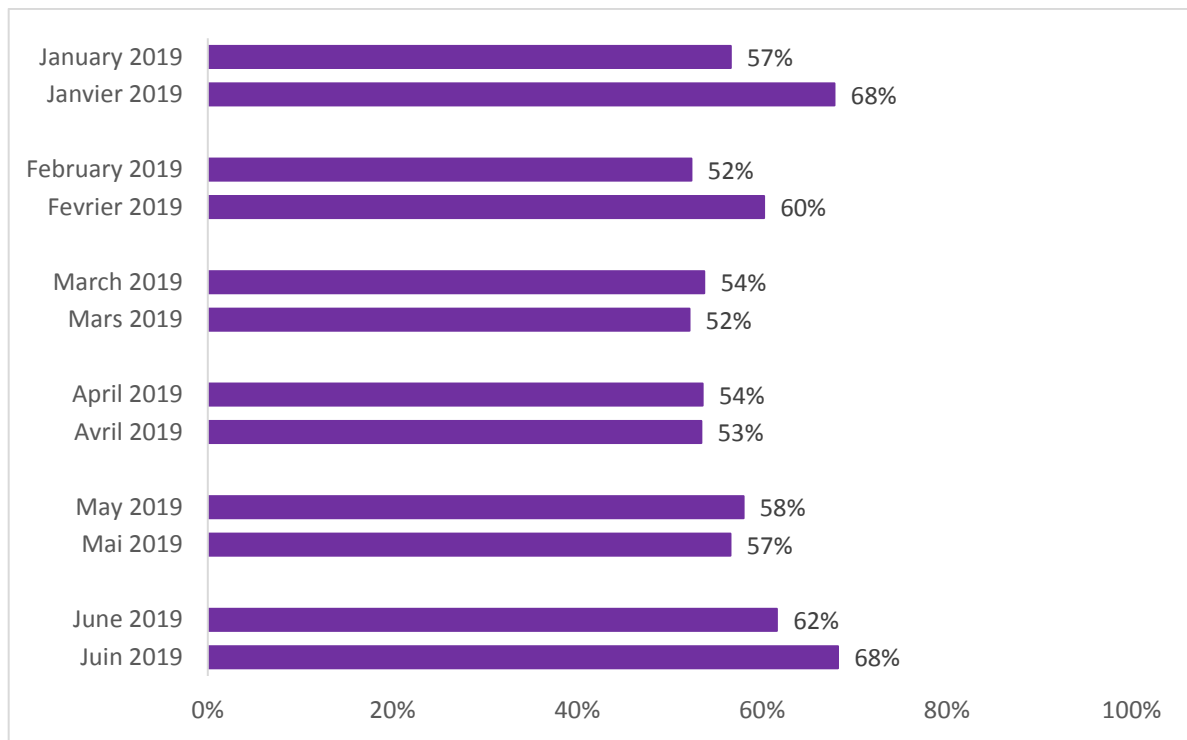


Figure 4. Bounce rate for January to June 2019 InfoWatch monthly issues.



3. Evaluation of Communication Tools

After identifying the category they were most familiar with, stakeholders were asked to evaluate the sources for the information in this category, the importance and value as a source of information, as well as how it compared to various other sources they may use.

Health Canada is generally considered the most important source, or certainly among the most important ones, for information related to the category selected by the respondent.

“Health Canada is the most important source.”

There were only a few participants who suggested that Health Canada was the only source of information regarding the safety of marketed health products.

For each of the individual categories, which were the focus of more in-depth evaluations, most participants identified other important sources of information:

- Broadly speaking, they include other regulatory agencies, professional and industry associations, colleagues, internal corporate networks, subscription and specialty services, scientific literature, manuals and compendiums, among others.
 - Health care professionals and in particular physicians (although the sample size was fairly small), appeared to rely on sources other than Health Canada more than other stakeholders.

“Many health care professionals don’t access these types of databases, [such as], MedEffect, Canada Vigilance Database and others, whether to input or search for information.”

“I receive the information another way and I don’t report it.”

(“Je reçois l’information autrement et je ne fais pas de signalements.”)

- Participants from industry, even more than other stakeholders, tended to consider the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as important sources of information with regards to the safety of health products.
- Respondents from global pharmaceutical companies also said they count on the internal resources of their network. They exchange information with colleagues around the world when there is anything of note occurring in their respective countries concerning one of the company’s drugs, a relevant class of drugs or a molecule used in one of their drugs.
- With respect to information directly related to the safety of marketed health products in Canada, it was suggested that even if it was found elsewhere or obtained from another source, the information referred to ultimately came from or was developed by Health Canada.

Without being prompted, certain stakeholders stated that they look at what is being done by the FDA and the EMA, and to a much lesser degree Australia's Therapeutic Goods Administration (TGA), as a frequent indicator of the direction that will be taken by Health Canada.

"The FDA, the EMA and the Australia sites, because there are a lot of similarities between Australia and us."

("Le site de la FDA, de l'EMA et de l'Australie, car il y a beaucoup de similarités entre l'Australie et nous.")

When specifically asked how the information from Health Canada generally compares to that of other regulatory agencies, most respondents went beyond simply contrasting the information and delved into a more general assessment of how the various agencies differed:

- Health Canada is frequently seen as lagging the U.S. and Europe, particularly on recalls/safety and guidance/regulations. Due to this, communications also appear to be lagging.

"But one has the impression that Health Canada takes less of a stance than the others."

("Mais on a l'impression que Santé Canada prend moins position que les autres.")

- When it comes to Health Canada as a regulator, it is seen, by a number of participants and particularly those in industry, as less proactive and less detailed, descriptive/prescriptive or "complete" than the EMA and especially the FDA. They opined that the FDA tends to provide more information, as well as clear and direct guidance on what to do or on what it is changing, thus leaving less to interpretation.
- Health Canada's lack of detailed guidance often leads to the need to ask questions and communicate directly with Health Canada staff to get clarity. Some see this positively, insofar as "you can have dialogue with Health Canada." Others prefer "more detail, so people know what to do as opposed to guessing." For those working for organizations that have an existing relationship with Health Canada and who see themselves more as "partners," this is often not an issue; however, for those who do not have a pre-established direct line to Health Canada staff, this sometimes proves to be a frustrating experience that in some cases negatively taints their overall assessment of the communications and of the Department.

As was often mentioned in the top-of-mind general discussion, when speaking about the tools, Health Canada's website, overall, is for the most part said to be much less user-friendly than those in other jurisdictions.

"The USFDA and European Medicine Agency, it's easier to find information on these websites. They are a little easier to navigate."

- The issue of the search engine was raised, by some, early in the interview. Other respondents raised it in the context of this comparative assessment. They lamented the

fact that searches conducted on the “Health Canada website,” are actually conducted across all Government of Canada sites. The search then turns up numerous pages of results that do not pertain at all to the information being sought, unlike the dedicated FDA and EMA sites.

“It's not user-friendly. There is a lot of information, but it's poorly categorized. Searches are now done on Canada.ca and not on Health Canada and the results you get back are hellish! We're now going to Google first.”

(“C'est pas user-friendly. Il y a beaucoup d'info mais, mal classifié. Les recherches sont maintenant sur Canada.ca et pas sur Santé Canada et le retour d'information, c'est l'enfer! On va maintenant sur Google en premier.”)

- A number of participants also stated that the site is outdated and has a lot of broken links, or that you click on a series of links, only to have to click on even more links. As one person put it, “after five clicks you've lost me.”
- Comparisons aside, searching the Health Canada site is clearly a major pain point for most of those who seek information.

“...A lot of clicks to get to what I'm looking for. I have to work for it but (I have) a lot of tricks and bookmarks to help out.”

Many of the stakeholders interviewed will, for the most part, characterize the quality of Health Canada products as good, if not excellent.

There were virtually no issues with the language used, in any of the communication tools discussed. Although some felt it was often “governmenteez” or has a quite formal tone, this was seen to be fitting for both the communicator (Health Canada) and its audience (professional stakeholders in the health care sphere).

However, timeliness is a definite issue for many, saying that Health Canada tends to lag and not be proactive in sharing information. However, it was also mentioned by those who have been in the health care field for longer periods of time, that Health Canada is getting better, often specifically mentioning the Transparency Initiative as a catalyst for this move in a positive direction in the past few years. There is still a sense that more can be done to be truly transparent. It was said for example that when it comes to guidance and regulations, a consistent feedback loop is missing. Stakeholders expressed that it would be nice to receive acknowledgement when they respond to a consultation and for Health Canada to keep them in the loop when decisions are made, when guidance is finalized, and to let them know what they did with feedback. While this is related to stakeholder engagement in general, the lack of transparency in communications negatively affects stakeholder opinions of the organization and its communications as a whole.

The most positive assessment of Health Canada is with regards to perceptions of trust and of having public confidence:

- Most stakeholders see Health Canada, as a trusted source of information about Marketed

Health Products.

- Similarly, a number of participants also believe that Health Canada enjoys a certain level of public confidence and is perceived as a generally independent, neutral and reputable source.
 - Certain respondents, however, are concerned that it may not be as trusted as in the past or that it may not be the go-to source any longer. It was suggested that this is the result of today's information landscape; all the noise and clutter that the public must sift through, notably, social media.

“Health Canada should be more vocal because there is a lot of confusion and misinformation. They are making strides but need to take this seriously.”

“Health Canada is uniquely positioned to be a home base for information. They have to get better at this. Not because of their failures, but because of the depth of challenge in general with people accepting any authority on scientific information in this day in age.”

The quality of the written French of some of the online tools was mentioned by several respondents.

- All comments were unprompted and included the following:
 - There were errors in French both with written communications as well as with the website;
 - There were inconsistencies between what was written in French and what was written in the equivalent English versions. This was of particular concern in the case of guidance and guidelines; and,
 - Some information could not be found in French.

4. How Information is Received

The majority of the stakeholders interviewed receive information from Health Canada via email. Virtually all of them prefer this approach because emails arrive in their inbox where they can be filtered, managed, filed and transferred to others. That said, some suggestions were made as to how to improve this form of communication:

- Many advocated for a subject line that grabs their attention and that allows them to determine the relevance, as well as the urgency of the communication. One respondent expressed it this way: “depending on the subject and certain ones I’ll say ‘oh, I don’t know! I need to send this to an expert who has the knowledge.’ I’ll send a needs assessment with a notice asking *need to act?*”
- Emails should also be succinct and provide hyperlinks for more detailed information.
 - One important caveat is ensuring that links work and remain active for a reasonable amount of time (if not forever). Many negative comments were formulated with respect to links that don’t work or those that send you into an endless loop.
- It was also suggested that, when appropriate, the action required be indicated.

The use of RSS feeds is also an effective way of keeping up-to-date. It is rarely the sole means for participants to ensure they receive all pertinent information, but more of an additional method.

A few respondents also proposed that Health Canada/MHPD be more active on social media, as an additional means of communicating with stakeholders.

- Some expressed apprehension with such messaging because the media and the public, among others, may misinterpret information and create undue concern. This could in turn lead to negative consequences, for example, a shortage for a particular drug.

Health care practitioners appear to have a lower awareness of the tools than other stakeholders who, unlike these practitioners, are not necessarily on the front line (such as those who work for industry, associations, NGOs, health care administration or research). They have formed their own habits and use other sources in order to obtain information.

- Some suggested that Health Canada should leverage associations, NGOs, professional orders, regulatory bodies, etc., in order to help them disseminate information and to get a wider and deeper reach within the health care community. While there were certainly those who said that they already share pertinent information, for example with peers or with members of their organization (who may be front-line health care practitioners), this is not because Health Canada has asked them to do so or is providing them with easily sharable documents. A more concerted effort to working with these groups could be less onerous than efforts required to change current practices.

- A recurring example was the wide-spread unawareness of, and therefore under-utilization by front-line health care providers, of the MedEffect and the Canada Vigilance Adverse Reaction Online Database for reporting purposes, as well as in using the tool for reference. It was often mentioned that these tools are only as useful to search as the information that is being entered. Until front-line practitioners see the benefits of using these tools, the outputs will likely remain sub-par and under-utilized.

“Make clinicians aware that reporting adverse events is important, lends to data quality, making it more useful and improves prescribing and patient care....Doing that without it coming across as double-documentation and a lot of work.”

Those who use tools that are not pushed but rather reside on the Health Canada website somewhere (such as product monographs, various databases, guidelines and regulations) are more likely to say that they are not easy to find/access. Some other issues were also mentioned specifically:

- On guidance and regulation documents and on consultations regarding changes, a main concern was that there does not appear to be one spot on the website to see all current and open consultations listed in a logical fashion (by date, topic, etc.). There was also some feedback that “version control” is not always clear, and that the documents often do not clearly show what has changed or what the proposed changes are, leaving stakeholders to repeatedly have to compare various documents to figure out what it is that is proposed and what they are actually asked to comment on.
- Those who often search the monographs for information, specifically mentioned that those hyperlinks do not appear static, and change every time they search for a specific medication or ingredient. This then frustrates them, as they can’t save the link to their favourites or share it with others. There was also some mention that in their current forms (PDF), the monographs themselves aren’t easily searchable for key words or content within each one.

“Frustrating that the monograph does not have a fixed URL.”

5. Relevance and Clarity and Use of Information

Generally-speaking, the information respondents receive or find in databases and on the website tends to be “the right information.”

However, a number of the stakeholders interviewed raised issues about the information, beyond its relevance.

- Either the issues were very specific to an individual’s personal point of view and for which there is no consensus to speak of, or they have been raised repeatedly by numerous respondents throughout the interviews.
 - For example, the latter issues include difficulties in finding information through the search function on the site and information that is not up-to-date, or issues related to pediatric medicines.
- Some found it difficult to get answers to questions, especially if these were sent to a “generic mailbox.”
 - Past experience has shown them that response time is often long and they tend to be bounced from person to person to get answers.
 - When they had questions or required complementary information, many stakeholders preferred to contact someone they knew at Health Canada for clarification. This appears to be especially true when it comes to guidance documents and notices of consultation, and among stakeholder organizations who often work closely with Health Canada on issues.

“I have emailed for clarification. Sometimes a person I know, otherwise have reached out to the individual noted on the email. But if it was a generic “info” email, turnaround time tends to be slow. I try to avoid that.”

Regardless of the aforementioned issues, if people subscribed to emails and RSS feeds, it was because they have, or at some point in the past, had, an interest in the information.

Indeed, everyone who receives information reported looking at it immediately or at a designated point in time, as part of their routine.

The information was usually skimmed through for relevance and read in depth when it was warranted.

Virtually everyone reported that they shared some of the information they received at one time or another. In fact, when asked what is typically done with this information, or whether it changes behaviour, the answer for the most part was that it does not change their behaviour (besides perhaps adding to their to-do-list that they need to respond to a request for consultation) and that their typical action is to also share it. This could be internally or externally.

- Many of the stakeholders interviewed acted as dispatchers, but always evaluated the

importance and the relevance of the information contained in the communications in order to decide if it merited being shared, with whom and with what degree of urgency. Again, this is likely because we did not speak to many front-line health care providers.

Once deemed appropriate, the form that the information-sharing takes will vary by stakeholder.

- Some may add a link to a newsletter, simply forward it with a note using email, and others may rewrite or summarise the information, along with an analysis of the implications.
- All of it depends on the relevance and urgency of the communications and, of course, established ways and procedures of the organization.

Besides sharing it, uses for the information varies greatly by stakeholder group, by the individual responsibilities of each respondent and, of course, the nature of the information itself.

- This can include filing the information for future use, changing labels, and changing production procedures to comply.

There is an acknowledgement, by most who have been engaging regularly with Health Canada over a certain number of years, that Health Canada has been improving in the past few years with respect to clarity of information, language used in communications, and overall transparency.

- Some said, nonetheless, that it remains a work in progress.
- However, there is not a sense that messages are totally unclear or that information is not conveyed in a way that (professional) stakeholders can understand.
- Some mentioned that the public, or lay persons, would likely have a more difficult time understanding the information if they were the audience for the tools.
- There is also a general understanding that this is information “from government” and that stakeholders expect what they are seeing or receiving to fit that mould.

“It is not easy to follow and understand... they have to have info that is more readable for the general population.”

It should be noted that given the number of front-line health care providers who were part of the study and the fact that many did not regularly look at, or receive information from Health Canada directly, there were generally not a lot of “behaviour changes” as a result of such communications.

6. Recommendations

The Health Canada website and the subscription services and communications tools were two major areas for suggested improvement identified by almost all stakeholders across all classifications and communication categories.

The Website

The Health Canada website, or at least that which is front-facing for the stakeholders who were interviewed, should ideally be redesigned to incorporate the following considerations:

- Ensure that the website is more user-friendly, intuitive, and easy to search. It also should undergo extensive user-testing by stakeholders.
 - It should be possible to search within the Health Canada part of Canada.ca, or even within the MHPD section.
 - It should, in appearance and for search purposes at least, be a stand-alone website much like the ones found in other jurisdictions listed below:
 - The U.S. Federal Drug Administration;
 - The European Medicines Agency; and,
 - The Australian Government's Therapeutic Goods Administration.
- Consider including specific sections for various stakeholders. At a minimum it could include the following three stakeholder groups:
 - Consumers;
 - Health Professionals; and,
 - Industry.
- Consider including other sections based on compelling topics, for example, "What's New," "Safety Information," and "Recalls."
 - These sections or areas could be created on the existing site, whether or not a complete redesign is undertaken. The objective is not to replace communications, but to provide another source to ensure that nothing is missed.
- Improve the interconnection between information found under the auspices of one sector or directorate and another. Consider that few stakeholders have a sense of Health Canada's complex structure.
 - Interconnections should be invisible to the user. Users should not be sent to another site, but simply have access to the information they seek regardless of the site or microsite they are on.
 - The structure of the site and the information should not mimic the internal structure of Health Canada. It should be structured to reflect the reality of the audiences and stakeholders it is trying to serve, and group information accordingly.

- Check the French websites for consistency with what is available in English. This includes making sure all information is available in both languages.
- Adjust or revamp the search engine so it produces results that are more precise and more relevant to the information a stakeholder is searching for and expecting to receive.

Subscription Services and Communications Tools

There are issues related to the awareness of some services and communication tools, how to register for these tools, and to specific content that must be addressed.

Ideally, stakeholders should be made aware of the various communications products and tools that are available to them. In other words, not only communicating the information, but also about the tools and communications products that are out there. The PDF document that was provided to respondents, prior to the interviews, would be a good start in terms showing the products that are available from MHPD. The following considerations should be incorporated:

- Clearly indicate the intended audience for each product to manage expectations with respect to the type of language in the content.
- Develop and implement a single subscription service, for all communications tools and products.
 - Stakeholders should have a means of seeing what they can subscribe to, contained in one place.
 - The tools and products should be categorized by topic and by the stakeholder group.
 - The publication frequency of each product and tool should be indicated.
 - Subscribers should be able to do, at any time, the following:
 - Determine the products and tools to which they are subscribed;
 - Have the ability within certain broad communications to select narrower topics of interest;
 - See what other products and tools are available, including new ones; and,
 - Have the ability to unsubscribe.
- Create a system with an account for stakeholders to register for all communication tools and products.
 - This would also allow Health Canada and MHPD to have a better and more accurate profile of stakeholders.
 - An additional benefit would be to more accurately match the communications with the type of stakeholder.
 - Periodic requests for subscription updates could then be sent, asking users to update their information if it has changed, or to inform them of new products that may be of interest to them.

- Leverage and work with stakeholder groups.
 - The first goal would be to create awareness of all the products and communications, and to explain why it is important that they receive this information and interact with it (i.e. contribute their information, in the case of databases).
 - The second goal would be to ask them to spread the information and help them create content that they can disseminate more broadly. This is especially true in the case of associations with memberships. It would also be important to welcome feedback from these groups, so that they are treated more like partners with a stake in the effort.
 - With a lower awareness of these tools among health care professionals, a special focus on these stakeholders is recommended.

- Provide stakeholders with consistent messaging about the communications.
 - For example, at each conference or meeting, consider a standard hand-out on a registration table with a list of communications; a standard slide in each presentation that outlines what MHPD does, how it communicates and what it communicates.

APPENDIX A: Invite Letter

Hello,

Health Canada's Marketed Health Products Directorate (MHPD) oversees a wide range of products regulated under various legal frameworks, including pharmaceuticals, biologics, including cell and gene therapies, natural health products, and medical devices. MHPD works to protect Canadians by monitoring and assessing the safety and effectiveness of health products on the Canadian market, while minimizing and managing their risks, and communicating those risks to healthcare professionals and/or the general public.

Health Canada has engaged *Pollara Strategic Insights*, a national market research firm, to carry out a series of key stakeholder interviews to evaluate the effectiveness of its external communications approach and various communications tools including: **Guidance and Regulations Documents; Risk Communications; Health Product Safety Information; and Communications around Transparency Initiatives for the Public**. Health Canada is also seeking recommendations on how to improve its communications to better meet information needs related to health product safety and effectiveness.

As an important stakeholder who may use these tools, your opinion is important to us and you are invited to share your views in this research project through a confidential telephone interview with a researcher from *Pollara*. Your insights and comments will greatly assist Health Canada in making future communications more accessible and relevant to its intended audiences.

In the next few weeks, you may be contacted by a representative from *Pollara* to schedule a one-hour interview. If you are interested in participating, you can also directly contact Richard Leigh-Bennett, Vice President, at RichardLeigh-Bennett@pollara.com or by telephone at 613-793-7753 (French letter: Marcel Proulx, Senior Associate at Marcelproulx@pollara.com / 514-232-8270). The interview will be conducted in the official language of your choice. Should you believe that someone else from your organization would be better suited to participate in the interview, please feel free to refer them instead. Further details and background information will be shared prior to the interview.

If you have any questions or concerns about this research, please contact Tracey Hazelwood, Manager, Strategic Partnerships and Integrated Engagement, Health Canada, by email at tracey.hazelwood@canada.ca, or by telephone at 613-866-4687.

We thank you in advance for your cooperation in this important research project.

Sincerely,

Hamida Rahim

Director / Directrice

Bureau of Strategic Engagement & Integrated Management Services (BSEIMS)/ Bureau de l'engagement stratégique et des services de gestion intégrée (BESSGI)

Marketed Health Products Directorate / Direction des produits de santé commercialisés

Health Canada / Santé Canada

APPENDIX B: Interview Guide

Introduction

- Thank stakeholder for participating, confirm this is still a good time, reminder about length of interview.
- I am INSERT NAME, a senior researcher with Pollara, a research firm that has been retained by Health Canada to carry out a series of key stakeholder interviews to evaluate the effectiveness of its external communications approach and various communications tools. Health Canada is also seeking recommendations on how to improve its communications to better meet information needs related to health product safety and effectiveness.
- It is for these reasons that we are asking you to participate in this research.
- My role is to ask you questions about communications around the safety of health products. Feel free to share your opinions freely and honestly; this is not a test of your knowledge.
- You can be assured that Pollara, as an independent third party, will hold your comments in strict confidence. Health Canada will not know who was interviewed or what specific stakeholders or organizations have said.
- Pollara will provide Health Canada with a full report aggregating the findings from this research. The finalized report will be available in the Library and Archives Canada.
- Confirm that they received the communications tools / links to the tools and have had a chance to look at them.
- If anyone else is listening in, introduce them.

Part 1 – General

Just so we are on the same page: marketed health products are pharmaceuticals (prescription and over the counter drugs), biologics and biotechnology products, natural health products, and medical devices, that are authorized for sale in Canada.

- If prompted for more details, the full definition: A marketed health product includes prescription and non-prescription medications; natural health products; medical devices; biologics (includes biotechnology products, vaccines, fractionated blood products, human blood and blood components, as well as human cells, tissues and organs), radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims.

First I have some general questions, before we get to the discussion of the materials:

1. Does your day involve advising on, prescribing and/or using any of the marketed health products in your work? This could be something you do as a professional, maybe you are part of an advocacy group, etc.? You don't need to give any personal or professional details. (may need to reread the definition above)

2. Do you **go looking for** information on the safety of the marketed health product(s) or does the information **get sent to you, or both**? Do you typically refer to industry, government, social media, etc., for information about marketed health products?
 - a. What other sources of information do you use for this type of information?
3. In general, what information do you want to receive from Health Canada regarding the safety of marketed health products?

Part 2 – Products used by stakeholders

Now, let's talk about the specific communications tools we sent you to have a look at.

1. You were sent a document listing four types of communications or information, each with some examples. Which one of these were you the most familiar with before we sent them to you? (Prompt: Guidance and regulations? Risk communications? Health product safety information? Communications around transparency to the Canadian public?)
2. Which of the other four types were you also familiar with? [Interviewer to check off on list below]
3. *If the stakeholder is not familiar with any of the four types in the package: Why not?* (Awareness? Not clear? Not useful? Other sources better?) [Interviewer to choose document to talk about and address in the following questions, assuming they had a chance to look at them pre-interview]

INTERVIEWER NOTE: USE TABLE BELOW TO KEEP TRACK OF THE BUCKETS FAMILIAR WITH. ASK ABOUT BUCKETS MOST FAMILIAR WITH AND THEN SECOND MOST FAMILIAR.

Buckets with its Tools	Most Familiar Bucket	Other Familiar Bucket(s)
Guidance and Regulations (<i>only one tool</i>)		
<p>Risk Communications</p> <ul style="list-style-type: none"> • <i>CMDNET – Canadian Medical Devices Sentinel Network</i> • <i>Annual Trends Report</i> • <i>Health Product InfoWatch</i> • <i>Recalls and Safety Alerts</i> • <i>Health Product Risk Communications (HPRC’s), including Dear Health care professional letter (DHCPL), Public communication, Notice to hospitals.</i> • <i>Information Updates</i> • <i>Public advisory</i> • <i>Recall notice</i> • <i>Foreign product alert</i> 		
<p>Health Product Safety Information</p> <ul style="list-style-type: none"> • <i>Product Monographs</i> • <i>Directions for use/Product Labelling</i> • <i>The Drug and Health Product Register</i> 		
<p>Transparency Initiatives</p> <ul style="list-style-type: none"> • <i>Summary Safety Reviews (SSRs)</i> • <i>List of New Safety and Effectiveness Reviews (SR table)</i> • <i>Medical Devices online initiative for reporting adverse reactions</i> • <i>MedEffect Canada</i> • <i>Canada Vigilance Adverse Reaction Online Database</i> 		

Part 3 – Questions for each bucket that SH says they are familiar with

Now I'd like to talk about **INSERT BUCKET NAME FROM TABLE ABOVE**.

NOTE: GO THROUGH QUESTIONS FOR MOST FAMILIAR BUCKET. REPEAT FOR SECOND BUCKET (IF MENTIONED) GIVEN TIME.

1. What is typically the first or most important source for this type of information? What other sources do you use for this type of information? (for example: Health Canada website, media, pharma sales representatives, professional associations, scientific literature, conferences, foreign regulatory agencies, friends, social media, etc.)
2. How does Health Canada's information in general compare to those other sources or regulators (i.e., the US Food and Drug Agency)? (probe: from other regulators? From industry?)
 - a. When it comes to the products: quality, timeliness, etc.
 - b. When it comes to perceptions: trusted, having public confidence, etc.
3. Are the most appropriate formats to disseminate this information being used by Health Canada
 - a. If you receive this information, is it coming to you in the most convenient way (probe: what way(s)?) (Prompt: Email? Web postings? Blogs? Faxed letters? – probe for specifics.)
 - b. If you haven't received this, how would you like to get it? (Prompt: Email? Web postings? Blogs? Faxed letters? – probe for specifics.)
4. How often do you use/read them (i.e., every time you get a notice? You look something up when you have a question or concern?)
5. Are they read carefully, or just skimmed?
6. Do the communications tools or products contain the right information?
 - a. If not, what content is missing?
7. Is the information easy to follow / understand and clearly written?
 - a. If no: Please explain how they can be improved.
8. Do you share them with colleagues?
9. How do you use this information?
10. Does this information typically influence your behaviour? How?
 - a. If no: Why not?

NOTE: IF FOCUSING ON GUIDANCE AND REGULATIONS, COMMUNICATION TOOLS OR RISK COMMUNICATIONS, ASK Q11-12 OR Q13-15, RESPECTIVELY. IF NOT, MOVE TO Q16

Guidance and Regulations

11. Do you find the guidance easy to find and access?
12. When new guidance comes out, letters are sent in advance. Do you receive these? Do you get them in a timely fashion?

Risk Communications

13.If familiar: How did you first hear of these risk communications?

14.If familiar: Do you typically take action after receiving these communications? (Probe: deliver a warning sticker, reduce prescription, use a checklist, contact a HCP for clarification etc...?)

15.Regarding a point of contact for you as a stakeholder to share their concerns: is this useful? Have you used it?

16.How can the approach be improved?

17.Anything else you'd like to share about these documents in particular?

Part 4 – Final comments

18.Besides the tools we have been discussing that I specifically asked you to focus on, do you have any comments about any of the other documents that you may have reviewed before this interview?

19.Health Canada continues to communicate new health product safety information as it becomes available. How can we make this information more useful to your practice as a healthcare professional?

20.Are there any other comments or suggestions before we wrap up?

Part 5 – Thank you and next steps

- Thank the stakeholder on behalf of Pollara and Health Canada
- What will come next:
 - Emailing the stakeholder with a summary of the interview for confirmation of comments in the next day or two, then given 48 hours to confirm that we documented their answers correctly / make edits or provide additional comments for our records.
 - Results from the research will be public at Library and Archives website within six months of the conclusion of the project.

APPENDIX C: Thank you note

Subject: Thank you on behalf of Health Canada

Dear (Name),

On behalf of Health Canada and Pollara Strategic Insights, we'd like to thank you for sharing your views on the various communication tools used by Health Canada to communicate risks and other information about marketed health products. Your feedback and opinions are very valuable and will assist Health Canada in making future communications more accessible and relevant to its intended audiences.

We are currently in the process of compiling all the feedback and preparing a report of what we heard in the interviews. Within six months, the final report will be public and posted online through [Library and Archives Canada](#).

Once again, our sincerest thanks for taking the time to talk with us and provide your insights.

The Pollara Team

APPENDIX D: List of Communication Tools Sent to Participants

Health Canada Communication Tools

*These four categories of communication tools include a few documents that may or may not be familiar to you. If the document is unfamiliar, you will have an opportunity to share this with the interviewer. We have provided links and descriptions for your reference. **You are not expected to be knowledgeable on any of the communication tools used by Health Canada.***

1. Guidance and regulations (Guidance Documents, guidelines and all regulation-related communications)

Industry and other healthcare professionals have specific guidance and regulations they must adhere to in order to meet Health Canada's requirements. If you are a healthcare professional, or represent industry, these may be familiar to you. Please see the links below for examples of such guidance.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada.html> then scroll down to *Guidance Documents and Guidelines*.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents.html> for examples of advertising regulations.

2. Risk communications

Risk Communication tools may also be familiar to healthcare professionals:

Canadian Medical Devices Sentinel Network Bulletin (CMDSNet)

The CMDSNet issues a monthly bulletin to keep the members of the network aware of a number of items related to adverse events associated with medical devices. For instance: updates to the program, recent reports of adverse events, recent regulatory actions and outcomes which have resulted from their reports, lessons learned, highlighted issues, recently completed and upcoming safety reviews, and educational opportunities. A list of all reports submitted to the Network is also included with the monthly bulletin. ***The distribution of the bulletin and list of reports is limited to Health Canada and those in the CMDSNet, and are not to be distributed beyond the Network, and therefore, no example is provided.***

For more information:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/medeffect-canada-canadian-medical-devices-sentinel-network-pilot-project.html>

Annual Trends Report

The primary objective of the Annual Trends Report is to provide the numbers and trends of adverse drug reaction case reports and medical device incident reports to Health Canada on an annual basis. The data are based on reports submitted to Health Canada through the Canada Vigilance Adverse Reaction Online

Database (more below) for reporting adverse reactions to drugs, the CV-MDS (where people report problems with medical devices), and CMDNet.

<https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html>

Health Product InfoWatch

This is a Health Canada monthly publication to raise awareness and to provide clinically relevant information to healthcare professionals concerning marketed health products and their safety. In some cases, information is intended to stimulate reporting of similar adverse reactions.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html>

Recalls and Safety Alerts

Health Canada sometimes needs to recall a product that is on the market, or issue a safety alert. There are several ways these recalls and safety notices are communicated. These are detailed below.

- **Health Product Risk Communications (HPRC's):** Includes three types of communications
 - Dear Healthcare Professional Letter (DHCPL);
 - Public communication; and,
 - Notice to hospitals. (Type I risk: 48 hours - Type II risk 2-10 days). Communications are targeted to healthcare professionals, mainly written by industry and endorsed by Health Canada.
- **Information Updates:** Health Canada's communication for less urgent risk issues, e.g., some labelling updates, can take anywhere from 2-3 days to a week or more.
- **Public advisory:** Health Canada's communication to warn the public of a potential hazard.
- **Recall notice:** This communication is written and distributed by Industry. An "extract" of the information is posted by Health Canada at regular intervals on Health Canada's Recalls and Safety Alerts website link (see below).
- **Foreign product alert:** Health Canada's communication related to unauthorized products from other countries which may have been brought into the country by travellers or purchased online.

You can search for recalls and safety alerts through this link:

<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3>

3. Health Product Safety Information

Health Product Safety Information tools may also be familiar to healthcare professionals and industry:

Health-related products in Canada must be safe and effective. Each drug product has information associated with it, and this information is easily accessible through the drugs and health products portion of the Health Canada website. In addition, Health Canada has specific guidelines for each product that includes providing clear directions and ensuring the proper labelling of products.

Product Monographs

A Product Monograph is a factual, scientific document on a drug product that describes the properties, claims, indications, and conditions of use of the drug, and contains any other information that may be required for optimal, safe and effective use of the drug.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>

Directions for use/Product Labelling

These are the directions and labels on each product.

The Drug and Health Product Register (DHPR)

The DHPR was created to make information on health products available to Canadians.

<https://hpr-rps.hres.ca/index.php?lang=en>

4. Communications around Transparency/Transparency Initiatives for the Public

Transparency tools may also be familiar to healthcare professionals and industry:

Summary Safety Reviews (SSRs)

SSRs are Health Canada's summaries of its safety reviews of products and drugs on the market. These are intended to provide greater transparency to Canadians. They are brief 3-page summaries that outline what was assessed, what was found and what action was taken by Health Canada, if any. These are found in the DHPR. Here is the link:

<https://hpr-rps.hres.ca/reg-content/summary-safety-review-result.php?lang=en&term=>

New Safety and Effectiveness Reviews

Health Canada posts lists of new safety reviews to increase transparency with Canadians and inform them of the products and risks that Health Canada is assessing. Once a new safety and effectiveness review is completed, an SSR (see above) is published to inform Canadians of what was found and what action was taken by Health Canada, if any.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/new.html>

Medical Devices Online Incidents Database

The Medical Device Online Incidents Database is an online initiative for reporting adverse reactions to medical devices. It contains medical device incident reports and information regarding recalls in a user-friendly, searchable, online format. There is also a full data extract available for download.

https://hpr-rps.hres.ca/mdi_landing.php

MedEffect Canada

MedEffect Canada provides consumers, patients, and health professionals with an easy way to: report

an adverse reaction or side effect; obtain new safety information on drugs and other health products; and, learn and better understand the importance of reporting side effects.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>

Canada Vigilance Adverse Reaction Online Database

The Canada Vigilance Adverse Reaction Online Database contains information about suspected adverse drug reactions reported to Health Canada by consumers, health professionals and market authorization holders.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html>