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Drug and natural health products recall guide

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Canada

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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Également disponible en français sous le titre :
Guide pour le retrait de drogues et de produits de santé naturels

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Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

Table of contents

The following shows the three types of icons in this document, and the way they are intended to be used.

Important: Key or cautionary information for people to know.

Information: Supplementary information like quotes and legal references.

Tip: Things for people to do or understand.

About this document

1. Purpose

This guide is for anyone working with drugs or natural health products. It will help facilitate understanding and compliance with sections of the *Food and Drugs Act* (the Act), the Food and Drug Regulations (FDR) and Natural Health Products Regulations (NHPR) that relate to recalls.

Health Canada conducts compliance verification activities, including inspections, to assess compliance with the *Food and Drugs Act* and associated regulations. When conducting compliance verification activities, Health Canada will use this document as a guide in assessing compliance with the recall requirements.

Recall – A responsible party's removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates the Act or the Regulations.

Recalls are public information. Visit the Health section of the Government of Canada website to find information about each drug and natural health product recall, as well as:

- public advisories
- information updates
- notices to stakeholders
- communications to health care professionals

For information about a particular recall, search the Health product section of the Recalls and safety alerts database.

Specifically, this guide will tell you how to:

- notify Health Canada about a recall
- develop and execute a recall strategy
- submit a final recall report to Health Canada

If Health Canada believes you are selling a drug that poses a serious or imminent risk to health, Health Canada may order a recall pursuant to paragraph 21.3(1)(a) of the Act.

21.3 (1) If the Minister believes that a therapeutic product presents a serious or imminent risk of injury to health, he or she may order a person who sells the product to

- **(a)** recall the product

Therapeutic product –means a drug or device or any combination of drugs and devices, but does not include a **natural health product** within the meaning of the Natural Health Products Regulations;

For more information about our approach to regulatory compliance and enforcement, including measures we may take to enforce the rules, refer to our *Compliance and enforcement policy for health products* (POL-0001).

2. Scope

This guide covers the requirements for drug and natural health product recalls.

The requirements outlined in this guide apply to establishments that work with drugs or natural health products, such as:

- fabricators
- importers
- distributors
- packager/labellers
- wholesalers (for drugs only)

This guide does **not** apply to product withdrawals or stock recovery. Use these actions when there is no health and safety risk and there is no contravention of the applicable legislation, or the product has not been distributed.

To learn how to conduct recalls for medical devices, see the *Medical Devices Recall Guide* (GUI-0054).

3. Introduction

Drug and natural health product companies are required to follow rules related to product recalls. This guide provides information on how to comply with these rules.

Guides like this one are meant to help industry and health care professionals understand how to comply with rules and regulations. They also provide guidance to Health Canada staff, so that the rules are enforced in a fair, consistent and effective way across Canada.

Guides are administrative and do not have force of law: they allow for flexibility. Health Canada is open to considering other ways of conducting a recall, provided that your method satisfies all applicable regulations. If you wish to use a different approach, we encourage you to consult with Health Canada first to ensure you meet the requirements.

Guides are not intended to cover every conceivable case and will be subject to periodic reviews and updates. In the case of a discrepancy between this guide and the regulations, the regulations always take precedence. Read this guide along with the relevant sections of the Act, the FDR and the NHPR, as well as the relevant Health Canada guides and policies, including:

- *Compliance and enforcement policy for health products* (POL-0001)
- *Good manufacturing practices guide for drug products* (GUI-0001)
- *Good Manufacturing Practices Guidance Document for Natural Health Products*
- *Guide to Reporting Drug Shortages and Discontinuations* (GUI-0120)

To help ensure a health product is safe, effective and of high quality, Health Canada may:

- request relevant information or materials from your establishment

- define conditions under which a product may be recalled that are not specifically described in this guide

If you read this guide and still have questions about your responsibilities, you may contact Health Canada.

Guidance

4. Roles and responsibilities

Establishments in the distribution chain

Recall actions require collaboration: they could potentially involve all parties in the distribution chain. This chain begins with the manufacturer and proceeds sequentially through importers, distributors, wholesalers, retailers and consumers. The effectiveness of the recall process depends, in part, on the extent to which each party:

- understands its own roles and responsibilities
- defines and documents its expectations of other establishments
- communicates and shares recall information

Everyone in the distribution chain is responsible for:

- notifying their consignees (i.e. anyone who received, purchased or used the affected product) about the recall, as applicable
- returning, disposing of or correcting the recalled product

Quality Agreements with other parties in the supply chain including wholesalers, distributors or storage sites should clearly define the responsibilities for each party in the recall strategy.

Maintaining systems that support recall effectiveness

In addition, anyone conducting the activities listed below for drugs or natural health products must establish and maintain a system of control that permits the complete and rapid recall of any lot or batch of a product.

You should be able to initiate your recall procedures at any time, during or outside normal working hours.

For **drugs**, this requirement comes from section C.02.012 of the FDR. It applies to:

- fabricators
- packagers
- labellers
- distributors
- importers
- wholesalers

For **natural health products**, this requirement is stated in section 50 of the NHPR. It applies to:

- manufacturers
- packagers
- labellers
- distributors
- importers

To learn more about maintaining systems of control that support effective recalls, and to read the exact regulatory text for these requirements, see:

- Written systems of control (drugs)
- Operations (natural health products)

The responsible party

The responsible party takes the lead on initiating and overseeing a recall. Their responsibilities during a recall include:

- ensuring all of the affected product is effectively recalled

- ensuring that affected products, including products within their direct control and returned products, are identified and placed into quarantine until disposition is determined
- communicating about the recall with Health Canada which includes:
    - submitting an initial notification of the recall
    - communicating about the recall's progress
    - submitting a final recall report
    - responding to requests for evidence or further information

The responsible party for a **drug** recall could be the product's:

- manufacturer
- importer
- distributor
- person in Canada responsible for the sale of the product
- wholesaler

The responsible party for a **natural health product** recall could be the product's:

- manufacturer
- importer
- distributor
- licence holder

The responsible party for a drug or NHP may use a third party to carry out the requirements related to a product's recall. The responsible party must confirm the role of the third party to Health Canada in writing at the time of the recall notification.

Distributors and storage sites for natural health products must follow the good manufacturing practices, as defined in the NHPR; however, they are not required to hold a site licence. As per the Regulations, distributors are responsible for ensuring an effective recall system to the retail level.

The responsible party may wish to contract out certain tasks associated with conducting a recall. The responsible party remains accountable for the recall and is still the point of contact with Health Canada.

If you are the responsible party during a recall, you may be subject to compliance and enforcement actions in accordance with the Act and Regulations if you fail to:

- comply with the regulatory requirements
- effectively recall the affected product

Notifying Health Canada about the recall action

Responsible parties are expected to notify Health Canada at the time a risk to health, which may lead to the recall of a distributed health product, is identified, in accordance with the Act, the Regulations, and the *Recall Policy for health products* (POL-0016).

Per section C.01.051 of the FDR or section 25 of the NHPR, the responsible party must notify Health Canada after deciding to recall a drug or natural health product. The responsible party may submit this notification, along with required information, using the *Drug and Natural Health Product Recall Reporting Form* (FRM-0356).

For more specific guidance on how to notify Health Canada about a recall, refer to the Recall notification section in this guide. To read the exact regulatory text, see Section 6 (for drugs) and Section 7 (for natural health products).

Consignees

When consignees receive a recall notice, they should:

- Immediately carry out any instructions in the recall notice.
- Respond promptly to the responsible party, as requested.
- Extend the recall to their own consignees, when advised by the recall notice to do so.

Health Canada

Health Canada verifies that recalls initiated by the responsible party are conducted effectively and reported according to the Regulations.

5. Recalling drugs and natural health products

This section tells you how to complete all stages of a drug or natural health product recall. Unless stated otherwise, the following guidance is for the responsible party initiating the recall.

When a product has a potential health risk or contravenes the legislation Health Canada administers, you may need to initiate a recall for the product.

Health risk assessment

Before deciding to conduct a recall, you should:

- evaluate the risk associated with a product that presents a risk to the health of Canadians
    - assess the risk over the product's shelf life (i.e. both now and at the expiry date)
    - ensure your assessment accounts for any reported adverse reactions and intended use population
- assess whether there are contraventions of the legislation Health Canada administers

Use the results of your health risk assessment to assign a health risk classification (Type I, II or III) for the recall, as follows:

- **Type I:** Assign this type to a situation in which there is a reasonable probability that the use of (or exposure to) a recalled product will cause serious adverse health consequences or death.
- **Type II:** Assign this type to a situation where the use of, or exposure to, a recalled product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Type III:** Assign this type to a situation where the use of (or exposure to) a recalled product is not likely to cause any adverse health consequences.

Recall notification to Health Canada

You must notify Health Canada that you have decided to conduct a recall **forthwith** (for **drug products**) or **three days after initiation of the recall** (for **natural health products**). Health Canada interprets "forthwith" as within 24 hours of having made the decision to recall a drug

product. You may submit all required information using the online *Drug and Natural Health Product Recall Reporting Form* (FRM-0356). The form includes:

- name of the product
- affected lot numbers
- quantity of product manufactured, imported and distributed
- immediate actions you will take to address the product's risk to health
- reason for the recall
- health risk classification

Follow up your initial notification with a written report containing full information about the recall within 72 hours of the decision to recall.

If you are in the process of obtaining further information, forward it to Health Canada as soon as it becomes available.

Drugs: For a list of all information you are required to submit under section C.01.051 of the FDR, see Food and Drug Regulations reporting requirements for recall.

Natural health products: For a list of all information you are required to submit under section 62 of the NHPR, see Natural Health Product Regulations reporting requirements for recall. This requirement is also stated for every licensee in section 25 of the NHPR.

Health Canada also requests that you provide, where applicable:

- a detailed investigation report identifying the recall's root cause, when available
- any adverse reaction reports for the product
- distribution records for the affected lots
- any additional information that assists in identifying the recalled product
- a health risk assessment

You should identify any vulnerable populations that may be impacted by the recall (e.g. infants, children, pregnant women, surgery patients, immune-system-compromised patients). Indicate the recall's impact on available treatment for the indicated medical condition.

You should advise Health Canada of any potential disruption to product supply. Where applicable (see box below), you must take appropriate steps to advise Canadians of drug shortages by reporting drug shortages and discontinuations on Drug Shortages Canada. To learn about your specific responsibilities for reporting drug shortages, see our *Guide to Reporting Drug Shortages and Discontinuations* (GUI-0120).

For drug product recalls only: You should advise Health Canada if you consider the product you are recalling to be medically necessary. Health Canada requests that you consider the questions provided in Appendix B to determine whether your drug meets this definition. Provide this information to Health Canada using the Template for determination of medical necessity of a drug product available from Health Canada (FRM-0378).

Shortage means a situation in which an authorization holder for a drug is unable to meet the demand for the drug.

Drug [for mandatory drug shortage reporting] means
any of the following drugs for human use in respect of which a drug identification number was assigned:
(a) drugs included in Schedule I, II, III, IV or V to the *Controlled Drugs and Substances Act*,
(b) prescription drugs,
(c) drugs that are listed in Schedule C or D to the Act, and
(d) drugs that are permitted to be sold without a prescription but that are to be administered only under the supervision of a practitioner.

Recall strategy

In addition to the product information outlined in the Recall notification section of this guide, you should provide Health Canada with a recall strategy as soon as possible after deciding to initiate a recall. A recall strategy is a planned course of action taken by a responsible party in conducting a recall. It includes, but is not limited to, the depth of recall, the need for public communication and the plan for conducting effectiveness checks for the recall.

Key factors to consider when determining an appropriate recall strategy are the:

- risk classification
- product's distribution channels
- extent of the product's distribution

You should also take into account:

- the type of product and how it is used
- the results of your health risk assessment
- how easy it is to identify the recalled product
- the degree to which the product's deficiency is obvious to the consumer or user
- the degree to which the product remains unused in the marketplace
- any vulnerable population that may be affected by the recall
- other sensitivities (e.g. public health concerns)
- continued availability of medically necessary products (applies to pharmaceutical drugs for human use only)

Health Canada expects that your strategy will name the specific distribution chain levels involved in all recall actions, including pharmaceutical samples distributed by sales representatives. If the recall does not extend to the lowest distribution level (i.e. retail, hospitals, clinics, pharmacies), a written rationale for this decision should be included.

For complex distribution chains which involve a number of consignees (e.g. wholesalers, cross licensees, distributors, etc.), you should clearly define the responsibilities for each party in a quality agreement or in the recall strategy. For example, you should determine when consignees at subsequent levels should be notified. You should clearly identify who is responsible for actions like follow-up with non-responders, conducting effectiveness checks, and collecting and destroying affected products.

When the responsible party sells their products directly to the end user, such as through online sales, their recall strategy should include how the end users will be contacted. The responsible party should take a risk based approach, which may require direct contact with each consignee or a public communication to advise of the recall.

Health Canada may independently evaluate the health and safety risk of the potentially harmful or non-compliant product to verify your health risk assessment. Health Canada sometimes recommends that establishments change a recall strategy as a result of a higher-rated risk. To avoid significantly delaying the process, Health Canada can recommend changes to a recall strategy while the recall is in progress.

Parts of a recall strategy

Recall strategies address the following aspects of a recall:

1. timelines
2. recall communications (notifying consignees, including users who are not readily identifiable, about the recall)
3. communication of risk to the general public or a targeted audience, if appropriate
4. effectiveness checks
5. progress reports

Timelines

Clearly set out timelines for finishing each part of the recall. Base timelines on factors such as the:

- complexity of the recall action
- number and geographic location of consignees
- risk associated with the affected product
- continued availability of medically necessary drug products

Recall communications

Your recall strategy defines the method and content for all communications associated with the recall. Provide a copy of your recall communications to Health Canada as soon as it is available. Health Canada will assess whether your communications are sufficient to mitigate the identified risk to health presented by the product. Health Canada expects you to notify consignees in English and French within the timelines defined in the Communication timelines section of this guide.

Ensure the format, content and extent of your communication is appropriate for the product's level of risk and for your recall strategy. Health Canada recommends that recall communications be brief and to the point. Do not include promotional material or anything that may detract from your message.

Contents of recall communications

Find a sample template for drug recall communications in Appendix C.

In general, recall communications specify:

- a description of the product, including its:
  - risk type (I, II or III)
  - name
  - size
  - lot number(s)
  - market authorization number
  - expiry date
- other descriptive information (e.g. photographs of the product, date manufactured) that could enable its immediate and accurate identification, if needed
- the risk associated with the product, for example, issues with product efficacy or effectiveness or identified Adverse Drug Reactions
- the reason for the recall, in concise terms
- actions to be taken by the consignee, including instructions to stop further distribution or use immediately
- instructions for how to recall the affected product, including:
  - specific steps for its return, disposal or correction
  - a request for a response to confirm the consignee received the communication and understands any required action

To encourage a quick response from consignees, your recall communications might include:

- pre-addressed cards
- telephone replies using a toll-free number
- a form to complete and return by fax or e-mail

Clearly identify your contact name and information. Request a timeframe within which the consignee should reply.

- instructions to all consignees involved in the chain of distribution to notify their own consignees of the recall and to provide instructions on how to proceed to recall the affected product. Emphasize the consignees' responsibility to notify any of their accounts that received the affected product in order to achieve a complete and rapid recall
- instructions to retailers, pharmacists or health care practitioners to notify their clients of the recall and provide instructions on the actions to take with the affected product, if end users need to be notified of the recall

For returns of controlled drugs or substances, provide an authorization to the consignee in order to comply with the FDR Part G requirements for the sale of controlled substances.

How to do recall communications

Recall communications to consignees can be accomplished in several ways, including by:

- personal on-site visit by responsible party
- phone
- fax
- e-mail
- special delivery letter (e.g. registered mail, courier)

You may contact all potential consignees, such as all pharmacies in Canada, to confirm whether they have received the product or not. If you choose this communication method, you must have acceptable procedures in place to ensure adequate follow up and effectiveness checks.

Use these guidelines for issuing a recall communication:

- Ensure contact information for recipients is current.
- Clearly mark envelopes and letters—for example, by displaying the statement **Drug** (or **Biologic**, etc.) **Recall** in **bold, red type using all capital letters**.
- Mark fax cover sheets and letters in bold type.
- Label recalls associated with Type I and II risks **Urgent** in **bold, red type using all capital letters**.

- Document and confirm telephone calls or personal visits in writing.
- Mark e-mails **Urgent,** in **bold, red type using all capital letters**.

Sending an e-mail is only considered acceptable if you receive a written response, such as by e-mail or fax, from the consignee; a read receipt would not be considered an appropriate response.

Make follow-up contact by telephone with anyone who fails to respond to the initial recall communication. Do not assume that a fax delivery confirmation you receive means the notice was received by the correct person.

If your establishment has a website, posting the recall communication online is an additional method of recall notification only. It is generally not sufficient to use this as your only way of notifying consignees.

Communication timelines

Your recall strategy should specify prescribed timeframes to initiate contact with affected clients. Use these guidelines:

- For **Type I** recalls, Health Canada strongly recommends that you make initial contact with direct consignees within **24 hours** of notifying Health Canada.
    - Ideally, first contact should be verbal; in person or by telephone.
    - Follow up with a written notice, fax, e-mail or courier letter. Keep records of all communication attempts.
    - Provide Health Canada with confirmation (e.g. a fax back form, e-mail response or telephone log) that 100% of consignees received and understood the recall instructions.
- For **Type II** recalls, make initial contact within two (2) working days of notifying Health Canada. Satisfactory confirmation of contact includes, for example, a fax-back form, e-mail response or telephone log.
- For **Type III** recalls, make initial contact within three (3) working days of notifying Health Canada. Satisfactory confirmation of contact includes, for example, a fax-back form, e-mail response or telephone log.

Reasonable follow-up efforts

Include an expected response time for consignees in your recall strategy. This should reflect your own timeline for initial communication and method of follow-up (e.g. mail or courier).

If consignees do not respond to the initial notification, you must follow up. “Non-responders” are people from whom you do not receive a return fax, e-mail, courier or phone message. Health Canada expects your recall procedures to define how you will follow up with non-responders. At minimum:

- Type I: No non-responders may remain. Due to the high level of risk, all consignees must be aware of the recall as soon as possible. If needed, make a personal visit to inform consignees of the recall. If any non-responders remain, provide a justification that includes careful records of each follow-up attempt.
- Type II: Follow up with non-responders two additional times using different contact methods. Keep careful records of each follow-up attempt.
- Type III: Make one additional follow-up effort, preferably using another means of contact.

Public risk communications

A risk communication alerts the public that the recalled product presents a serious risk to health. Risk communications are appropriate for urgent situations (Type I and occasionally Type II recalls)—for example, when a widely distributed product currently in the possession of consumers is recalled. Health Canada may also recommend that you issue a risk communication based on:

- the impact on product supply by the recall of an individual product or the recalls of a number of products
- specific subpopulations who use the product
- medical necessity (for drug products only)

In cases where Health Canada believes the public must be alerted to a serious risk, Health Canada may issue its own press release or advisory. For consistent messaging, provide Health Canada with your risk communication as soon as possible. If we find your communication inappropriate,

inadequate, or untimely, we will inform the public without using a coordinated approach.

Your recall strategy should specify the type of risk communication you will use—for example:

- a general public advisory through national or local news media
- a risk communication made:
  - through specialized news media (e.g. professional, trade or ethnic press)
  - to specific audiences (e.g. pharmacies, physicians, hospitals)
- a notice on your company website

Additional Health Canada guidance on public communications can be found in the *Guidance Document for Industry – Issuance of Health Professional Communications and Public Communications by Market Authorization Holders*.

Effectiveness checks

Health Canada expects you to use information collected from consignees' responses (as well as the number of non-responders) to periodically create recall effectiveness reports. Effectiveness checks verify whether consignees have received the recall notification and taken appropriate action. If it appears that your recall has been ineffective to date, you will need to develop corrective actions to manage it more effectively.

You should establish criteria for how to figure out your recall's effectiveness based on these checks. Relate your criteria to the recall's health risk classification (Type I, II or III). Regardless of the risk, we expect you to have evidence that **all** consignees have been contacted. This is an important measure of a successful recall.

Initial preliminary reports on effectiveness checks (# of consignees who have confirmed receipt of the recall notification) should be available for reporting to Health Canada, upon request, within the following timelines:

1. Type I - Within 5 business days
2. Type II - Within 10 business days
3. Type III - Within 15 business days

Specific records you may use to periodically check a recall's effectiveness include:

- dates of attempted contacts

- responses received at each attempt
- names of people contacted
- means of contact (e.g. phone or fax number, e-mail or mailing address)
- details of communications once contact is successful
- records showing how consignees complied with the recall
- copies of completed response forms and related correspondence

Progress reports to Health Canada

You should provide progress reports to Health Canada during the course of the recall. The reporting interval should be included in the recall strategy. The reporting interval should be agreed upon with Health Canada and will normally be two to four weeks, depending on the recall's urgency.

Recall progress reports should normally specify the:

- number of consignees notified of the recall and date and method of notification
- number of respondents and quantity of affected product(s) in their possession
- number of non-respondents
- next expected follow-up date with non-responders and method of communication, when applicable
- number of products returned or destroyed and quantity of products accounted for
- number and results of effectiveness checks
- estimated timeframe for completion of actions, if revised from the original timeframe included in the recall strategy

Progress reports may include information on the root cause of the risk to health of the recalled product or the contravention to the Act and/or regulations. The report may include short term and long term actions that you will take to resolve the root cause.

Recall closure: final report

When your recall is complete, you should provide Health Canada a final report with a detailed plan for identifying the root cause of the problem that led to the recall.

Your report should specify, as appropriate:

- the amount of product that:
    - you recovered
    - was destroyed by consignees, if requested in your recall notice
    - was not located with consignees or that cannot be tracked
- how you disposed of—or intend to dispose of—any recovered product (ensure you can make evidence available on request such as a Certificate of Destruction)
- the recall's final completion date
- confirmation that all consignees received the recall information and ensure you can make confirmation information available on request (see section Communication timelines for what is acceptable confirmation)
- a detailed corrective action plan to address the recall's root cause and prevent its recurrence, using measures such as:
    - design changes
    - process validation
    - increased quality control

6. Food and Drug Regulations requirements for recalls

In each section below, you will find the provisions in Part C, Divisions 1 and 2 of the Food and Drug Regulations (FDR) followed by a rationale for the rule (why the rule is important) and Health Canada's interpretation of it (what you need to do to be compliant), where needed. Each regulation relates to drug product recalls.

For complete guidance on the good manufacturing practices requirements found in Part C, Division 2 of the FDR, refer to Health Canada's *Good manufacturing practices guide for drug products* (GUI-0001). It applies to the following types of drugs:

- pharmaceutical
- radiopharmaceutical
- biological
- veterinary

Reporting

Part C, Division 1, section C.01.051

Where a manufacturer who sells a drug in dosage form or a person who imports into and sells in Canada a drug in dosage form commences a recall of the drug, the manufacturer or importer shall forthwith submit to Health Canada the following information:

(a) the proper name of the drug, the common name of the drug if there is no proper name, the brand name of the drug and the lot number;

(b) in the case of an imported drug, the names of the manufacturer and importer;

(c) the quantity of the drug manufactured or imported;

(d) the quantity of the drug distributed;

(e) the quantity of the drug remaining on the premises of the manufacturer or importer;

(f) the reasons for initiating the recall; and

(g) a description of any other action taken by the manufacturer or importer with respect to the recall.

Rationale

Responsible parties must inform Health Canada when they commence a recall of a drug product from sale or further distribution.

Interpretation

The responsible party for a drug product recall should:

- Submit the information specified in section C.01.051 of the FDR to Health Canada within **24 hours** of having made the decision to recall. You may use the *Drug and Natural Health Product Recall Reporting Form* (FRM-0356).

  Note: You may also contact Health Canada verbally or in writing to provide initial notification. If the recall addresses a high-risk situation, we encourage you to notify us by phone.

- Follow up your initial notification with a written report containing full information about the recall within **72 hours** of the decision to recall. If you are in the process of obtaining further information, forward it to Health Canada as soon as it becomes available.

Manufacturing control

Part C, Division 2, section C.02.012 (1)

(1) Every fabricator, packager/labeller or distributor referred to in section C.01A.003, importer and wholesaler of a drug shall maintain:

(a) a system of control that permits complete and rapid recall of any lot or batch of the drug that is on the market

Rationale

Recalls remove from the market drugs that represent a health risk to Canadian consumers. Drugs are also recalled when there is a contravention to the Act and its regulations.

Drugs that have left the premises of their fabricator, packager/labeller, distributor, wholesaler or importer may be found in a variety of locations. Depending on the severity of the product's risk to public health, products may need to be recalled at one or more levels of distribution. Proper systems of control ensure that recalled drug products can be quickly located and removed from further sale or use.

Interpretation

Written systems of control

If you fabricate, package/label, distribute, wholesale or import drugs in Canada, you must have written systems in place that allow you to recall a drug product to the consumer level. Maintain a standard operating procedure for recalls that specifies the following:

1. You will notify Health Canada of the recall per section C.01.051 of the FDR.
2. You will take any action to recall a product promptly and according to a pre-determined plan.
3. You have a recall procedure available and in writing. It is known to anyone involved in the recall. It outlines how you will notify and implement a recall, and how to decide its extent.
4. The person(s) responsible for initiating and coordinating all recall activities is/are identified in the recall procedure.
5. The recall procedure can be put into operation at any time, during and outside normal working hours.
6. Distribution records enable you to trace all of a drug product during a recall. The records fully account for all distributed product including:
    - drug products in transit
    - samples that have been removed by the quality control department
    - professional samples that have been distributed

7. To facilitate efficient recalls, wholesalers only obtain drug products from companies that hold a drug establishment licence (as required in Part C, Division 1A of the FDR).

8. When an importer or distributor assumes some or all of the wholesaler's responsibilities during a recall, a written agreement clearly describes each party's respective responsibilities.

9. You will identify recalled products and store them separately in a secure area until you decide how to dispose of them.

10. You will assess the recall's progress and efficiency, and, record your assessments at intervals. You will also send a final report that includes a final reconciliation.

11. You will notify all Canadian and foreign establishments involved in the fabrication, distribution or importation of the recalled product of the recall.

Regularly review these procedures and keep them up-to-date. Document any reasons for revisions to them. Use a system of control to ensure you use only current recall procedures.

Your written recall system, including the standard operating procedure described above, must facilitate a rapid and effective recall. It should include details such as:

- all internal and external staff involved in the recall action as well as their functions and responsibilities
- channels and means of communicating the recall
- how you plan to control the recalled product and returned stock
- your procedure for doing effectiveness checks
- how many contacts must be made to follow up with consignees
- which records must be kept for effectiveness checks and reporting

Specific details of factors identified in the recall system or standard operating procedure may be provided in the recall strategy.

For further information about document control requirements and methods, refer to the *Good manufacturing practices guide for drug products* (GUI-0001).

Additional guidance

- Good Manufacturing Practices (GMP) guidelines recommend the following parties to keep written records of drug product manufacturing activities:
    - fabricators
    - distributors
    - packagers/labellers
    - testers
    - importers
    - wholesalers
- In the event of a complaint or suspected defect, the distributor or importer may need to access a contract fabricator's records to check product quality. To ensure contract fabricators comply with the regulations, their recall procedures should specify that any relevant records be made accessible to the distributor or importer.
- There must be a record of traceability from the distributor, importer or licensed wholesaler to the retail store.
- Lot numbers do not generally need to be traced per patient.
- Patients should be notified of Type I recalls by public advisory or communication to health care professionals if the product is only used in a health care setting, and by media release. This communication can be done by Health Canada and the responsible party. The responsible party will inform pharmacies if they are expected to contact all patients.

Records

Part C, Division 2, sections C.02.021–C.02.023

C.02.021

(1) All records and evidence of the fabrication, packaging/labelling, finished product testing referred to in section C.02.018 and storage of a drug in dosage form that are required to be maintained under this Division shall be retained for one year after the expiration date of the drug unless the person's establishment licence specifies some other period.

(2) Subject to subsection (4), all records and evidence of the fabrication, packaging/labelling, finished product testing referred to in section C.02.018 and storage of an active ingredient that are required to be maintained under this Division shall be retained in respect of each lot or batch of the active ingredient for the following period unless the person holds an establishment licence that specifies some other period:

(a) in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed; or

(b) in any other case, one year after the expiration date of the lot or batch.

(3) Subject to subsection (4), all records and evidence of the raw material testing referred to in section C.02.009 and of the testing of packaging/labelling materials that are required to be maintained under this Division shall be retained for five years after the raw materials and packaging/labelling materials were last used in the fabrication or packaging/labelling of a drug unless the person's establishment licence specifies some other period.

(4) If a fabricator is required to maintain records and evidence in respect of the same active ingredient under subsections (2) and (3), they shall maintain them for the longest period that is applicable.

C.02.022

(1) Every wholesaler, distributor referred to in section C.01A.003 and importer of a drug in dosage form shall retain records of sale of each lot or batch of the drug, which enable them to recall the lot or batch from the market, for one year after the expiration date of that lot or batch unless their establishment licence specifies some other period.

(2) Every distributor of an active ingredient referred to in paragraph C.01A.003(a) and every wholesaler and importer of an active ingredient shall retain records of sale of each lot or batch of the active ingredient, which enable them to recall the lot or batch from the market, for the following period unless the person holds an establishment licence that specifies some other period:

(a) in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed; or

(b) in any other case, one year after the expiration date of the lot or batch.

C.02.023

(1) On receipt of a complaint or any information respecting the quality of a drug or its deficiencies or hazards, every fabricator, packager/labeller, wholesaler, distributor referred to in section C.01A.003 and importer of the drug shall make a record of the complaint or information that contains the following:

(a) the results of any investigation carried out under subsection C.02.015(2) and, if applicable, the corrective action taken; or

(b) the name and business address of the person in charge of the quality control department to whom the complaint or information was forwarded under subsection C.02.015(2.1) and the date on which it was forwarded.

(2) Records referred to in subsection (1) shall be retained for the following period unless the person holds an establishment licence that specifies some other period:

(a) in the case of a drug in dosage form, one year after the expiration date of the lot or batch of the drug; and

(b) in the case of an active ingredient,

i. if the active ingredient has a retest date, three years after the lot or batch has been completely distributed, or

ii. in any other case, one year after the expiration date of the lot or batch of the active ingredient.

Rationale

Good documentation is an essential part of the quality assurance system and should therefore be related to all aspects of GMP. Its aims are to define the specifications for all materials and methods of fabrication, packaging/labelling, and control; to ensure that the quality control department has all the information necessary to decide whether or not to release a batch of a drug for sale; and to provide an audit trail that will permit the examination of the history of any batch that is suspected to be defective.

Evidence that drugs have been fabricated and packaged/labelled under prescribed conditions can be maintained only after developing adequate record systems. The information and evidence should provide assurance that imported drugs are fabricated and packaged/labelled in a like manner to those produced in Canada.

Interpretation

The process of completing a drug recall includes enquiring into possible causes of the problem and taking corrective action. Records kept to fulfil the requirements of C.02.021 may provide part of the evidence used in this enquiry.

How to maintain and use records

To use the records required by sections C.02.021–C.02.023 when planning or conducting the recall of a drug product:

- Ensure you keep the recalled product's distribution list available. After Health Canada has been notified of a recall, the inspector assigned to monitoring the recall may request a copy.
- You may keep records in electronic format provided that backup copies are also maintained. Electronic data must be readily retrievable in a printed format. During the retention period, electronic records must be secured. Health Canada expects that they will be accessible within 48 hours to the:
    - fabricator
    - packager/labeller
    - distributor
    - wholesaler
    - importer

You can find more information on electronic records in the PIC/S Annex 11: Computerised Systems that has been adopted by Health Canada.

- If you fabricate, package/label, distribute, wholesale or import drugs in Canada, maintain distribution records for all sales of drugs—including professional samples—as follows:
    - Keep records of all sales readily accessible, in a manner that will permit a complete and rapid recall of any lot or batch of a drug.

      Note: This requirement does not necessarily involve tracking by lot number.
    - Keep records showing that all consignees who received a recalled drug were notified of the recall.

- Also keep records of:
    - complaints relating to drug quality: their receipt, investigation and any corrective actions taken
    - information received from any source about the quality or risks of a drug

Reviewing information about drug product complaints

Your quality control department is responsible for reviewing all complaints and other information concerning potential deficiencies or risks with products. These reviews must be done according to written procedures, as follows:

- Record the complaint in detail. Thoroughly investigate each complaint.
- Take appropriate follow-up action following your investigation.
- Record all decisions and measures done as a result of the complaint. Reference these to the corresponding batch records.
- Regularly review complaint records for any indication of specific or recurring problems that require attention.

Determining a drug's level of risk

Before initiating a recall, use the records required by C.02.023 to conduct a health risk assessment for the drug product. Gather, correlate and evaluate these records to assess the nature and extent of the identified health risk. Consider the following factors when determining the degree of health risk posed by the product:

- Have any illnesses or injuries been reported due to its use?
- What degree of risk is anticipated for the population that is expected to be at the greatest risk (e.g. children, surgical patients)?
- What degree of risk is anticipated for the whole user population?
- How likely is the risk to occur?
- What are the immediate and long-range consequences of the risk happening?

Support your conclusion about the product's risk to health as completely as possible using scientific documents. In order to fulfill section C.01.051 (f) of the FDR ("reasons for initiating a recall"), you must report your conclusion to Health Canada as part of the recall's initial notification.

7. Natural Health Products Regulations requirements for recalls

In each section below, you will find the provisions in Parts 1 and 3 of the *Natural Health Product Regulations* followed by a rationale for the rule (why the rule is important) and Health Canada's interpretation of it (what you need to do to be compliant), where needed. Each regulation relates to natural health product recalls.

The *Good Manufacturing Practices Guidance Document for Natural Health Products* provides detailed guidelines about Part 3 of the NHPR.

Records

Part 1, section 23

(1) Every licensee who sells a natural health product shall maintain the following records:

(a) a list of all ingredients contained in each lot or batch of the natural health product that has been made available for sale; and

(b) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale.

(2) The records shall be maintained by the licensee for a period of one year following the expiry date of the natural health product to which that record relates.

Rationale

Good documentation is a key part of a quality system and promotes compliance with GMP requirements. Documentation may exist in a variety of forms, including paper-based, electronic or photographic media.

The various types of documents and media used should be fully defined in the quality system. The documentation system's main objective must be to establish, control, monitor and record all activities which directly or indirectly impact all aspects of the quality of natural health products. This includes information from all stages of the product lifecycle, and all records related to the quality of natural health products.

Records must be reliable, complete, consistent and accurate.

Interpretation

If you are the product licence holder of a natural health product, you are responsible for:

- maintaining the information set out in section 23 of the NHPR
- making it available when requested by Health Canada

Complying with section 23 will help you provide the information that is referred to in section 62 and required by section 25 (see Recall reporting, below).

Recall reporting

Part 1, section 25

Every licensee who commences a recall of a natural health product shall provide the Minister with the information referred to in section 62 within three days after the day on which the recall is commenced.

Part 3, section 62

Every manufacturer, importer or distributor who commences a recall of a natural health product shall provide the Minister with the following information in respect of that natural health product within three days after the day on which the recall is commenced:

(a) the proper name and the common name of each medicinal ingredient that it contains;

(b) each brand name under which it is sold;

(c) its product number;

(d) the number of each lot or batch recalled;

(e) the name and address of each manufacturer, importer and distributor of the natural health product;

(f) the reasons for commencing the recall;

(g) the quantity manufactured or imported into Canada;

(h) the quantity that was distributed in Canada;

(i) the quantity remaining in the possession of each manufacturer, importer and distributor of the natural health product; and

(j) a description of any other action that the manufacturer, importer or distributor, as the case may be, is taking in respect of the recall.

Rationale

Responsible parties must inform Health Canada when they commence a recall of a natural health product from sale or further distribution.

Interpretation

If you are a product licence holder, manufacturer, importer or distributor who commences a recall of a natural health product:

- Submit the product recall information outlined in section 62 of the NHPR to Health Canada within **three calendar days** after initiating the recall.
- You may provide this information using the *Drug and Natural Health Product Recall Reporting Form* (FRM-0356).

Operations

Part 3, section 50

Every manufacturer, packager, labeller, importer and distributor shall establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of the natural health product that has been made available for sale.

Rationale

Recalls remove from the market natural health products that represent a health risk to Canadian consumers. Natural health products may also be recalled when there is a contravention to the Act and its regulations.

Natural health products that have left the premises of a manufacturer, packager, labeller, distributor, or importer can be found in a variety of locations. Depending on the severity of the health risk, it may be necessary to recall a product. Manufacturers, packagers, labellers, distributors and importers are expected to be able to recall to the consumer level if necessary.

Interpretation

Establish written procedures to define controls that ensure a product can be effectively recalled. This includes being able to notify Health Canada. Specifically, your system of control should:

- identify individual(s) responsible for initiating and coordinating recall activities
- ensure your recall procedure can be put into operation at any time, during and outside normal working hours
- ensure your recall procedure outlines the steps for implementing a recall (e.g. determining extent of the recall; notifying affected parties)
- maintain distribution records to enable the tracing of each lot
- identify and store recalled products separately in a secure area until you determine how to take further action
- assess and record at intervals the progress and efficacy of the recall. Issue a final report, including a final reconciliation, to Health Canada
- notify all Canadian and foreign sites involved in the manufacturing, packaging, labelling, importing and distribution that the product has been recalled

Quality assurance

Part 3, section 51 (1)

(1) Every manufacturer, packager, labeller, importer and distributor shall:

(a) have a quality assurance person who:

i. is responsible for assuring the quality of the natural health product before it is made available for sale, and

ii. has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Part;

and

(b) investigate and record every complaint received in respect of the quality of the natural health product and, if necessary, take corrective action.

Rationale

Before initiating a recall, you must gather, correlate and evaluate records to assess the nature and extent of the identified health risk. Use the records required by section 51(1)(b) as part of the documents you evaluate in order to determine the possible health risk.

Interpretation

To ensure your records support this requirement:

- Maintain laboratory records of tests and investigations.
- Set up and follow written procedures for handling product complaints. These procedures must include determining whether further investigation and corrective action are required.
- Document all complaints. Include:
  - the name and description of the product
  - its lot number
  - the source and nature of the complaint
  - any response provided to the complainant
- If you conduct an investigation, include the findings as well as any follow-up action you take in your written records.

Records

Part 3, section 53

Manufacturers

Every manufacturer who sells a natural health product shall maintain the following records at the site at which the natural health product is manufactured:

(a) the master production document for the natural health product;

(b) a list of all ingredients contained in each lot or batch of the natural health product;

(c) records of any testing conducted in respect of a lot or batch of raw material used in the manufacture of the natural health product;

(d) records of any testing conducted in respect of a lot or batch of the natural health product;

(e) a copy of the specifications for each natural health product that is being manufactured at the site;

(f) records demonstrating that each lot or batch of the natural health product was manufactured in accordance with the requirements of this Part;

(g) a record of each determination made by the manufacturer in accordance with section 52 and the information that supports that determination;

(h) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(i) a list of all natural health products that are being manufactured at the site;

(j) a copy of the sanitation program in use at the site.

Part 3, section 54

Packagers

Every packager who sells a natural health product shall maintain the following records at the site at which the natural health product is packaged:

(a) records of any testing conducted in respect of the material used to package the natural health product;

(b) records demonstrating that each lot or batch of the natural health product was packaged in accordance with the requirements of this Part;

(c) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(d) a list of all natural health products that are being packaged at the site;

(e) a copy of the sanitation program in use at the site.

Part 3, section 55

Labellers

Every labeller who sells a natural health product shall maintain the following records at the site at which the natural health product is labelled:

(a) records demonstrating that each lot or batch of the natural health product was labelled in accordance with the requirements of this Part;

(b) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(c) a list of all natural health products that are being labelled at the site;

(d) a copy of the sanitation program in use at the site.

Part 3, section 56

Importers

Every importer who sells a natural health product shall maintain the following records:

(a) the master production document for the natural health product;

(b) a list of all ingredients contained in each lot or batch of the natural health product;

(c) records of any testing conducted in respect of a lot or batch of the natural health product;

(d) a copy of the specifications for the natural health product;

(e) a record of each determination made by the importer in accordance with section 52 and the information that supports that determination;

(f) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale; and

(g) a copy of the sanitation program in use by the importer.

Part 3, section 57

Distributors

Every distributor shall maintain the following records at the site at which the natural health product is stored:

(a) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(b) a list of all natural health products that are being stored at the site; and

(c) a copy of the sanitation program in use at the site.

Part 3, section 58

Record maintenance

Every person required under this Part to maintain a record that relates to a lot or batch of a natural health product shall maintain that record for a period of one year following the expiry date of the natural health product to which that record relates.

Rationale

Good documentation is an essential part of your quality assurance system—you need it for all aspects of GMP. Good record keeping:

- defines the specifications for all materials and methods of manufacturing, packaging, labelling and control

- ensures that your in-house quality assurance program has all the information necessary to decide whether or not to release a lot of a natural health product for sale
- provides an audit trail that will permit investigation of any lot of a natural health product that is suspected to be defective

Evidence that natural health products have been fabricated and packaged/labelled under prescribed conditions can be maintained only after developing adequate record systems. The information and evidence should provide assurance that imported natural health products are fabricated and packaged/labelled in a like manner to those produced in Canada.

Interpretation

Conducting a natural health product recall includes investigating possible causes of the problem and taking corrective action. The records kept to fulfil the requirements of sections 53 to 57 may provide part of the evidence for this investigation.

After Health Canada has been notified about the recall, the inspector assigned to monitoring the recall may request a copy of distribution records for the recalled product. You must keep distribution records available per sections 53 to 57.

Manufacturing, testing and distribution records must be kept for at least one year after the lot expiry date, per section 58.

For further details about record-keeping requirements, see the Good Manufacturing Practices Guidance Document for Natural Health Products.

Appendices

Appendix A – Glossary

Acronyms

FDR: Food and Drug Regulations

GMP: Good manufacturing practices

NHP: Natural Health Product

NHPR: Natural Health Products Regulations

PIC/S: Pharmaceutical Inspection Cooperation Scheme

Terms

These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* (the Act), Food and Drug Regulations (FDR) or Natural Health Product Regulations (NHPR), the definition in the Act or regulations prevails.

Active ingredient – A drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect. (FDR)

Adverse reaction - A noxious and unintended response to a marketed health product covered by this document and includes "adverse drug reaction" as defined in the Food and Drug Regulations and "adverse reaction" as defined in the Natural Health Products Regulations.

> Adverse drug reaction as defined in the Food and Drug Regulations is a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function.
>
> Adverse reaction as defined in the Natural Health Products Regulations is a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.

Brand name (drug) – With reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French:

(a) that is assigned to the drug by its manufacturer

(b) under which the drug is sold or advertised

(c) that is used to distinguish the drug (FDR)

Brand name (natural health product) – A name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual:

(a) that is used to distinguish the natural health product

(b) under which a natural health product is sold or advertised (NHPR)

Compliance – The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

Consignee – Anyone who received, purchased or used the product being recalled.

Correction – The repair, modification, adjustment, relabeling or inspection (including patient monitoring) of a product without its physical removal to some other location.

Distributor – See "manufacturer" (drugs).

Divisions 1A and 2 to 4 apply to the following distributors:

(a) a distributor of an active ingredient or a drug in dosage form that is listed in Schedule C to the Act

(b) a distributor of a drug for which the distributor holds the drug identification number (FDR C.01A.003)

Distributor (natural health products) – A person who sells a natural health product to another person for the purpose of further sale by that other person. (NHPR section 1)

Drug – Includes any substance or mixture of substances manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals

(b) restoring, correcting or modifying organic functions in human being or animals

(c) disinfection in premises in which food is manufactured, prepared or kept (the Act)

Effectiveness check – Includes a survey of those affected by the recall (consignees) to verify they have received the recall information and are aware of any appropriate action to be taken and may include verification of the action taken.

Exposure assessment - A process that involves producing a qualitative and/or quantitative estimate of the magnitude, frequency, duration, route and extent of human exposure to an agent.

Fabricate – To prepare and preserve a drug for the purpose of sale. (FDR)

Food and Drugs Act – A federal statute regulating the health and safety of food, drugs, natural health products, cosmetics and medical devices. The Minister of Health is responsible for the administration of the Act.

Hazard characterization - A process that involves the qualitative and/or quantitative evaluation of the nature of the adverse effects that humans may experience under expected levels of exposure to an agent.

Hazard identification - The process of recognizing that an agent has an inherent capacity to cause an adverse health effect; may be based on informal information or studies conducted under specific conditions.

Health product – Includes any product under the mandate of Health Canada and regulated under the FDA, such as: pharmaceutical, biological and radiopharmaceutical drugs for human use; veterinary drugs; medical devices; natural health products; blood; cells, tissues and organs for transplantation; and semen for assisted conception.

Health risk classification – A numerical designation that may be assigned by Health Canada to a particular product to indicate the relative degree of risk to human health presented by the product, as follows:

- Type I: a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.
- Type II: a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
- Type III: a situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences.

Types I and II include situations where a product which does not have generally recognized or scientifically supported therapeutic value is promoted in such a way that avoidance of recognized therapy may occur and where such avoidance could lead to injury or death.

Health risk assessment – The scientific characterization of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to hazards. The process consists of the following steps:

1. hazard identification
2. hazard characterization
3. exposure assessment
4. risk characterization

Homeopathic medicine –Medicines that are manufactured from or contain as medicinal ingredients only those substances or sources referenced in the Homeopathic Pharmacopoeia of the United States (HPUS), the Homöopathische Arzneibuch (HAB), the Pharmacopée Française (PhF), the European Pharmacopoeia (EP) or the Encyclopedia of Homeopathic Pharmacopoeia as amended occasionally, and that are prepared in accordance with these pharmacopoeias. Homeopathic medicines are regulated as natural health products.

Importer –A person who imports into Canada a drug or natural health product for the purpose of sale.

Inspector –Any person designated as an inspector under section 22 of the Act.

Label – Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. As described in package/label, the action of labelling refers to affixing the inner or outer label to the drug. (FDA)

Lot – A quantity of any drug or natural health product in dosage form, a raw material or packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number that appears on the label of the finished product.

Lot number – Any combination of letters, figures or both, by which a drug or natural health product can be traced in manufacture and identified in distribution.

Manufacturer or distributor (drugs) A person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word, or mark controlled by them, sells a food or drug. (FDR A.01.010).

Manufacturer (natural health products) – A person who fabricates or processes a natural health product for the purpose of sale. Does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient. (NHPR section 1)

Medically necessary – A drug that is used to diagnose, treat or prevent a serious disease or medical condition is considered medically important. A medically important drug for which there is no other adequately available drug product judged by Health Canada to be an appropriate substitute may be considered medically necessary.

Natural health product – A substance set out in Schedule 1 of the NHPR or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans

(b) restoring or correcting organic functions in humans

(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Also, in accordance with subsection 2(2) of the NHPR, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the Food and Drug Regulations (FDR), is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of the FDR.

Pharmaceutical Inspection Cooperation Scheme - The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a worldwide organization and co-operative arrangement between 52 participating international pharmaceutical Regulatory Authorities and leads the international development, implementation and maintenance of harmonized Good Manufacturing Practices (GMP) standards and quality systems of inspectorates in the field of medicinal products.

Potency (NHP) – The amount per dosage unit of the standardized component(s) that further characterizes the quantity of the ingredient. Required only when a claim on the potency is to be on the label, or is required for a specific product (e.g. when literature supports the product with that standardized component). In Appendix 1 of the natural health products *Good Manufacturing Practices Guidance Document*, potency refers to the degree of dilution of a homeopathic medicine. (NHPR)

Product withdrawal – The removal from further sale or use or correction of a distributed product where there is no health and safety risk and no contravention of the legislation or regulations. It is not considered to be a recall.

Quantity – The amount of medicinal ingredient(s) per dosage unit. It is always required for a product, as it is the amount of medicinal ingredient in the product. (NHPR)

Quarantine –The status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection. (ICH Q7)

Recall – A responsible party's removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates the Act or the Regulations.

Recall depth – The level of distribution from which a product is recalled (e.g. wholesale, retail, user or consumer).

Recall strategy – A planned course of action taken by a responsible party in conducting a specific recall, including but not limited to the depth of recall, the need for public advisories and the extent of effectiveness checks for the recall.

Regulations – A form of law, often referred to as delegated or subordinate legislation. Regulations have the same binding effect as an Act and usually state rules that apply generally, rather than to specific persons or things. Regulations are not made by Parliament, but are made by persons or bodies to whom Parliament has delegated authority.

Responsible party – The person responsible for initiating and conducting the recall. Generally, responsible parties may include manufacturers, distributors, importers, persons in Canada responsible for the sale of the product and wholesalers for drugs, and, manufacturers, importers, distributors or product licence holders for natural health products.

Risk characterization - A process involving the qualitative and/or quantitative estimation of the severity and probable occurrence of known or potential adverse effects in a given population, based on hazard identification, hazard characterization and exposure assessment. The estimate includes information from biophysical studies, and where appropriate,

integrates information related to social, cultural, ethical, and economic contributors to the risk, with consideration also being given to risk perceptions.

Sell – Offer for sale, expose for sale, have in possession for sale and distribute, regardless of whether the distribution is made for consideration. (FDA)

Stock recovery –The removal or correction of a product that has not been distributed or that has not left the direct control of the party ordering the removal or correction. It is not considered to be a recall.

Voluntary disposal – An action by a responsible party to prevent further distribution of a non-compliant product, by actions such as disposal, destruction, reconditioning or returning it to the manufacturer.

In considering whether voluntary disposal is an appropriate compliance action, Health Canada considers the following factors:

- the degree of cooperation offered by a responsible party on prior occasions
- whether the product will be rendered non-saleable/usable

Wholesaler – A person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at retail sale:

(a) a drug in dosage form that is listed in Schedule C or D to the Act, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001(1) of the FDR;
(b) an active ingredient: or
(c) a narcotic as defined in the Narcotic Control Regulations; or
(d) a drug containing cannabis as defined in subsection 2(1) of the *Cannabis Act*.

Appendix B – Questions for determining medical necessity of a drug product

Health Canada recommends that you consider these questions to determine whether a drug product that you plan to recall is medically necessary in order to assess the potential shortage implications that may result from the recall. You should report the medical necessity of a recalled drug product to Health Canada as part of your initial recall notification.

1. Is the product used to diagnose, prevent or treat a serious, life-threatening or severely debilitating disease or medical condition?

   If yes: What is the name of the disease or medical condition? Consider potential effects of stopping therapy. Is the drug acutely life-saving over time? Does it reduce intolerable symptoms of disease?

2. What are the labelled indications for this product? Consider all indications included in the product monograph. Include relevant information about approval (or specific lack of approval) for use in pediatric or geriatric populations.

3. How is the drug product presented (e.g. sterile injection, immediate release tablet, modified release tablet)?

4. Are there other marketed products with:

   - the same active ingredient
   - the same route of administration
   - the same approved indication(s)
   - similar strengths

   If yes: Document alternative products and their manufacturers. This may include innovative products or generic products.

   If no: Are there products with the same active ingredient but different routes of administration that could be substituted for this one? What are they?

5. Are there marketed products with different active ingredients that have with similar indications (and, where relevant, the same routes of administration)? What are they?

Note: There might be substitution concerns (e.g. for a highly titrated drug). Switching might also lead to concerns about effectiveness.

6. What is the market share of the affected product(s) by strength in comparison with any alternative products you identified in question four? What units were used to make these calculations? (To make direct comparisons, convert units to milligrams [mg] and express them as a percentage of the total Canadian market share.)

7. How is the market share calculated (i.e. is it based on units sold to retail pharmacies and hospital pharmacies, or extended units sold)?

8. Do you fully report sales data for the affected drug product(s) to IQVIA?

9. Are there niche on-label sub-populations that may need this medication? Is it used as a second- or third-line therapy for patients who have failed to respond to other therapies?

10. Are there important, identified off-label uses of the product that may make it medically necessary? Do you foresee that this would not apply to a majority of products, with some exceptions (e.g. old chemotherapies that are used off-label in several oncology settings)? You may identify this information through a literature search and by verifying clinical practice guidelines. Identify sources of information.

11. Does the drug have any unique characteristics that may make it medically necessary? For example, is it a life-saving medication with a quicker onset of action? Is it a liquid for children or patients who cannot swallow pills? Are the excipients important for any particular patient population (e.g. is it a benzyl-alcohol-free formulation to be used in infants)? Is the format size critical for certain health care system needs?

12. Is there an ongoing shortage of any approved alternatives that may put further pressure on the ability of the health care system to absorb a shortage of the product? Document any known information about the general supply situation. Check the Drug Shortages Canada site for a list of products in shortage.

    Note: Whether a drug appears in the Drug Shortage Database does not confirm that there is enough supply of product alternatives to make up the gap caused by a recall.

Appendix C – Sample Drug recall communication template

When to use this template

This template is an example of a drug recall communication. Use this template when:

- You have initiated a drug or NHP product recall.
- You are required to inform companies that will be affected by the recall.

How to complete this template

The template is composed of two documents:

1. template drug or NHP recall letter
2. product return form

Drug or NHP recall letter

To complete the drug or NHP recall letter, refer to the text that appears in **bold** and **in brackets**. Modify and/or remove text in **bold** before sending your letter. Refer to instructions **in brackets** to help you fill in the information that applies to your recall.

For **Type I** and **II** drug or NHP product hazards, mark the recall notification **Urgent** in bold, red type using all capital letters.

Product return form

Once you have completed the drug recall letter, fill out the product return form. Modify and then delete text in **bold**. To include clear instructions for how to return required information, be sure to fill in the:

- "return by" date
- name of the person in charge of receiving returns (i.e. your customer service centre)
- your establishment's fax number

- your establishment’s telephone number
- method of return shipment (i.e. courier)
- your mailing address for returns

Sample drug or NHP recall letter

URGENT DRUG RECALL

yyyy-mm-dd

Re: **Product name, size, lot number(s), expiry date**

[Include any other relevant descriptive information, as needed.]

Dear **Name of consignee**,

A drug product you have received or sold is being recalled from the Canadian market.

[Specify the hazard associated with the product. State whether the recall is Type I, II or III as well as the reason for the recall.

For example: "We are initiating this recall due to an out-of-specification stability test result on the potency assay. The lot met specifications at the time of release. There are (no) adverse reaction reports or complaints associated with the potency assay related to this lot. The risk classification associated with this product is Type III. This is defined as a situation in which the use of, or exposure to, the product is not likely to cause adverse health consequences."]

Due to this recall, you are required to:

- Immediately stop all sale or distribution of these lot number(s).
- Advise your consignees of this recall.
    - Consignees must return the product with the above lot number(s) to you.
- Immediately conduct an inventory assessment. Fax or e-mail the attached Product Return Form to the attention of: **Name, fax number and e-mail address for the appropriate customer response centre**.
- Return all stock for the above listed lot(s) to: **Your address**.

Please complete these actions by [Specify a timeframe for the consignee to respond to the notification]. We have notified Health Canada about this recall.

Thank you for your cooperation and assistance. Please do not hesitate to contact us if you need further information.

Sincerely,

Name of contact
Company name
Mailing address
Phone number
E-mail address

Attachment: Product Return Form

Sample Product Return Form

URGENT

RE: DRUG RECALL

Please return by **Month-Day-Year** to **Contact person**, Customer Response Centre, **Name of establishment**.

Fax number: **xxx-xxx-xxxx**
Telephone number: **xxx-xxx-xxxx**
E-mail address: **E-mail address**

Indicate the amount of product per lot you currently have in stock. If you do not have stock in your possession, mark "0" for each lot. We will follow up with you if we do not receive a reply by: **yyyy-mm-dd**.

CLIENT INFORMATION	
Name :	Address :
PRODUCT DETAILS	
Product number :	
Product name :	
Lot number :	Quantity in stock :
Lot number :	Quantity in stock :
Lot number :	Quantity in stock :
Lot number :	Quantity in stock :
AUTHORIZED SIGNATURE	
Signature of authorized person:	Date (yyyy-mm-dd):
Printed name:	

Return all products with these lots, along with a copy of this form, by [Insert method of return shipment—e.g. Purolator Collect] to:

Your return address

Attention: Person in charge, Customer Response Centre

Appendix D – References

Legislation

Food and Drugs Act
https://laws-lois.justice.gc.ca/eng/acts/F-27/index.html

Food and Drug Regulations
https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html

Narcotic Control Regulations
https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/

Natural Health Products Regulations
https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/index.html

Health Canada guidance

Compliance and enforcement policy for health products (POL-0001)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html

Drug and Natural Health Product Recall Reporting Form (FRM-0356)
https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/compliance-enforcement/drug-recall-reporting-form-eng.html

Good Manufacturing Practices Guide for drug products (GUI-0001)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001/document.html

Good Manufacturing Practices Guidance Document for Natural Health Products
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/good-manufacturing-practices.html

Guidance Document for Industry – Issuance of Health Professional Communications and Public Communications by Market Authorization Holders
https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-document-industry-issuance-health-professional-

communications-public-communications-market-authorization-holders-health-canada-2010.html

Guide to Reporting Drug Shortages and Discontinuations (GUI-0120)
https://www.canada.ca/en/public-health/services/publications/drugs-health-products/reporting-drug-shortages-discontinuations.html

Medical Devices Recall Guide (GUI-0054)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-devices-recall-guide-0054.html

Recall Policy for health products (POL-0016)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016.htmlWebsites

Drug Shortages Canada
https://www.drugshortagescanada.ca/

Compliance and Enforcement
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement.html

Health section of the Government of Canada website
https://www.canada.ca/en/services/health.html

Recalls—Health Canada
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/recalls.html

Recalls and safety alerts database (health products)
https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php

Appendix E – Health Canada contacts for reporting drug and natural health product recalls

Contact Health Canada to submit recall information or for general enquiries on the recall of drugs or natural health products.

Location of recalling firm	Recall reporting address
New Brunswick, Newfoundland and Labrador, Nova Scotia, Prince Edward Island, Québec	Health Products Compliance Unit East 1001 Rue St-Laurent Ouest, Longueuil, Québec, J4K 1C7 Phone : 450-646-1353 Toll free : 1-800-561-3350 Fax : 450-928-4184 E-mail : HC.qoc-coq.SC@canada.ca
Ontario	Health Products Compliance Unit Central 2301 Midland Ave., Toronto, Ontario, M1P 4R7 Phone: 416-973-1600 Toll free: 1-800-267-9675 Fax: 416-973-1954 E-mail: HC.insponoc-coon.SC@canada.ca
Manitoba, Saskatchewan, Alberta, British Columbia, Yukon, Northwest Territories, Nunavut	Health Products Compliance Unit West Suite 400 – 4595 Canada Way, Burnaby, British Columbia, V5G 1J9 Phone: 604-666-3350 Toll free: 1-800-267-9675 Fax: 604-666-3149 E-mail: insp_woc-coo@hc-sc.gc.ca