Health Canada Santé Canada

Distributing samples of prescription drugs, non-prescription drugs and natural health products

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. We

- work to reduce health risks
- ensure that high-quality health services are accessible

Également disponible en français sous le titre :
Distribution d'échantillons de médicaments d'ordonnance, de médicaments sans ordonnance et de produits de santé naturels

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Foreword

Guidance documents inform industry and health care professionals about how to comply with statutes and regulations. They also help Health Canada staff apply our mandate and objectives in a manner that is:

- fair
- effective
- consistent

We may accept alternate approaches to the principles and practices described in this document, if they are supported by adequate justification.

You should discuss any alternate approaches, in advance, with the relevant programme area, to make sure that you will meet all the statutory or regulatory requirements that apply.

We reserve the right to:

- request information or material
- define conditions not specifically described in this document

We are committed to ensuring that:

- such requests are justifiable
- decisions are clearly documented

Legal disclaimer

This document does not constitute part of the *Food and Drugs Act* or its associated Regulations. In the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence.

This document is an administrative document, intended to facilitate compliance by the regulated party with the Act, the Regulations and the applicable administrative policies. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Table of Contents

1. Summary

Health Canada's role in the regulation of the distribution of prescription, non-prescription drugs (NPDs) and natural health products (NHPs), as samples, is to help ensure that samples are:

- safe
- effective
- of high quality

We also ensure that the proper conditions are in place to enable Canadians to access samples.

Industry may distribute drugs including NHPs as samples as a strategy to encourage their use on a trial basis. This may provide benefits to Canadians, practitioners and pharmacists, by increasing their knowledge of available health product options to meet their needs.

NPDs and NHPs may be provided as samples to practitioners and pharmacists for further distribution, if they are within their scope of practice under provincial or territorial law. When distributed as samples, drugs including NHPs may help practitioners to determine which product would be most appropriate for their patient. Samples such as toothpastes and sunscreens can also support public health initiatives.

Prescription drugs may be provided to practitioners and pharmacists for further distribution to their patients if they are authorized to prescribe or dispense these drugs under the laws of the province or territory in which they practice.

Drugs including NHPs may be distributed directly to consumers (the general public) only if they are on:

- *List D: List of Certain Non-prescription Drugs for Distribution as Samples* (List D) of the *Food and Drug Regulations* (FDR), or
- *List A: List of Certain Natural Health Products for Distribution as Samples* (List A) of the *Natural Health Products Regulations* (NHPR)

Distribution of some drugs as samples is **not** permitted. These drugs are:

- narcotics
- controlled substances
- prescription drugs containing cannabis
- prescription drugs outside a practitioner's or pharmacist's prescribing authority in the province or territory in which they practice.
- NPDs and NHPs outside a practitioner's or pharmacist's scope of practice in the province or territory in which they practice.

1.1 Purpose of this document

We intend this document to help stakeholders interpret the legislative and regulatory requirements for distributing samples of:

- prescription drugs
- NPDs
- NHPs

Throughout this document the word “drugs” will mean:

- prescription drugs
- NPDs
- NHPs

1.2 Scope and application

This guidance is on the conditions under which drugs may be distributed as samples to:

- consumers
- pharmacists
- practitioners

This guide does not apply to medical devices or drugs for veterinary use.

In addition, this document does not provide guidance on practitioners’ or pharmacists’ scope of practice; it only focuses on federal level requirements.

1.3 Policy objectives

The policy objectives we aim to achieve include:

- ensuring that the level of regulatory oversight for the safety, efficacy and quality standards of drugs continues to apply when drugs are being distributed as samples

- ensuring that the proper regulatory restrictions/conditions are in place to mitigate risks that may be associated with the distribution of drugs as samples

- aligning federal regulations with provincial and territorial laws, to better meet the changing needs of the health care system

2. Guidelines on distributing drugs as samples

Compliance and enforcement actions are taken in accordance with the Compliance and enforcement policy for health products (POL-0001). The determination of whether a drug is being distributed, or being caused to be distributed, as a sample will be based on any facts, circumstances and contextual factors surrounding the distribution that may be relevant to such determination. These include whether the distribution of a drug is:

- free of charge (or at a lower cost),
- intended or likely to induce the use of the drug on a trial basis,
- intended or likely to encourage future purchases of the drug, or
- in a lesser quantity of the drug than normally available for sale at retail.

Note: To conform with existing practices, samples of drugs that can only be obtained through a practitioner or pharmacist should be free of charge and be accompanied by the Patient Medication Information approved by Health Canada, if available.

Examples of the distribution of drugs on List A of the NHPR or List D of the FDR as samples to consumers include samples distributed:

- through retail outlets,
- at organized events, such as:
    - trade shows,
    - campus events, or
    - sports and entertainment events
- or, as part of:
    - charitable activities, or
    - public health initiatives.

Depending on how the drugs are regulated, an individual or organization may distribute drug samples by two pathways:

- directly to adult consumers (those 18 years of age or older)
- to a practitioner or pharmacist, for further distribution to their patients, in accordance with their scope of practice

The individual or representative of an organization who are distributing a drug as a sample should be:

- at least 18 years of age
- able to answer questions on the drug's
    - risks
    - benefits
    - proper directions of use, etc.

2.1 Requirements for all drugs distributed as samples

The distribution of a drug as a sample is considered a "sale" under the *Food and Drugs Act* (FDA).

Distributing drugs as samples and all associated activities must comply with all requirements related to the "sale" of a drug. This includes, but is not limited to:

- reporting adverse reactions
- getting a market authorization
- complying with advertising requirements
- complying with good manufacturing practices
- keeping records and executing recalls as necessary
- complying with packaging and labelling requirements
- obtaining a site or an establishment licence, as required
- amending and notifying post-market changes to the market authorization

As such, the product authorization cannot have been suspended or cancelled. A direction cannot have been issued to stop sale.

2.1.1 Conditions on the Expiry Date or Expiration Date

Drugs distributed as samples must **not** be distributed past their labelled expiry or expiration date. Once the labelled expiry or expiration date has passed, the drug is not recommended for use, as it may no longer have its labelled potency, purity and physical characteristics.

Furthermore, the drug **must** be distributed to a consumer or patient at least:

- 30 days before the labelled expiry or expiration date (if the date is in dd-mm-yy format) or
- one month before the labelled expiry or expiration date (if the date is in mm-yy format)

This helps ensure that consumers have time to try the product before it expires.

2.2 Distributing drugs as samples directly to consumers

2.2.1 Scope of drugs that can be distributed as samples to consumers

Only NPDs and NHPs that meet all of these criteria may be distributed as samples directly to adult consumers. They must meet all:

- criteria and qualifiers on List A or List D
- parameters set out in their market authorization

These drugs should also comply and be consistent with the specific conditions and parameters outlined in their most recently published Natural and Non-prescription Health Products Directorate (NNHPD) monograph. Relevant NNHPD monographs, in the Compendium of Monographs, are:

- Mouthwashes
- Antiseptic Skin Cleansers
- Primary Sunscreens
- Secondary Sunscreens
- Anti-Dandruff Products
- Diaper Rash Products
- Medicated Skin Care Products
- Acne Therapy Products
- Throat Lozenges
- Athlete's Foot Treatment
- Toothpastes

Note: Not all products listed in these monographs can be distributed as samples directly to consumers. To be distributed as samples to adult consumers, products must not go beyond the criteria and qualifiers on List A or List D.

2.2.3 Age restriction of recipients

Only NPDs and NHPs on List D or List A may be directly distributed as samples to an adult consumer (18 years or older).

Even if these drugs are authorized for sub-populations under 18 years of age, they may only be distributed as samples to adult consumers 18 years of age and older.

Individuals and organizations distributing drugs as samples should take appropriate steps to ensure adequate safeguarding against distribution of these drugs to those under 18 years of age. Factors to consider include the distribution:

- location (office building vs. schools and play areas)
- method (in-person distribution vs. blind or random mail distribution)
- context (at a seniors wellness conference vs. at an arena during a youth tournament)

2.3 Distributing drugs as samples to practitioners and pharmacists for further distribution to their patients

This section outlines federal requirements for drugs distributed as samples to practitioners and pharmacists. Provinces and territories may have additional restrictions on:

- practitioners and pharmacists
- conditions of distribution, such as place of sale
- individuals and organizations distributing drugs as samples
- the types of products permitted for distribution as a sample within their jurisdiction

Note: The age restriction in place for distributing to consumers does not apply to practitioners or pharmacists further distributing drugs to their patients in accordance with their scope of practice.

2.3.1 Requirements for distributing drugs as samples to practitioners and pharmacists

2.3.2 Orders and recordkeeping

Drugs distributed as samples that are **not** on List D or on List A may only be distributed in dosage form to a practitioner or pharmacist if you have a signed order from that practitioner or pharmacist. This requirement is per C.01.048(1) and 103.4(1) of the FDR and NHPR, respectively.

Drugs that **are** on List D or List A do not require an order from a practitioner or pharmacist before they may be given to a practitioner or pharmacist for further distribution.

The individual or organization receiving a signed order must keep the order and records of the signed order for at least two years for those products not listed in List D of the FDR or on List A of the NHPR. The records must contain the:

- name, address and description of each person to whom the drug is distributed
- brand name, quantity and form of the drug distributed
- date upon which each such distribution was made

These orders may also show that the order may be repeated, for any interval specified, as long as the total period is not more than 6 months.

3. Other information

3.1 Re-packaging and labelling for a sample size

Market authorization holders must report changes to packaging to Health Canada. This includes a new package format, size or fill volume, regardless of whether it is for a drug being distributed as a sample or not. If market authorization holders intend to distribute drugs as samples in a new package format, size or fill volume, they should consult these documents on how to meet packaging and labelling requirements:

Prescription drugs:

- Post-Notice of Compliance (NOC) Changes: Quality Document
- Post-Drug Identification Number (DIN) Changes Guidance Document
- Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs
- Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)
- Good manufacturing practices guide for drug products

Non-prescription drugs:

- Post-Notice of Compliance (NOC) Changes: Quality Document
- Post-Drug Identification Number (DIN) Changes Guidance Document
- Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)
- Good manufacturing practices guide for drug products
- Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products
- Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs

3.2 Products packaged together

Co-packaged products/kits package multiple drugs together. When products are packaged, there is a risk that the co-packaging may imply certain unapproved claims or pose a safety concern. For this reason, market authorization holders may be required to file a submission to obtain authorization to distribute their co-packaged product.

For more guidance on products sold together, please review the information in Table 1.

Table 1

Regulation governing the product	**Additional Guidance**
FDR	• Section 3.6.1 Co-packaged Products within the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use; • Section 4.2.2.2 Change to packaging within the Guidance Document Post-Drug Identification Number (DIN) Changes.
NHPR	An application for a market authorization is required for natural health products being sold together when: • there is a new brand name associated with the kit or • there are contraindications for the use of the products together or • there are changes to the labelling associated with the kit beyond what is provided for each product separately For more guidance on products sold together that are regulated under the NHPR, please reach out by email to hc.nnhpd-dpsnso.sc@canada.ca.

Note: The highest-risk product of the products sold together determines the level of oversight.

If the co-packaged samples consist of only drugs that meet the criteria in List D and/or List A, the samples may be distributed to adult consumers.

If the co-packaged samples contain one or more drugs not on List D or List A, the co-packaged product may only be distributed to practitioners or pharmacists, if the drugs are within their scope of practice under provincial or territorial law.

3.3 Drugs with risk management plans

Risk management plans allow for early identification of risks associated with the use of a drug and methods to minimize those risks. If a drug has a risk management plan, the plan would apply to the drug when distributed as a sample.

We expect the market authorization holder to meet the conditions and methods outlined in their risk management plans, to continue to protect the health and safety of Canadians. You can find more information on risk management plans in these guidance documents:

- Questions and Answers regarding the Implementation of Risk Management Planning
- Guidance Document – Submission of Risk Management Plans and Follow-up Commitments

4. Process for updating the Incorporation by Reference Lists

Health Canada initiates changes to List D and List A based on safety considerations.

4.1 Incorporation by Reference Lists in the *Food and Drug Regulations*

Before making any changes to List D of the FDR, we will notify stakeholders through a Notice of Proposal on the Canada.ca website.

Stakeholders will typically have 60 days to provide comments. We consider all comments before making an informed decision about any changes. We will post Notice of Modification on canada.ca to indicate when the changes come into effect, once a decision is final.

4.2 Incorporation by Reference Lists in the *Natural Health Products Regulations*

Changes to List A of the NHPR would require a regulatory amendment. Before making any changes in List A of the NHPR, we will consult stakeholders by pre-publishing in the *Canada Gazette*, Part I. The *Canada Gazette* consultation period gives stakeholders an opportunity to comment on proposed changes. We will consider all comments received, before making an informed decision about any change to List A of the NHPR. Final changes to the list will be published in the *Canada Gazette*, Part II.

For reference, you can find more information about Incorporation by Reference on Canada.ca website for food products.

Appendices

Appendix A – Glossary

a) Acronyms

FDA: *Food and Drugs Act*
FDR: *Food and Drug Regulations*
List A: List of Certain Natural Health Products for Distribution as Samples
List D: List of Certain Non-prescription Drugs for Distribution as Samples
NHP: Natural Health Product
NHPR: *Natural Health Products Regulations*
NNHPD: Natural and Non-prescription Health Products Directorate
NPD: Non-prescription drug

b) Terms

Consumer: a person who buys a drug for personal use, or a person who receives a drug as a sample for personal use.

Drug: for the purpose of this guidance, refers to prescription drugs, non-prescription drugs and natural health products.

Drug distributed as a sample: the determination of whether a drug is being distributed, or being caused to be distributed, as a sample will be based on any facts, circumstances and contextual factors surrounding the distribution that may be relevant to such determination. These include whether the distribution of a drug is:

- free of charge (or at a lower cost),
- intended or likely to induce the use of the drug on a trial basis,
- intended or likely to encourage future purchases of the drug, or
- in a lesser quantity of the drug than normally available for sale at retail.

Market Authorization: a licence for a health product issued under the regulations that authorizes the sale and advertisement of that health product.

Authorization may include, for example a:

- notice of compliance
- drug identification number
- natural product number/product licence

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, manufactured, sold or represented for use in:

a. diagnosing, treating, mitigating or preventing of a disease, disorder or abnormal physical state or its symptoms in humans;

b. restoring or correcting organic functions in humans; or
c. modifying organic functions in humans, in a manner that maintains or promotes health.

A natural health product does not include a substance set out in Schedule 2of the NHPR, 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.

Non-prescription drug: a pharmaceutical drug product that is available to consumers without a prescription from a practitioner. They are generally available to consumers at pharmacies or stores but could also require the assistance of a pharmacist.

Order: in the context of distribution of drugs as samples, a document that shows the:

- brand name of the drug
- quantity of the drug
- proper name or common name of the drug
- signature of the requesting practitioner or pharmacist

Pharmacist: a person who is

a. registered or otherwise entitled under the laws of a province to practise pharmacy; and
b. practising pharmacy in that province.

Practitioner: a person who is

a. entitled under the laws of a province to treat patients with a prescription drug; and
b. practising their profession in that province.

Prescription drug: a drug set out in the Prescription Drug List, as amended from time to time, or a drug that is part of a class of drugs set out in the Prescription Drug List.

Sell: includes offer for sale, expose for sale, have in possession for sale and distribution, whether or not there is payment involved.

Site licence or establishment licence: a licence issued under the regulations that authorizes, as the case may be, activities such as:

- importation
- testing
- storage
- labelling
- packaging
- preparation
- preservation, and
- manufacturing

Appendix B – List of related guidance documents

Packaging/Labelling

Prescription Drugs

- Good Label and Packages Practices Guide for Prescription Drugs
- Guidance Document: Labelling of Pharmaceutical Drugs for Human Use
- Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)
- Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs)

Non-prescription Drugs

- The Guidance Document: Drug Facts Table for Non-Prescription Drugs
- Guidance document: Labelling Requirements for Non-prescription Drugs
- Guidance Document: Labelling of Pharmaceutical Drugs for Human Use
- Guidance Document Questions and Answers: Plain Language Labelling Regulations
- Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs)
- Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products
- Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-Prescription Drugs
- Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)

Natural Health Products

- Labelling Requirements Checklist
- Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products

Changes to the Market Authorization

- Post Licensing Guidance Document
- Post-Notice of Compliance (NOC) Changes – Quality Guidance
- Post-Drug Identification Number (DIN) Changes Guidance Document
- Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document
- Natural Health Product Licence Amendment and Notification Form User Guide

Product Lifecycle

- Management of Drug Submissions
- Natural Health Products Management of Applications Policy
- Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs)

Import/Export

- Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084)

Good Manufacturing Practice

- Good Manufacturing Practices Guidance Document
- Good manufacturing practices guide for drug products (GUI-0001)

Advertising

- Guidelines for Consumer Advertising of Health Products
- The Distinction Between Advertising and Other Activities
- Regulation of Health Products Advertising in Canada – Overview for Physicians

Adverse Drug Reaction Reporting

- Reporting Adverse Reactions to Marketed Health Products – Guidance Document for Industry
- Submitting Summary Reports for Marketed Drugs and Natural Health Products – Guidance Document for Industry

Recall

- Recall Policy
- Product Recall Procedures

Other

- Incorporation by Reference
- Safe disposal of prescription drugs
- Compliance and enforcement policy for health products (POL-0001)
- Guidance Document – Submission of Risk Management Plans and Follow-up Commitments
- Questions and Answers regarding the Implementation of Risk Management Planning Product Monograph