A FRAMEWORK FOR THE DIGITAL PROVISION OF MEDICAL INFORMATION IN CANADA

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ABSTRACT

Canadian pharmaceutical companies provide Medical Information (MI) services to support healthcare professionals (HCPs) and patients/caregivers using their medicines. While HCP and patient/caregiver preferences for the use of digital channels continues to grow, the lack of a comprehensive Canadian compliance framework governing the digital provision of MI services is a key factor hindering companies' ability to meet this need. Meanwhile, the internet is dominated by a large volume of unregulated, easily accessible, and potentially low-quality information from diverse sources. The Pharmacovigilance and Medical Information Network (PVN-MI) is therefore proposing a framework of principles to support Canadian pharmaceutical companies with the digital provision of MI services. This framework is adapted from the 2023 Medical Information Leaders of Europe (MILE) framework titled "*A Principles Framework for Digital Provision of Medical Information for Healthcare Professionals*".[1] The Pharmacovigilance and Medical Information Network continues to invite stakeholders, including pharmaceutical companies, regulators, national industry associations and healthcare professional bodies to engage in refining and implementing this framework.

INTRODUCTION

The Canadian healthcare system is predicated on HCPs effectively utilizing all available resources to deliver the best possible patient care. Pharmaceutical companies play a vital role in this system by manufacturing medications, a fundamental component in modern healthcare. With medicines constantly evolving, HCPs must stay up-to-date on these medications for their safe and effective use. Health Canada acknowledges this need, stating that " it is important for industry to disseminate non-promotional, accessible information on human and animal health products to HCPs and the general public."[2] To address this, pharmaceutical companies, as innovators of medicines, have established the MI function. This bridges knowledge gaps among HCPs through scientific exchanges across various platforms including e-mail, telephone, and digital resources such as websites. Additionally, the MI function has a key role in responding to questions from patients/caregivers on the safe and effective use of their medications.

Medical Information services provide responses to unsolicited inquiries to aid HCPs in making informed treatment decisions in a manner that is:[3]

- Non-promotional
- Up-to-date
- Evidence-based
- Unbiased

Medical Information services also respond to unsolicited requests for information from patients/caregivers in a manner that is:

- Non-promotional
- Up-to-date
- Evidence-based
- Unbiased
- Consistent with the current Health Canada approved Terms of Market Authorization (TMA)
- Encouraging patients/caregivers to discuss concerns with their HCP

While there are many online resources available, including on-line drug compendia, published by respected third party organizations, not all are credible. This creates a risk where HCPs may access inaccurate, partial, or outdated information that could result in product misuse and patient harm.[3] In addition, patients or caregivers often rely on online resources and may easily be misinformed without the requisite scientific knowledge.[4] For example, in the late 1990s, a poorly designed and later retracted study, falsely concluded that the measles, mumps, rubella (MMR) vaccine caused autism. Despite the retraction, the impact of this false information led to lowered MMR vaccination rates for the next twenty years.[5]

MISINFORMATION

Misinformation, while not a new phenomenon, gained momentum with the rise of social media.[6] This was recently seen during the Coronavirus disease 2019 (COVID-19) pandemic, in which the typically lengthy and complex process of vaccine research was expedited in the public spotlight.[7] Rapid dissemination of demonstrably false information about COVID-19 and its potential treatment, particularly via social media, led to widespread confusion and misinformation as the public sought scientific information online.[8] In such scenarios, to counteract the spread of false information, the MI function would serve as the ideal trusted source to provide up-to-date, evidence-based, unbiased information.[5]

IMPACT OF COVID-19 PANDEMIC

The COVID-19 pandemic also accelerated a shift that was already well underway, with HCPs increasingly preferring digital access to medical information. A 2021 United States (US) survey found that 88.5% of HCPs searched for medical information either daily or several times per week, with 55.6% of HCPs using general online search engines such as Google frequently or very frequently. However, medical literature databases and pharmaceutical company resources were poorly utilized.[9] Healthcare professionals who are unaware of the MI function often resort to online resources unaffiliated with pharmaceutical companies. The information found may not be entirely accurate, referenced, complete, or tailored to their specific question.[10]

CHALLENGES IN A DIGITAL AGE

This digital shift has posed several challenges for the reliable exchange of medical information, particularly with the recent surge in popularity of artificial intelligence (AI). While AIs like ChatGPT have its benefits, there are limitations. For example, ChatGPT can generate false or outdated information, particularly in summarizing scientific information, as it cannot easily discern high-quality scientific publications from low-quality ones.[11]

Increased internet usage has led to more people seeking medical information via search engines. Although accessible, this unregulated information can be misleading, as low-quality sources like patient forums on Reddit can appear as credible, scientifically accurate resources. Additionally, online searches often result in US-specific information, which may not necessarily be relevant to the Canadian setting. Finally, as Canada is a bilingual country, a challenge lies in ensuring medical information is readily accessible in both its official languages - English and French.

CANADIAN REGULATIONS

While pharmaceutical company MI services are committed to supporting patient care through the provision of quality MI content, they have been unable to effectively transition from traditional channels to self-service digital solutions.

Many companies remain hesitant to expand MI services in the digital space due to perceived Canadian regulatory barriers and the absence of a clear framework for the digital provision of medical information.

The Food and Drugs Act (F&DA) in Canada outlines restrictions of prescription medicines advertising, specifically:

> **Promotion of a prescription drug** (Schedule F) to the general public is **limited** to **name, price** and **quantity** (Section C.01.044 of the *Regulations*).
>
> A drug (prescription or nonprescription) may not be advertised to the general public for the treatment, preventative or cure for any Schedule A disease (Section 3 of the *Act*).

The "Guidance on distinction between advertising and other activities for health products", a guidance document published by Health Canada, clearly states that medical information in response to an unsolicited request is not considered advertising. However, it does not provide a digital framework for the delivery of medical information. This gap leads to reliance on established promotional guidelines that are unsuitable for a non-promotional function. In Canada, such guidelines include "Electronic media in prescription drug labelling guidance," as well as Pharmaceutical Advertising Advisory Board's (PAAB) "Guidance document for Online Activities," and the 2024 PAAB Guidance on Gating Mechanisms for Healthcare Professional Targeted Digital Assets. [2,12,13,14] They provide guidance and examples on gating mechanisms to restrict access to promotional content.

PVN-MI NETWORK

The Pharmacovigilance and Medical Information Network, a Canadian non-profit organization incorporated in 2020, provides its over five hundred members with a platform to discuss practical solutions with industry peers and regulators. The organization has taken the lead in strategizing solutions to accelerate how Canadian HCPs and patients/caregivers can access timely and accurate medical information.[3]

The PVN-MI Board collaborates with Medical Information consortia from other jurisdictions, such as the US Pharma Collaboration for transparent Medical Information (phactMI) and (Medical Information Leaders in Europe (MILE). Recently, MILE published a guidance document to provide a framework for MI functions to develop digital resources for HCPs.[1] The purpose of this document is to build on the recommendations by MILE in a manner consistent with the specific nuances of the Canadian regulatory environment. This proposed framework outlines the principles for provision of digital MI platforms for Canadian HCPs and patients/caregivers.

In proposing this framework of principles, the PVN-MI maintains the importance for all pharmaceutical companies to comply with applicable federal regulations, legal requirements and integrity commitments.

GUIDING PRINCIPLES

This framework focuses on four guiding principles which include:

1. **Optimal User Experience**
2. **HCP Authentication**
3. **Surfacing Scientific Content**
4. **Content**

This framework applies a range of standard definitions which are defined in Table 1.

Table 1: Glossary

Term	Definition
Digital	For this framework, PVN-MI considers "digital" to refer to the provision of medical information content and services via digital and online platforms (e.g., apps, websites, chatbots, voicebots), excluding social media
Medical Information (MI)	Medication, device, or therapy information. This may be scientific, clinical, technical, or pharmaceutical
Off-Label	Information which relates to the use of a product outside of the conditions described within the approved Terms of Market Authorization (TMA) (e.g., beyond the approved therapeutic indications; information relating to special populations, dosing, or method of administration, which is beyond the current, approved TMA
On-Label	Information that is aligned with or supports the use as described within the current, approved Terms of Market Authorization
Product Monograph, Product Label, Terms of Market Authorization	Canadian regulatory document describing the approved conditions of medicines use
Scientific/Standard Response Documents (SRDs)	Product or therapy specific content created by the MI function in response to an MI inquiry
Word Stemming	By reducing words to their root, algorithms can identify relevant information regardless of prefix or suffix (e.g., stemming hepatitis, hepatology and hepatologist to hepatic)

OPTIMAL USER EXPERIENCE

Modern technology can enhance the user experience of MI services. It is important to consider the accessibility of services, the discoverability of content and, its suitability for digital channels. The Pharmacovigilance and Medical Information Network recommend that the design principles shared below should be considered to optimise the user experience.

ACCESSIBILITY

- Platforms clearly indicate the intended audience (i.e. HCP vs patient/caregiver audience)
- Appropriate language for the intended audience. Platforms or websites comply with Canada accessibility laws (e.g. Bill C-81) and guidelines (e.g. Web Content Accessibility Guidelines (WCAG))
- Straightforward verification for HCPs to get access to MI content (see section on HCP Authentication)
- Platforms are simple to understand and easy to navigate.
- Easy connection with the MI function for support if users cannot find the answer to their medical inquiry
- Websites deliver a consistent experience across devices (mobile responsive design)
- Content available in both official languages (English and French)

DISCOVERABILITY

- On label/consistent with label information could be indexed and retrievable through search engines (e.g. Google)
- Clear signposting from company corporate, commercial, and medical resources to digital MI platforms and services
- Straightforward access to content through free-text search, guided searching, natural language processing and artificial intelligence (AI) (see section on Surfacing Scientific Content)

SUITABILITY FOR DIGITAL

- Content designed for digital use (e.g. concise SRDs which are not too long and application of progressive formats such as videos, infographics, podcasts, etc.)
- Integrity of hyperlinks should be ensured

HCP AUTHENTICATION

In the context of providing digital medical information, PVN-MI considers self-validation as a suitable method to identify the intended audience, be it HCPs or the public. This approach is consistent with the procedures of MI contact centers, which rely on self-attestation when individuals initiate contact through traditional channels such as telephone or email. Individuals would only be required to declare their HCP status without additional authentication. PVN-MI is aligned with the view that, as MI provides non-promotional information, self-attestation is a sufficient gating mechanism. This approach does not violate direct-to-consumer advertising prohibitions because MI services are distinct from advertising.

While pharmaceutical companies should implement guardrails to limit content access to the intended audience, users also bear a personal responsibility to correctly identify themselves.

Companies should provide clear signposting to MI services and/or relevant resources to the general public and patients/caregivers, which further reduces the risk of inappropriately accessing HCP online resources. For example, companies could clearly indicate on certain content, 'This information is intended for healthcare professionals only.'

Advantages for end users and companies in implementing self-validation on digital MI platforms include:

- **Avoiding Significant Access Hurdles:** Self-validation eliminates time-consuming and cumbersome registration processes, thereby offering HCPs and patients/caregivers straightforward access to MI content. This deters the need for individuals to turn to other digital, potentially unauthoritative, but easy to access resources.
- **Alignment with HCPs Expectations:** HCPs expect easy access to information in a digital environment.
- **Improved Discoverability:** Self-validation eliminates registration mechanisms that could hinder the discoverability of on-label/consistent with label content on MI websites through search engines,
- **Maintaining High Standards:** Medical information content from a pharmaceutical company about its medicines is coming from a source of truth (TMA) and the information provided is held to a much higher standard than information from third party websites.

SURFACING SCIENTIFIC CONTENT

The PVN-MI network proposes that digital MI platforms (i.e. websites) should be able to compliantly surface scientific content and patient information online to deliver a positive user experience if the following principles are adhered to:

GENERAL PRINCIPLES

- Digital MI services align with industry best practice MI standards (i.e. evidenced-based, unbiased, accurate, balanced, referenced, up-to-date, unsolicited, non-promotional and responses should be specific to the question).
- Digital MI platforms must exclude any disguised promotion and only include judicious use of the brand name to enable initial retrieval and proper identification of relevant information relating to the product.
- Companies consider potential linkage issues between digital MI platforms and promotional content
- Off-label content for HCP audience should not be indexed by external search engines (ex. Google) and should only be available directly on the MI website behind a robust search functionality (see section on Free-Text and Voice Search Functionality).
- Patient information, including technical information (e.g. excipients, presence of latex, etc.) and device troubleshooting that is consistent with the TMA should be available in accordion/drop down format.
- Information consistent with TMA may be accessible through search engines, guided searching, or site navigation.

Search algorithms and tools should be designed with sufficient sophistication to ensure the appropriate level of specificity. Ideally, search algorithms should account for word stemming, medical synonyms and abbreviations.

FREE-TEXT AND VOICE SEARCH FUNCTIONALITY

A free-text search and or a voice-based content retrieval functionality offers an appropriate method to ensure that results are surfaced only when specifically requested using appropriate terminology by an HCP. Therefore, it is PVN-MI's proposal that both on- and off-label content should be made accessible to HCPs through these functionalities, to the extent necessary to answer specific questions about a particular medicinal product. These systems typically work by indexing specific attributes of the scientific content (title, keywords), full-text indexing of the entire document, or using natural language processing. Specific attributes can then be weighted or mandated to ensure only relevant content is returned.
For patient information, only on-label/consistent with label content should be accessible through free-text and voice search functionality.

UNSOLICITED NATURE

PVN-MI considers the digital provision of MI unsolicited in nature in the following circumstances:

- Healthcare professionals must proactively initiate searches for scientific content, based on their specific information needs.

- Companies should ensure that strategies in place to maintain content specificity (see next section on Ensuring Specificity).
- If SRDs are being provided, companies should limit search results to display only document titles or succinct summaries that support HCPs in identifying content relevant to their needs. Additionally, HCPs should be required to perform another proactive step by selecting content that matches their information need, demonstrating the request for information was intrinsically motivated.

ENSURING SPECIFICITY

Companies should demonstrate that they have put strategies in place to ensure specificity. Depending on the type of content provided, companies may need to deploy more stringent tactics to ensure specificity. These could include (not limited to):

- A product name should always be included to retrieve scientific content aligned to that product.
- Develop search algorithms that are systematic, logical, non-arbitrary, objective and support surfacing content with high relevancy.
- A process for search enhancement. This could include periodic reviews of search terms and search results to ensure relevancy or limiting the number of search results.
- Implementing natural language processing taking the above into account.

ADHERENCE TO MI STANDARDS

In the digital context it is important to recognize that search algorithms cannot guarantee 100% specificity. It is PVN-MI's position that if companies deploy the above-mentioned strategies coupled with the HCPs proactive search, it supports adherence to MI standards.

ON-LABEL INFORMATION

Medical information content supporting the current Health Canada approved TMA may be published on digital MI platforms without specific search logic and could be retrievable by search engines, in alignment with overall MI standards.

Digital MI platforms (i.e. websites, chatbots, etc.) supporting patients/caregivers may offer topics that contain information from the current, approved Product Monograph (e.g. through 'Frequently Asked Questions (FAQs),' which guide patients/caregivers through fixed menu options to obtain the response to their enquiries). The demand for these topics has been demonstrated, for instance, through high enquiry volumes on other channels, making them appropriate for inclusion in these tools. Topics could also be included based on their importance. In these scenarios, the patient/caregiver remains in control of the information they choose.

When providing scientific content, companies should ensure that upfront displays of information only include relevant information for the purpose of content navigation. There must be a proactive response from the patient/caregiver to retrieve the full information. To access content relating to a specific product, the patient/caregiver must always indicate which product their inquiry concerns. It is PVN-MI's position that if patients/caregivers are required to proactively obtain the information, digital MI platforms housing tools such as FAQs or chatbots, are adherent to the MI standards.

CONTENT

To ensure appropriate adherence to MI standards, scientific content on digital MI platforms should adhere to the following:

- The content provided should be up-to-date, referenced, evidence-based, unbiased, accurate, balanced, unsolicited, non-promotional, specific, and relevant to the information being sought by the HCP or patient/caregiver.
    - Where content from the current, approved Product Monograph is used, reference to the document should be easily accessible.
- The content offered should contain clearly visible and appropriate disclaimers and/or statements to comply with organizational processes. Examples could include informing HCPs of potential off-label use, indicating that the data provided is intended to inform HCPs in their clinical decision-making and does not constitute medical advice, or informing patients/caregivers that the content is not offering medical advice and that they should consult their HCP.
- Digital resources include clear signposting on reporting potential adverse events and/or product quality complaint information.

The PVN-MI recognizes the sensitivity of providing access to information relating to off-label use through digital MI platforms. To ensure the appropriate provision of off-label information in response to specific unsolicited questions from an HCP, PVN-MI recommends that such information should only be accessible behind a robust search functionality and not indexable by external search engines Digital MI platforms intended for the general public would exclude off-label information and only provide on-label/consistent with label information.

The PVN-MI also recognizes there are topics that are not specifically described within the Product Monograph, which could be important for the safe and effective use of medicines (e.g., excipients, presence of latex, and other technical information etc.). It is PVN-MI's position that these are consistent with the TMA and therefore should be as accessible as information within the Product Monograph for HCPs and the general public.

Companies should implement internal mechanisms for monitoring and evaluating of the platforms and content to ensure compliance with federal regulations, MI standards, and integrity commitments.

CONCLUSIONS

The proposed framework by the PVN-MI, building upon the MILE framework, represents a significant advancement in the digital provision of medical information (MI) for healthcare professionals (HCPs) and patients/caregivers in Canada. As the digital landscape continues to evolve, it is imperative that pharmaceutical companies adapt to meet the increasing demand for reliable and accessible MI services through digital channels. This framework provides a comprehensive set of guiding principles designed to ensure that MI services are non-promotional, evidence-based, and accessible, while also maintaining compliance with Canadian regulatory standards.

The framework emphasizes the importance of optimal user experience, which includes ensuring that MI platforms are accessible, easy to navigate, and available in both of Canada's official languages. The principle of HCP authentication is crucial to maintaining the integrity of MI services, ensuring that sensitive and specific medical information is accessible only to qualified professionals. By implementing self-validation methods, companies can provide HCPs with easy access to MI content without the cumbersome barriers of traditional registration processes.

The surfacing of scientific content is another critical component of the framework. Digital MI platforms must be designed to deliver accurate, up-to-date, and relevant information while avoiding any form of disguised promotion. The use of sophisticated search algorithms and free-text search functionalities ensures that HCPs can retrieve specific information efficiently, supporting their clinical decision-making processes.

The COVID-19 pandemic has underscored the necessity of reliable digital MI services, as misinformation can rapidly spread through unregulated online sources. The framework addresses this challenge by promoting the visibility and discoverability of Canadian MI websites and on-label/consistent with label content, thereby reducing the reliance on potentially inaccurate information from non-Canadian or unregulated sources.

Looking forward, the successful implementation of this framework will require ongoing collaboration among Canadian pharmaceutical companies, regulators, industry associations, and healthcare professional bodies. By working together, these stakeholders can refine and enhance the framework, ensuring it remains relevant and effective in the face of evolving digital and regulatory landscapes.

In conclusion, the PVN-MI framework sets a forward-looking standard for the digital provision of medical information in Canada. It aims to bridge the gap between traditional MI services and the modern digital needs of HCPs and patients/caregivers, ultimately supporting better patient care through the availability of accurate, unbiased, and easily accessible medical information. As the digital transformation of healthcare continues, this framework will serve as a foundational guide for Canadian pharmaceutical companies striving to meet the needs of HCPs and patients/caregivers in a compliant and effective manner.

DECLARATIONS

This paper has been adapted from *A Principles Framework for Digital Provision of Medical Information for Healthcare Professionals | Pharmaceutical Medicine (springer.com)*[1], which has been published under Open access (see Deed - Attribution-NonCommercial 4.0 International - Creative Commons).

DISCLAIMERS

The views expressed in this publication are those of PVN-MI and are not necessarily those of the authors' companies or other member companies. While PVN-MI has taken every effort to provide informed and professional guidance, this publication does not constitute legal advice. Individual pharmaceutical companies are responsible for their own decisions, and PVN-MI is not accountable for the interpretation or implementation of this guidance.

REFERENCES

1. Mohamed S, Dunnett S, Flores Á, Loew E, Stefne Pienaar. A Principles Framework for Digital Provision of Medical Information for Healthcare Professionals. Pharmaceutical Medicine. 2023 Mar 1;37(2):103–9.
2. Health Canada. Guidance on distinction between advertising and other activities for health products: Overview [Internet]. Government of Canada. 2023. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents/policy-distinction-between-advertising-activities.html
3. Rizos J, Noué MA, Quinn D. Collaborating as Industry to Improve HCP Access to Medical Information. PVN-MI Network. 2021 Sep;
4. Goettner K, Hermes-DeSantis ER, Kelsch G, Oreper J, Pandya K, Rai R. Patient Focused Whitepaper. PhactMI [Internet]. 2024 Feb 9; Available from: https://www.phactmi.org/api/assets/files/patient-focused-white-paper.pdf
5. Hussain A, Ali S, Ahmed M, Hussain S. The anti-vaccination movement: A regression in modern medicine. Cureus [Internet]. 2018 Jul 3;10(7):e2919. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6122668/
6. Office of the Surgeon General (OSG). Confronting Health Misinformation: The U.S. Surgeon General's Advisory on Building a Healthy Information Environment [Internet]. PubMed. Washington (DC): US Department of Health and Human Services; 2021. Available from: https://pubmed.ncbi.nlm.nih.gov/34283416/
7. Erku DA, Belachew SA, Abrha S, Sinnollareddy M, Thomas J, Steadman KJ, et al. When fear and misinformation go viral: Pharmacists' role in deterring medication misinformation during the "infodemic" surrounding COVID-19. Research in Social and Administrative Pharmacy. 2020 May;17(1).
8. Perlis RH, Lunz Trujillo K, Green J, Safarpour A, Druckman JN, Santillana M, et al. Misinformation, Trust, and Use of Ivermectin and Hydroxychloroquine for COVID-19. JAMA Health Forum [Internet]. 2023 Sep 29 [cited 2023 Oct 4];4(9):e233257. Available from: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2809985
9. Hermes-DeSantis ER, Hunter RT, Welch J, Bhavsar R, Boulos D, Noue MA. Preferences for Accessing Medical Information in the Digital Age: Health Care Professional Survey. Journal of medical Internet research [Internet]. 2021 [cited 2023 Mar 12];23(6):e25868. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8386376/
10. Rennick RE, Barrias A, Davies J, Jan De Wit, Eggert S, Flores A, et al. To Surf or Not To Surf? - Accessing Reliable, Accurate Medical Information. Journal of General Practice. 2019 Jan 1;7(2):1–5.
11. Hua S, Jin S, Jiang S. The Limitations and Ethical Considerations of ChatGPT. Data intelligence [Internet]. 2023 Dec 21;6(1):1–38. Available from: https://direct.mit.edu/dint/article/6/1/201/118839/The-Limitations-and-Ethical-Considerations-of
12. Pharmaceutical Advertising Advisory Board. Online Activities [Internet]. 2021. Available from: https://www.paab.ca/resources/online-activities/
13. Pharmaceutical Advertising Advisory Board. Guidance on Gating Mechanisms for Healthcare Professional Targeted Digital Assets [Internet]. 2023. Available from: https://www.paab.ca/resources/pdfs/Guidance%20on%20Gating%20Mechanisms%20for%20HCP%20Targeted%20Digital%20Assets.pdf
14. Pharmaceutical Advertising Advisory Board. Gating Mechanisms for HCP Digital Assets [Internet]. 2023. Available from: https://www.paab.ca/resources/gatingshortdoc/