Best Practices in Medical Information

Guidelines for Industry - Handling Requests for Medical Information in Canada.

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On behalf of the Pharmacovigilance and Medical Information network – Canada (PvN)

The mission of the Pharmacovigilance and Medical Information network - Canada (PvN) is to help shape the future of Pharmacovigilance and Medical Information by providing our members across Canada with an environment to meet and discuss practical solutions with industry peers and regulators to enable ongoing improvements.
Members are Pharmacovigilance and/or Medical Information professionals from Canadian pharmaceutical companies, responsible for developing and deploying the drug safety and medical information strategies within their organizations.
The philosophy behind our group is to:
- Describe and develop the future role for Drug Safety and Medical Information in Canada.
- Provide a platform for members to learn and share from one another in an open environment.
- Provide information to measure operational and organizational performance in a comparable manner.
- Encourage members to be more proactive.
- Share current ways of working and develop best practices.

Foreword

High quality, accurate, unbiased, and up to date information about medicines is essential for their safe and effective use in treating patients. Pharmaceutical companies' Medical Information teams are a leading source for such information and should be viewed as one of the most reliable sources for medical information on their products. The Medical information department is a customer facing team that helps improve the safe and effective use of a company's products by providing fair-balanced, non-promotional information in a timely manner to healthcare professionals and patients.

Appreciating the need for high standards in the provision of medical information in Canada, a working group within the Pharmacovigilance and Medical Information Network – Canada has proposed the following guidelines. The intent is that pharmaceutical companies across Canada adhere to the spirit of these guidelines as they pertain to the role of medical information.

When using these guidelines, it is essential to consider that:

- They contain general principles on Medical Information practice across Canada, within the context of a pharmaceutical/biotechnology company.
- They should not be regarded as complete and exhaustive.
- They have not been endorsed by Health Canada
- It is important to ensure that actions are compliant with Health Canada recommendations, the Canadian Food and Drugs Act & Regulations, Innovative Medicines Canada's Code of Ethical Practices, The Personal Information Protection and Electronic Documents Act, the Copyright Act of Canada, as well as legal and regulatory corporate requirements.

These guidelines have been developed with the understanding that they may require periodic revision to keep pace with evolving practices. Feedback from all parties interested in the provision of medical information in Canada is encouraged.

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Scope

These guidelines provide assistance to Market Authorization Holders (MAHs) in Canada with respect to handling requests for medical information originating from customers. Requests pertaining to both marketed and investigational products are within the scope of this document: In particular, the following situations are addressed:

- Solicited vs unsolicited requests
- Consumers vs health care professionals requests
- On label vs off label requests
- Media requests
- Social media requests
- Third party requests
- Patient Associations requests

Note that only requests originating from within Canada and pertaining to drugs authorized or under investigation in Canada are within the scope of this document. For foreign requests please refer to guidelines pertaining to the respective regions.

Abbreviations and Definitions

Abbreviations and definitions for a number of terms used in this document are set out below.

Adverse event (AE): Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Certain instances that may lead to increased risk of an adverse event also should be reported. These include, among other things, medication errors, such as incorrect prescribing, as well as any situation in which a fetus or baby may have been exposed to a product during pregnancy or breastfeeding.

For marketed medicinal products in Canada, this also includes special situation events such as unusual failure in efficacy, exposure at conception or during pregnancy/breastfeeding, medication error, overdose, abuse or misuse. Reports of off label use of a medicinal product are also captured, even if not associated with an adverse event.

We may learn of product issues in many ways – for example, through telephone calls, websites, information received from programs and studies, or in meetings or conversations. This information must be forwarded to the local drug safety unit or an appropriate contact within the required timeframe. In general, colleagues must forward all reports within 24 hours of awareness from when the information is first received.

Copyright: The sole right to produce or reproduce a work or a substantial part of it in any form.

CPS: Compendium of pharmaceuticals and specialties

Customer Feedback: Any communication (verbal, electronic or written) from a healthcare professional, consumer, patient, medical representative, other reporter, or distributor, which is a suggestion or opinion regarding a product, but does not allege any product deficiencies or defects.

CRM: Customer relationship management

FAQ: Frequently asked question

Inquiry/Request: A question or group of questions, received via the same source at the same date and time. It could be one phone call, one email, one fax, etc.

Inquirer: The person the inquiry/request originates from.

Health Care Professional (HCP): A physician, nurse, pharmacist, dentist or a professional belonging to other health related professions; Health Canada defines a qualified HCP as a person who is a member in good standing of a professional medical, nursing, pharmacists' or other health care practitioner association and entitled to provide health care under the laws of the jurisdiction in which the person is located and other individuals retained by the MAH who have the appropriate health care education and therapeutic expertise.

On Label request: A question or group of questions concerning the use of a product within the approved indication, dosage, combination, and patient population as described in the product monograph; Company employees may only promote their products in a manner that is consistent with the approved label (product monograph).

Off Label (OFL) **Request: Non approved use;** question or group of questions concerning the use of a product not consistent with the indication, dosage, or patient population described in the product monograph; requests about investigational products are also within the scope of OFL. All unsolicited requests for information concerning OFL uses are to be referred to companies' Medical or Medical Information teams.

Media Inquiry: An inquiry originating from journalists or members of the press.

Medical Information Inquiry: A medical question related to medicines or medical devices. The medical inquiries may contain adverse events and/or product complaints.

Receiver: A company employee who first receives the inquiry. For example if a physician asks a sales representative a question about a product, the physician is the inquirer and the sales representative is the receiver.

Product Complaint (PC): Any deficiency related to the quality attributes of a medicinal product or device (i.e. identity, strength, purity, appearance or damage) as well as recall and deviation inquiries.

Unsolicited request: an unsolicited request is one where the customer's question has not been prompted. Unsolicited requests are those initiated by persons or entities that are completely independent of the company.

Non-public unsolicited request: A non-public unsolicited request is an unsolicited request that is directed privately to a company using a one-on-one communication approach. *Example:* An individual calls or e-mails the medical information staff seeking information about an OFL use.

Public unsolicited request: A public unsolicited request is an unsolicited request made in a public forum, whether directed to a company specifically or to a forum at large. *Example:* An individual posts a question about OFL use of a specific product on a company's controlled website (or a third-party discussion forum) that is visible to a broad audience.

SOP: Standard operating procedure

Solicited request: a solicited request is one that has been prompted by someone working for (sales representative for example), or acting on behalf of the company. *Example: If a speaker (e.g., key opinion leader), presents data at a company-sponsored key promotional event and attendees then ask or submit requests for more information, these requests would be considered solicited requests.*

GENERAL CONSIDERATIONS

- **Access to the medical information service**

Companies must have a clearly identified function to handle medical inquiries. Medical information (MI) teams at pharmaceutical and medical device companies primarily respond to unsolicited inquiries about the company's products. Inquiries can originate from healthcare providers, patients, scientists or any individual inquiring about MI regarding the company's products. In Canada, the MI team must be able to provide the service in both French and English. The contact information for MI should be made easily accessible to the customers via any or all of the following channels, e.g. the company directory and website, wallet cards, customer relationship management systems (CRMs), third-party directories (CPS/eCPS).:

1- Company directory

The MI contact could be listed in the companies' phone directories. Where appropriate, a direct dial number to MI or an email address should be used.

2- Business cards

Many medical inquiries are received via company representatives. Wallet cards displaying MI contact information (email, phone, website if applicable, and fax) can be provided to field representatives for easy access to MI.

3- Company websites

As customers routinely seek medical information online, it is recommended that company sponsored websites include contact information for MI.

4- Third party directories (CPS/eCPS)

The contact information of the MI service should be made available in appropriate publications such as the Compendium of Pharmaceuticals and Specialties (CPS/eCPS), and key professional associations such as the Canadian Pharmacists Association (CPhA).

5- Product labels

MI contact information may also be listed on the product labels.

- **Key activities**

The MI function is often responsible for some or all of the following activities:

- Intake and response to unsolicited inquiries concerning marketed or investigational products
- Creating and maintaining scientific response documents and frequently asked questions (FAQ)
- Keeping abreast of scientific literature
- Staffing MI booths at conferences
- Review of promotional material
- Review of Product monographs
- Developing slide decks for the organization or customers
- Support in maintenance of hospital formulary documents
- Literature reviews/source articles
- Support of formulary submissions
- Competitor reviews
- Training of staff on products and disease states
- Reporting of AEs, product complaints and customer feedback associated with MI inquiries
    - In general it is recommended that MI work in close collaboration with other departments; including participating in product launches, sharing customer insights, being informed of new promotional campaigns as well as of key medical activities since these could prompt an increase in customer inquiries.
    - If part of the MI service is outsourced, procedures should be in place to ensure that the third party service level meets the company's and industry standards.

- **Medical Information Support at Conferences**

MI support is often provided by companies at their exhibition booths at scientific congresses. Appropriate procedures may be in place for supporting congress booths. To avoid breaches of promotional code of practice, the following principles should be followed:

- The MI booth should be discrete in comparison with the commercial stand.
- Ensure a physical separation and demographic split between the commercial area and the MI booth.
- For conferences taking place in Canada, locally based MI personnel may be available at the booth (or remotely via virtual means) to respond to or have systems in place to facilitate/channel requests from Canadian HCPs.
- For international conferences taking place in Canada, global MI personnel may also be available at the booth or remotely to answer or route foreign requests.
- Ensure the product monograph, when applicable, is upon request.
- MI services provided at the booth may include responding to information requests or providing clinical literature or copies of scientific articles. In this case copyright issues should be considered.
  It is important to ensure that the dissemination practices for materials at the booth are consistent with the rules of the congress and the code of practice for the host country.
- Use local medical and regulatory guidance to approve MI booth materials.
- Companies can consider making available approved standard response letters for Canada (electronically or in paper format) as long as this service does not breach the promotional codes (e.g. off label use). Appropriate disclaimers should be included.
- If a discussion with a HCP at a booth reveals an adverse event, a special situation event, or product complaint, it should be forwarded to the Pharmacovigilance department and/or the relevant department as per the company SOPs. This might include taking an initial report and providing a blank reporting form for follow up. The MI staff should collect as many details of the adverse event as possible and ensure the source documentation is sent to the pharmacovigilance department. Ideally, sent through an electronically validated process.

MANAGING INQUIRIES

- **Unsolicited versus solicited requests**

MI teams are responsible for responding to unsolicited medical inquiries. MI should not respond to solicited requests, mainly because of the risk to be perceived as undertaking promotional activities. This risk is greatest for requests on off label uses.
Best practices utilized by some companies to document the unsolicited nature of a request, include:

- Representatives may be required to obtain a signature on requests for information from healthcare professionals (HCPs).
- Electronic requests (e.g. via email or CRM system) may require some form of validation from the representative or a disclaimer to indicate the request is not solicited.
- Representatives could be asked to provide with each request the HCP's name, profession, and contact details (e.g. Phone and e-mail)

- **Inquiries from consumers/patients**

Patients are becoming increasingly aware of and involved in their own medical care. Many health information and patient organizations exist in Canada. It might be appropriate to communicate, where relevant, contact information for patient organizations and disease societies to consumers so they might obtain more information about specific

conditions. When responding to patients' inquiries, the company should not recommend a treatment, nor suggest what their healthcare professional should do. Patients seeking a medical opinion should be referred to their health care provider.

Off-label

Consumers/patients requesting OFL information should be referred to their health care provider.

On label

Responses to on label inquiries from consumers should only be made using the product monograph and the patient leaflet. When responding to consumers it is important to use appropriate language and avoid jargon or complex medical terms. The information provided should be in accordance with the educational level (if provided) or perceived degree of understanding of the patient.

- **Inquiries from the media**

Occasionally, MI teams may receive inquiries from the media. Procedures should be in place to route such inquiries to the appropriate team, usually the communications department or corporate affairs.

- **Website / Social media inquiries**

Because the Internet is widely used to search for information about medical conditions and treatments, companies may receive public requests for information about their products through product websites, discussion boards, chat rooms, or other public electronic forums that they maintain/sponsor and over which they have full control. MI should strive to collaborate with owners of corporate or brand sites (ie. social media sites) in order to ensure any MI inquiries are released to MI. Firms may also encounter requests for information on third-party sites (i.e., websites and other venues that are either entirely independent of a company's control and influence or not fully controlled by a company). Questions may be directed to the website users at large, rather than specifically to a company.

MI teams may choose to respond to public unsolicited requests only when the request pertains specifically to the company's named product. A public response to a public unsolicited request for OFL information about its product should be limited to providing the MI contact information and should ***not*** include any OFL information. The public response should convey that the question pertains to an unapproved use of the product and state that individuals can contact MI with the specific unsolicited request to obtain more information. The public response should provide specific contact information for the MI team personnel so that individuals can follow up independently to obtain specific information through a non-public, one-on-one communication. Company representatives who provide these public responses should disclose their involvement with the company. The response should not be promotional in tone or content.

- **Inquiries linked to adverse events (AEs) or Product Complaints (PCs)**

When a medical inquiry is also associated with an adverse event (or a special situation event), the report should be forwarded to the Pharmacovigilance department and reported according to the company reporting standard operating procedure and Health Canada regulations. All MI staff must be suitably trained to recognize potential Adverse Events and Product Complaints and handle them appropriately.

Inquiries about AEs, overdose, off label use, medication error, maladministration, drug abuse, misuse, drug interactions, lack of drug effect or use during pregnancy involving patients should be handled in accordance to company standard operating procedures. Data privacy laws should be respected and personal data handled appropriately.

Similarly when a medical inquiry is associated with a product complaint, the complaint should be forwarded to the Quality department and handled according to the company PC procedure and Health Canada regulations. If applicable,

when a medical inquiry is associated with a customer feedback comment, it should be forwarded to the marketing department and handled according to the company's procedures and ISO Medical devices requirements. Please note the departments involved may vary in some companies.
Reconciliation of AE/PC reports between departments should be considered for inspection/audit purposes. Inquiries linked to AEs or PCs should be documented as such in the MI system and a reference number (AE or PC complaint number) should be added to the case in the MI System for reconciliation purposes.

- **Inquiries via third parties**

1- Sales representatives and other commercial staff

HCPs often ask questions about the products that sales representatives or other commercial staff discuss with them. If a representative cannot answer the request, either because it is OFL in nature, or beyond their knowledge level, it may be sent to the MI team. Commercial staff should be trained on relevant MI procedures. The MI team should communicate regularly with the commercial staff and use opportunities to maintain this relationship. Eg attending sales meetings.
It is important to ensure that sales representatives understand what MI can and cannot do, as well as the value that MI brings to the organization.

In particular, responses to off label requests from HCPs received via sales representatives are to be sent directly to the HCP from MI; the sales representative is not to be copied on the response; however the sales representative should be notified by MI when the response has been provided. Submission of OFL requests can be easily done electronically via most CRM systems, which allow for validation of the unsolicited nature of the query. Once fulfilled by MI, requests can easily be closed within the CRM system, and a notification sent to the sales representative.
Typically the response to the HCP would be a detailed letter, and may include enclosures (e.g. clinical articles, results of literature search, summary of studies).

It is good practice to:

- Monitor the number of requests.
- Ensure that the responses provided are specific and narrowly tailored to the questions asked based on standard responses.

A phone call to the HCP may be an appropriate method of fulfilling a request. This allows a more specific response, and allows for the HCP to ask further questions or discuss the topic in more detail. However, this approach can be time consuming as access to healthcare professionals may be limited due to their work demands.

Insights: It is considered good practice for MI to provide periodic reports that may include top level details of inquiries received by source/region/type to share with the rest of the company. Sharing this information with internal stakeholders including any identified issues or trends has the potential to impact the company's strategy and help improve its service offering and commitment to its customers. Reports should be tailored to business needs and preserve customer privacy and confidentiality.

2- Other

Medical inquiries may be received via other personnel including field medical personnel. The MI team should train other company staff as appropriate so that it is clear how MI inquiries are to be handled. Those are normally directed to the MI team or can be handled differently depending on the nature of the inquiry. Staff should refer to their company's SOP on MI handling.

- **Inquiries from health care professionals including Off label and inquiries regarding marketed and investigational products**

Requests for Clinical or Treatment Decision Advice
In response to a request for advice from an HCP, HCPs must be advised that the treatment decision remains their sole responsibility however the company should be as helpful as possible in sharing expertise, knowledge and information to aid treatment decision making.

Requests concerning OFL Uses or Unapproved drugs
Information may be supplied in response to unsolicited inquiries from HCPs related to off label or unapproved drugs. Objective, factual and non-promotional information can be provided to the HCP by the MI team, who must be made aware of the off label status. The prescriber should also be made aware that using a product outside its indication, its dosage or patient population is his/her sole responsibility.

Information on unlicensed/investigational drugs may be provided to HCPs upon request. Information may also be provided proactively to those involved in planning the introduction of new products (Eg. reimbursement bodies; scientific recommendation bodies). In general requests from HCPs regarding investigational compounds are answered with publicly available information. Any such information should not contain content that promotes (expressly or implicitly) the safety, efficacy or availability of investigational drugs. Pipeline presentations shall contain purely scientific information about the drug candidates, for example:

- The identity of investigational drug candidates (using the non-proprietary generic names).
- The development status of the investigational drug candidates.
- The status of the applicable clinical trials.
- The end points of those clinical trials.
- Non-confidential information about alliance partners from whom the company may have obtained rights to the drugs.
- Off label responses and any disseminated pipeline materials shall include appropriate statements and disclosures that certain information may relate to OFL uses, including, but not limited to a prominently displayed statement that the information concerns a use that has not been approved by Health Canada.

- **Inquiries regarding another company's or a third party's products**

Medical Information staff should not answer questions pertaining solely to another company's product. MI staff receiving inquiries concerning products that do not belong to the company's portfolio (even with the same active ingredient) should inform the requestor accordingly. As a courtesy and if known the MI contact at the other company can be provided, or the request forwarded. If there is a co-distribution agreement between two companies, one or both MI teams may be able to answer questions. A situation where information regarding a competitor's product would be provided as part of a response are questions pertaining to efficacy or safety comparison; or a drug interaction. In this situation, only publicly available information from the competitor's product monograph or comparative data from published literature data would be supplied.
In some instances a company might receive an inquiry about a global product for which they do not hold the authorization in Canada. The request may be directed to the company holding the MA in Canada or the company importing the product. In situations where there is a request for a company product not marketed in Canada but that is available in other countries, MI, sometimes in collaboration with the medical affairs department, would direct the HCP to contact Health Canada as per company medical governance procedure as it pertains to compassionate request/special access.

- **Information about company's products**

Companies should have procedures in place to ensure the most current product monograph is displayed in relevant hardcopy and electronic publications as well as on the company's website. Note this does not necessarily fall under the responsibility of Medical Information. In addition to Health Canada, details of changes to product monographs must be communicated promptly to all employees especially customer facing company personnel. Such changes could also be sent to publications and organizations such as the CPS/eCPS
Similarly when products are discontinued/withdrawn/divested, in addition to Health Canada, drug information centers could be notified. In the case of divested products, a procedure must be agreed for transfer of information to the new MAH in order to maintain an adequate MI service for the products involved.

- **Composition/content questions**

Allergens or religious belief are increasingly raising concern among consumers. Often MI teams will receive inquiries pertaining to the composition/content of a drug. It is often not recommended to state that a product does not contain a particular allergen in the absence of evidence ie if specific testing has not been conducted on the finished product. The use of statements such as "free," or "does not contain," could give users allergic to a specific allergen a false sense of security when using a medical product. In addition, the use of the term "free" or "does not contain" does not address the potential for accidental contamination during or after manufacturing. When responding to such requests, it is recommended that a consistent, scientifically accurate statement be used by all manufacturers wishing to convey that a specific allergen was not used as a material in the manufacture of the product or product container. An example of an acceptable statement would be **"Not made with.**" The disclaimer can also include: "The safety of (Product) has not been established in patients who are allergic to (ingredient)…"

OPERATIONAL CONSIDERATIONS

- **Procedures for handling medical inquiries**

Companies should have a clear process in place to receive/route/track medical inquiries. The majority of inquiries are usually received via phone or email; procedures should also be in place to cover inquiries by other means, e.g. fax, letters, digital. Procedures should be in place to ensure that customers are routed to the appropriate department as rapidly as possible. Whenever possible, the receiver should obtain the following information from the inquirer to ensure proper and timely handling of the request. Customer personal information should be handled in accordance to privacy laws.

- Full name of the receiver

- Date received

- Means of receipt (phone, fax, email…)

- Identity of the inquirer (patient/consumer, HCP, other)

- Product/dosage form (including lot number and expiry date when available)

- Question(s)

-Request type (on label, off label, AE, PC, other including investigational and not marketed/discontinued products)

- Preferred language (English or French)

Phone inquiries

- Calls should be answered with minimal delay. The use of answering machines should be avoided whenever possible when dealing with MI inquiries. Voice messages should be returned promptly.
- There should be a procedure to ensure coverage throughout office hours including lunch time as well as after-hours procedure for emergency inquiries.
- It is recommended for the company representative to identify themselves by name or department.
- Staff handling MI inquiries should be trained to recognize and process/escalate adverse events, special situation events, and product complaints.

Email inquiries

- E-mails should be checked daily during business hours, on a regularly established frequency. It is recommended that a general e-mail box be established for MI rather than for inquiries to be sent to an employee's email.
- It is preferable that emails are acknowledged if the response is expected to take more than 24h.
- A procedure should be in place to ensure urgent requests on safety or other sensitive topics are expedited.
- For global companies, inquiries received from outside of Canada and/or pertaining to a product sold outside of Canada should be forwarded to the appropriate affiliate; in case of co-marketing agreements in the same country between partners, there should be clarity in the agreement on which company is responsible for the MI service.
- If part of the MI service is outsourced, procedures should be in place to ensure that the third party service level meets the company's and industry standards.

Other inquiries (fax, letters): similar to emails, letters and faxes should be monitored regularly and dealt with promptly.

- **Requests for articles/reprints – copyright**

Articles are covered by copyright law and appropriate clearance should be obtained.
A disclaimer may be included when provided an article/reprint to an external customer, e.g.

Due to copyright restrictions this article is intended for your own personal use and we ask that you do not forward to additional recipients or print multiple copies for distribution.

Precise wording can be obtained from your library or legal department.

- **Internal review of medical information responses**

It is recommended to have an internal review and approval process in place for the review of MI response documents.

- **Use of disclaimers**

Standard disclaimers should be prominently displayed in MI responses. Some examples include:
General: *The safety, efficacy and quality of the products have been evaluated only for their use as stated in the approved product monograph. The information provided herein is intended to provide medical and scientific information. The Information is strictly non-promotional and does not provide medical or prescribing advice to health care professionals.*

The information provided is a response to an unsolicited request from a healthcare professional and is for such use only.

The information submitted is intended to assist health care professionals and patients in forming their own conclusions and making decisions, but may not represent a comprehensive listing of all available publications on the subject. The views and opinions expressed by the authors of the referenced studies do not necessarily represent the opinion of the Company.

Drug Interaction: *The treatment approach for patients who receive concomitant treatment with X and Y should be decided by their physician, based on an individual risk-to-benefit assessment for the patient.*

Off label: *The safety, efficacy and quality of the products have been evaluated only for their use as stated in the approved product monograph. The use of product X for Y indication is not approved by Health Canada.*

- **Medical Information resources**

MI teams provide written and verbal responses to inquiries. To increase efficiency and consistency within regions, scientific response documents and/or FAQ documents should be used to standardize the responses to inquiries. This is ideally achieved via a MI system or database accessible globally. MI teams must have a minimum set of up to date resources to enable them to provide comprehensive information for all the products they support. This may include product monographs, FAQs, and standard letters that can be developed globally and stored in a database. MI systems help MI teams provide better customer support, increase efficiency, track inquiries and responses, analyze inquiries, issue reports, and improve collaboration. In addition to ensuring that all team members are providing consistent responses globally (taking into consideration local regulatory differences), an MI system is also an important asset during inspections or audits. Published references on company products must be easily retrieved and access to relevant unpublished information should also be made available to MI staff including safety data (periodic safety update reports), stability data and clinical studies. A procedure must be in place to ensure that this information is kept current.

- **Qualification, training and reporting structure of medical information staff**

Qualification and training:
MI staff should have suitable qualifications and/or experience. This could include a degree in pharmacy, pharmacology or a life science or equivalent qualifications or experience. It is preferred that MI staff have clinical experience (medicine, pharmacy, nursing) to be able to address patient care related questions. Staff should have the required scientific and medical training to communicate complex scientific and clinical information and interact with healthcare providers.

MI staff should receive on the job training appropriate to their level of responsibility and have an up to date working knowledge of the therapeutic areas they support. They must also have detailed knowledge of the company products. It is good practice to maintain up to date job descriptions and training records for all roles.

Reporting structure:
MI teams are often part of the medical affairs department and report to the head of medical affairs or equivalent. MI teams may also report to External Medical Communications group. In smaller companies however the reporting structure may vary. In order to remain non promotional, MI teams should not report to a commercial group (eg. marketing or sales). MI teams in larger companies may also be divided into local (country, regional) MI teams and global medical information (GMI) teams. In smaller companies one country may be responsible for supporting the whole world with assistance from MI vendors/outsourced call centers.
Local MI team develops content and responds directly to inquiries from Canada.
Global Medical Information (GMI) teams create global content that local MI teams adapt to meet their local needs by changing the disclaimers and adding specific Health Canada approved labeling information. GMI may also handle escalated inquiries from the local team. GMI creates global MI policies. More companies are moving towards developing global MI practices, procedures, policies, and responses. Local MI teams may or may not have a reporting relationship

with global medical information. Most often it is an affiliate relationship. GMI would usually select the global MI database in partnership with local affiliates.

- **Code of conduct**

As a customer facing team, MI staff must demonstrate high standards of customer care with a helpful, responsible attitude and superior communication skills. Written responses must not contravene company policy or Health Canada requirements; all effort should be made to ensure responses are complete/comprehensive, accurate, fair-balanced and non promotional in tone and content, and within the scope of the Medical inquiry; comparisons between products must be based on an objective review of the scientific evidence and must reflect the evidence fairly and without exaggeration; the information must be relevant to the inquiry (narrowly tailored) and to the needs of the inquirer.

- **Records retention**

It should be agreed upon with the company's legal department what types of records should be maintained and for what length of time; in general MI shall maintain records for each request including but not limited to the following:

- An electronic copy of the written request and response provided including a list of any documents included with the response.
- An electronic copy of the approval of all off label responses.
- The request records and information recorded in the MI tracking system will be maintained according to the company's document retention policy.

- **Key Performance indicators**

MI teams should have appropriate systems in place to monitor performance and should carryout regular internal audits. MI departments are often involved during pharmacovigilance audits/inspections in order to verify that requests with safety components are appropriately tracked, routed and reconciled per adverse event/safety information reporting procedures. It is also becoming increasingly common for the MI department to be audited by internal Quality departments. When external vendors (call/contact centers) are used to provide MI, it is good practice to audit the third party as part of the vendor qualification process, as well as conduct regular audits thereafter. Systems should be in place to monitor quality and performance on an ongoing basis.

1- Response time

MI departments should strive to answer medical inquiries in a timely manner based on the individual customer's needs. Determination of response time should be patient centric. Acceptable timelines can be agreed upon with the requestor. They may be dictated by the product portfolio e.g. a rapid response time for medicines that are used in critical indications or stability questions. Urgent requests must be responded to in an appropriate timeframe even when staff availability is limited during office hours e.g. lunchtime or during department meetings. Companies should consider this in relation to their product portfolio, with particular regard to the potential risk to patients if information is not available in an appropriate timeframe.

Processes must be in place to quickly route phone inquiries to the right person.
Whenever possible, multiple communication channels should be made available to customers e.g. phone, email, video, fax, website, other.

2- Standard Response review cycle

It is considered best practice to review standard letters/responses periodically (for example every 6 month, 1 year, or 2 years), according to internal timelines and procedures, and taking into consideration the product lifecycle status.

3- Coverage

The expectation is that MI provide coverage during regular business hours. After hour coverage may be provided at each company's discretion based on their individual customers' needs. During business hours MI staff must be able to be reached with minimal delay when information is required urgently. There is no consensus on how quickly to respond to MI requests outside normal office hours or during public holidays. On call company staff or an answering service may be available to route urgent requests after hours.

4- Customer feedback/survey

It is considered best practice to gauge external customer satisfaction via surveys on an ongoing basis. Customers' views of the quality of service and information provided should be assessed regularly.
External surveys should assess:

- The completeness of the response
- The format of the response
- The timeliness of the response
- The quality of the response compared to other pharmaceutical companies (especially useful for benchmarking)
- How the information was used and what actions were taken as a result

It is also considered best practice for MI to conduct internal surveys of key internal stakeholders including field medical, sales representatives, and call center. Internal surveys should assess:

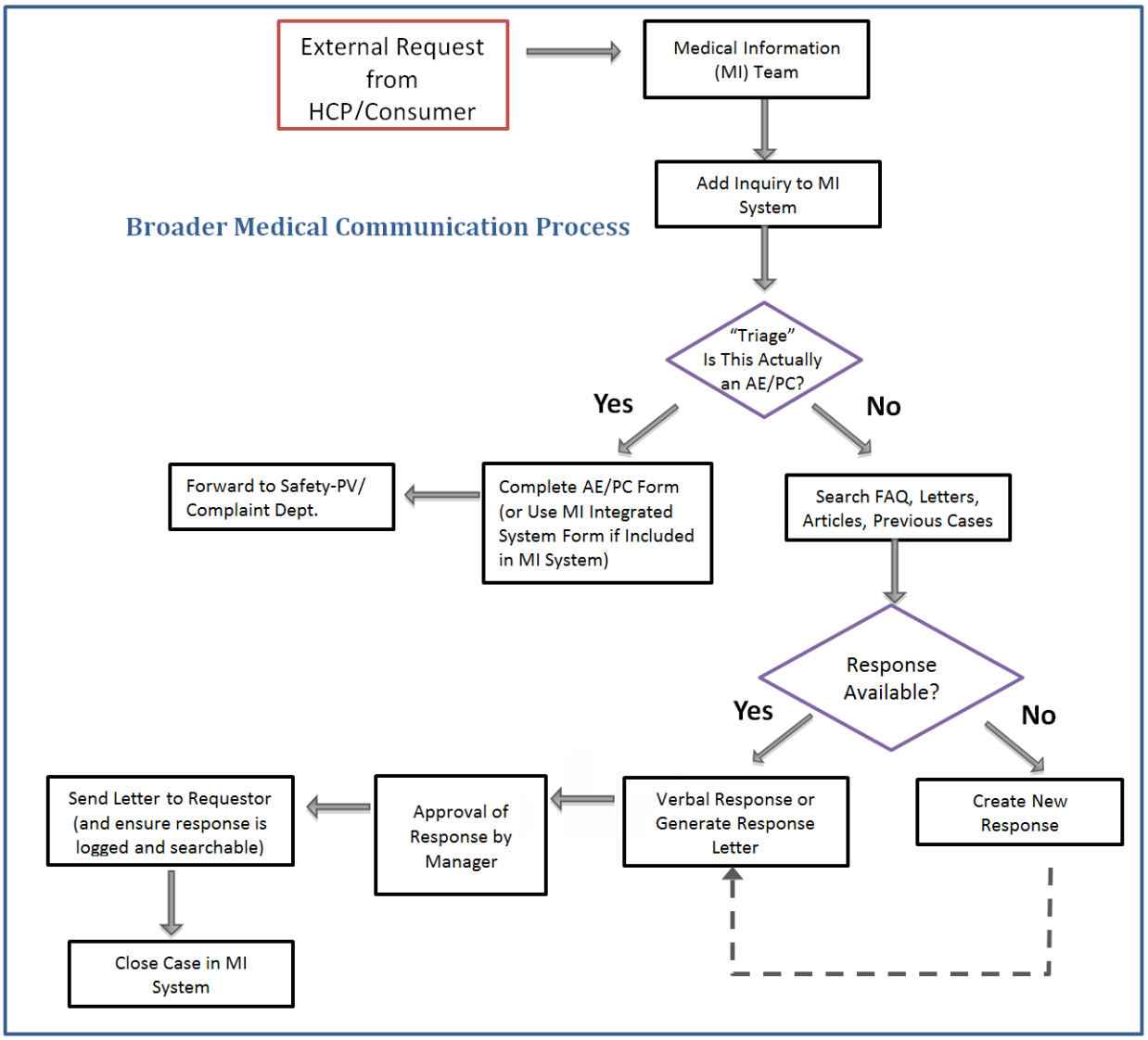
- Their satisfaction with the current support,
- Opportunities to improve/expand existing support
- Gaps/training needs
- Their usage of MI services, features and barriers to use

Any actionable insight should be addressed. Surveys can be a great tool for MI to demonstrate their value proposition and benefit to the organization.

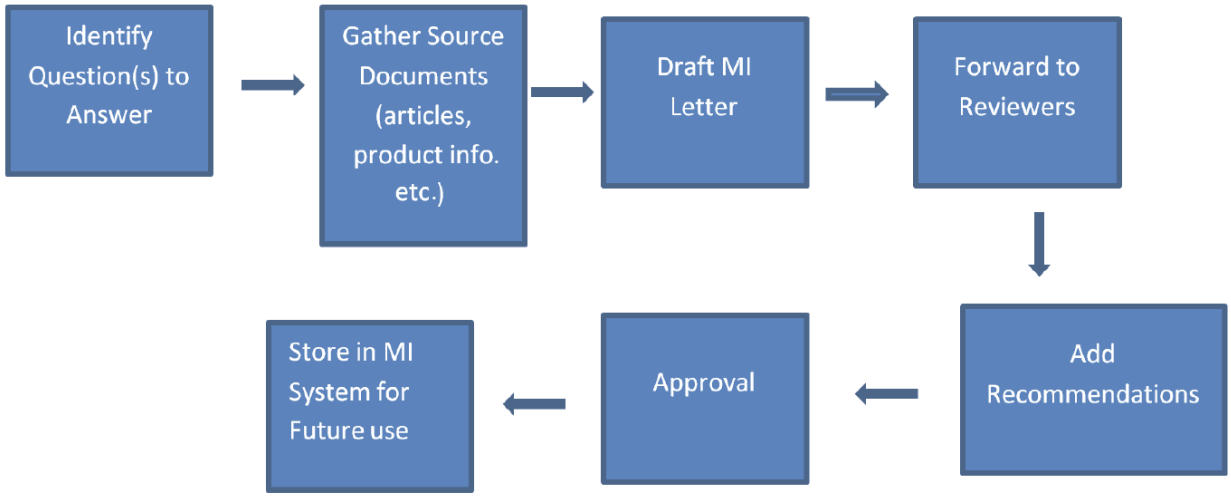
Appendices

Appendix A: Broader Medical Communication Process
Appendix B: Typical Medical Information Inquiry Flow

Appendix A


External Request from HCP/Consumer
Medical Information (MI) Team
Add Inquiry to MI System
Broader Medical Communication Process
"Triage" Is This Actually an AE/PC?
Yes
No
Forward to Safety-PV/ Complaint Dept.
Complete AE/PC Form (or Use MI Integrated System Form if Included in MI System)
Search FAQ, Letters, Articles, Previous Cases
Response Available?
Yes
No
Send Letter to Requestor (and ensure response is logged and searchable)
Approval of Response by Manager
Verbal Response or Generate Response Letter
Create New Response
Close Case in MI System

Appendix B: Typical Medical Information Inquiry Flow (when a standard response is not available)



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