Health Canada Santé Canada

Draft Guidance Document

Electronic media in prescription drug labelling

This guidance document is being distributed for comment purposes only.

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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L'utilisation des médias électroniques pour les étiquettes des médicaments sur ordonnance

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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1. Introduction

1.1 Purpose

This guidance document describes Health Canada's expectations for distributing information about a prescription drug product using an electronic platform linked to that product's label.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

1.2 Scope and application

The scope of this document is currently limited to prescription drugs for human use. The use of electronic labelling for the purpose of a clinical trial is **not** within the scope of this document.

This document applies to product-specific electronic platforms, containing drug and other information, that are linked to prescription drug labels.

In this context, an electronic platform refers to any type of electronic technology used to distribute information. Websites are a common example of an electronic platform.

A link refers to any type of reference on a label which points to or provides access to an electronic platform such as a:

- barcode
- web address

A drug label refers to any legend, word or mark attached to, included in, belonging to or accompanying a drug. Traditionally, this definition has been applied to a drug's:

- package inserts
- inner and outer labels
- product monograph (PM)
- any other physical materials generated by a sponsor that are included in the drug package or supplied at the time of dispensing

Electronic platforms that only contain electronic versions of approved PMs (or package inserts), but that do not provide any other product-specific information, are not subject to the same obligations described in this document. Examples of such platforms include corporate websites that contain electronic versions of approved PMs, in addition to corporate and other general information. You are permitted to include a link to such platforms on their product's label and are not required to resubmit electronic versions of approved PMs to Health Canada for assessment.

Electronic platforms that are not linked to a product's label are not bound by the same obligations as those platforms that are linked, particularly with respect to federal labelling laws. Because of this important difference, this document only focuses on platforms that are linked to a product's label.

It is also important to note that the guidance provided in this document is based on Health Canada's existing legal framework. As such, information distributed through an electronic platform generally cannot replace information that is required by law to appear on a drug's physical label (that is, inner and outer labels). The use of electronic media in prescription drug labelling is voluntary and supplementary to existing legal requirements.

This document complements other Health Canada guidance documents related to prescription drug labelling and advertising, such as:

- Guidance Document: Labelling of Pharmaceutical Drugs for Human Use
- Good Label and Package Practices Guide for Prescription Drugs
- Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs
- The Distinction Between Advertising and Other Activities
- Guidance Document - Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising

1.3 Policy objectives

Health Canada's objective is to ensure that you comply with federal laws when distributing drug and other information electronically. This includes federal labelling and advertising laws under the:

- Food and Drugs Act (FDA)
- Food and Drug Regulations (FDR)

This document also conveys certain expectations that may not be explicitly expressed in legislation or in regulation, but are nonetheless important in support of universally recognized principles such as patient safety and accessibility.

We reserve the right to request information or material, or define conditions not specifically described in this document, in order to allow adequate assessment of the safety, efficacy, or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

1.4 Background

Health care providers and their patients have become increasingly reliant on digital technologies as a source of health information. To facilitate access to this information, some sponsors have submitted applications to Health Canada seeking authorization to add useful information to prescription drug labels. This information includes:

- 2D bar code
- links, such as a web address/URL

These links guide users to a product-specific electronic platform with the help of an electronic device.

2. Guidance for implementation

2.1 Legal framework

The legal framework that governs the use of electronic media in prescription drug labelling includes:

- the Food and Drugs Act (FDA)
- the Food and Drug Regulations (FDR)
- certain provisions of the Controlled Drugs and Substances Act (CDSA) and its Regulations for prescription drugs containing controlled substances

Under this legal framework, you are permitted to distribute information through an electronic platform that is linked to a prescription drug label, for example the:

- package insert
- inner and outer label

However, you must comply with the rules set out by the Acts and Regulations that form this framework, particularly federal laws related to prescription drug labelling and advertising.

Any personal information collected through interaction with an electronic platform is subject to the Personal Information Protection and Electronic Documents Act (PIPEDA), the federal privacy law for private-sector organizations.

Information you can distribute through electronic platforms

Health Canada recognizes the PM, including Part III (also known as the patient medication information or consumer information section), as the complete and factual account of a product's:

- claims
- properties
- conditions of use
- safety and efficacy

However, you may wish to distribute more information in order to help prescription drug users better understand your product and the condition for which it was prescribed. This information can include:

- alternative presentations of parts of the PM, such as a video that demonstrates how to accurately administer a medication
- more general, non-drug specific information, such as disease management strategies or lifestyle recommendations

Broadly speaking, the FDA does not prohibit you from distributing information beyond that which is legally required, provided that the information complies with Section 9 of the FDA (https://laws-lois.justice.gc.ca/eng/acts/F-27/page-3.html). To ensure compliance with this provision, you should be mindful of a product's Terms of Market Authorization (TMA). The TMA is understood to mean the collection of labelling information associated with a product that has been approved by Health Canada as part of its regulatory drug review process.

Any information which meets the definition of a 'label' or 'advertisement' in the FDA would be subject to specific legal requirements under the:

- FDA and its regulations
- CDSA and its regulations for drugs containing controlled substances

Federal labelling laws apply to electronic platforms linked to a prescription drug label

The FDA provides the following definition for a label: "includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package." This definition is often used to refer to physical labels such as inner and outer labels or package inserts. However, the words "belonging to" expand the definition of a label to include a legend, word or mark that extends beyond that which is physically connected to the drug. In this context, the words "belonging to" can apply to electronic information under certain conditions.

Health Canada considers information on an electronic platform to meet the definition of a label when:

- reference to the electronic platform is made on a drug's label, for example through a link, **and**
- the electronic platform which has been referenced contains information that speaks directly to topics covered by the label of the drug in question, that is drug information

Electronic materials that meet both of these conditions, henceforth referred to as electronic labels, must comply with federal drug labelling laws. Information is not considered to be part of a drug's label if it is:

- on an electronic platform that is not linked to the label
- unrelated to topics covered by the label of the drug in question, for example, general health information.

In this way, an electronic platform can contain both labelling and non-labelling information.

Although an electronic platform can sometimes be an extension of a drug's label, it does not mean that all information required to appear on a label can be transferred to an electronic platform. As the terms "inner label" and "outer label" are narrowly defined in the FDR to only mean the label which is "on or affixed to the immediate container or the packaging of a food or drug," the relocation of information required to appear on inner and outer labels to an electronic platform is generally not permitted.

The majority of labelling requirements under the FDA and FDR pertain to information that must appear on a drug's physical package, namely its inner and outer labels. However, certain provisions apply to all forms of labels, including electronic labels.

You must provide mock-ups of every label with each of the following submission types:

- Drug Identification Number application (DINA) or Drug Identification Number application for a biological product (DINB) (Section C.01.014.1(2) of the FDR)
- (abbreviated) new drug submission ((A)NDS) or supplement to an (abbreviated) new drug submission (S(A)NDS) for assessment (Sections C.08.002(2) and C.08.003(3.1) of the FDR)

Federal advertising laws apply to electronic platforms linked to a prescription drug label

Federal advertising laws apply to advertising in any medium, including electronic media. The FDA defines an advertisement as "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device." Representations that are deemed advertising are subject to the following key provisions:

- the promotion of a drug is limited to authorized drugs (Section C.08.002(1) of the FDR)
- a drug may not be advertised in a manner that is false, misleading or deceptive (among other conditions) (Section 9 of the FDA)
- the promotion of a prescription drug to the general public is limited to name, price and quantity (Section C.01.044 of the FDR)
- a drug may not be advertised to the general public for the treatment, prevention or cure for any Schedule A disease, disorder of abnormal physical state (Section 3 of the FDA)
- controlled drugs, narcotics and targeted substances may not be advertised to the general public (Section G.01.007 of the FDR, Section 70 of the Narcotic Control Regulations and Section 78 of the Benzodiazepines and Other Targeted Substances Regulations)

These provisions strictly limit the degree of prescription drug advertising that you can conduct. However, the information would be considered non-promotional in nature and exempt from the key provisions if the information was presumed:

- to inform health care providers administering the drug
- intended solely to educate patients for whom the drug has been prescribed

You must ensure that only these patients and their health care providers have access to this information. Distributing this type of information outside of this context could be considered promotional, and therefore trigger the key provisions.

These guidelines are intended to help you comply with federal laws and to ensure that universally recognized principles, such as patient safety and accessibility, are respected when distributing information through an electronic platform linked to a prescription drug label.

2.2 Guidelines

Links and barcodes

Guideline 1: Take into account the overall legibility of the prescription drug label when deciding on the location and the format of the link, and incorporate the link in a way that maximizes user accessibility.

The FDR requires that the format of a label, including the manner in which its text and any graphics are displayed on it, does not impede the comprehension of information that is required to appear on the label. This regulation is intended to improve the safe use of drugs by making drug labels easier to read and understand. You must consider the overall design of the label, including the placement of any key text or graphics, when incorporating a link to an electronic platform such as a URL or 2D barcode.

You should also make an effort to facilitate access to the platform so that as many users as possible can benefit. Links that are novel, overly complex or lacking context could impede access for some users. You should consider these strategies to maximize user accessibility:

- If there is sufficient space on the label, offer users more than one way to access the electronic platform. For example, a 2D barcode should ideally be accompanied by a URL so that consumers can type the URL into an internet browser if they lack a device to scan the 2D barcode.
- Select a user-friendly URL, using words rather than a series of numbers or random alphanumeric characters. A shorter URL may also be easier to enter into a browser.
- If space permits, include a short statement near the link to explain its purpose and provide instructions for use.

Advertising

Guideline 2: Ensure that the design and content of the platform do not violate federal advertising laws

Distributing prescription drug information electronically can expose you to the risk of advertising violations, even when this information is intended for non-promotional purposes. For example, prescription drug information (beyond name, price and quantity) which is accessible to the general public could be considered promotional and in violation of federal advertising laws. You should take appropriate measures to prevent potential compliance issues.

When designing a platform intended for patients or health care providers, you should incorporate a robust 'gating' mechanism (a virtual barrier that requires user authentication) on the platform to prevent public access. A "noindex" meta tag should also be used for every page behind a gating mechanism to prevent public access through search engine results.

You should also consider other potential risks unique to electronic media such as the use of metadata in Search Engine Optimization (SEO) or Search Engine Marketing (SEM). Metadata for non-gated pages should not contain direct or implied product claims that would contravene the regulations.

You must also ensure that all materials (in all media formats) distributed through an electronic platform comply with federal advertising laws, even if the platform is gated. Whenever such materials contain a reference to a drug product, you must assess whether the information is promotional and whether it contravenes federal advertising laws.

You should consult the policy described in The Distinction Between Advertising and Other Activities (https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents/policy-distinction-between-advertising-activities.html) to help determine whether information is promotional or not. In general, information on a platform (which is intended for patients and health care providers) will be considered non-promotional if it:

- does not expand upon or conflict with the drug's PM
- is limited to the drug for which the platform was designed
- is gated by a robust mechanism to ensure access is limited to patients who have been prescribed the drug

Given the complexities associated with digital advertising, we strongly encourage you to submit your electronic platforms for review to an independent advertising preclearance agency prior to launching a platform. This will help ensure the platform is adequately protected from potential advertising violations.

Content and sources

Guideline 3: Ensure that drug information on a platform is consistent with the approved Product Monograph, and that non-drug information is derived from trusted, high-quality sources

Any information on an electronic platform is considered to meet the definition of a label under the FDA if it:

- speaks directly to topics covered by the label of the drug in question, **and**
- is linked to a drug's label, including the inner and outer label, package insert or PM

Because the PM serves as the standard against which all labelling information is compared, drug information on an electronic platform must be consistent with the most up-to-date version of the approved Canadian PM. Like physical labels, electronic labels must be for assessment and receive authorization prior to distribution. We will assess electronic labels as part of established regulatory drug review processes.

While we review electronic labels on electronic platforms as part of our regulatory review process, non-labelling materials (that are non-promotional in nature) are generally beyond our regulatory oversight. Nonetheless, patients and health care providers will rely on the accuracy of non-drug information distributed through such platforms. As such, you should ensure that this information, which could be disease or other health information, is derived from reputable and up-to-date scientific sources. When appropriate, references should be included to demonstrate the reliability of this information. You should also be careful not to express this information in a way that creates a false or misleading impression about the drug.

Separation of information

Guideline 4: Separate Health Canada approved electronic labels from other types of information on the platform

Electronic platforms may contain both information that would be classified as a label as well as non-labelling materials, such as disease or general health information. In order to help end-users distinguish between approved labels and other types of information, and to facilitate the submission and review of labelling materials, you should avoid blending these two types of information on the platform and should clearly separate them (for example, place them on different areas or webpages of a website). Avoid using statements such as "Health Canada approved" when organizing various content on a platform. These statements may be considered in violation of Section C.01.007 of the FDR, as described in the guidance document for Labelling of Pharmaceutical Drugs for Human Use (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/labelling-pharmaceutical-drugs-human-use-2014-guidance-document.html#a25).

Plain language labelling

Guideline 5: Present information in a way that is clear, understandable and accessible

The 2014 Plain Language Labelling (PLL) Regulations were enacted to improve the safe use of drugs by requiring labels that are clear, understandable and expressed in plain language. While these Regulations generally implicate physical labels, you should apply similar standards to electronic labels.

The application of PLL requirements to physical labels has required consideration of print-specific features such as:

- type style and size
- use of white space
- colour and contrast

Electronic platforms can be a more complex medium. Unlike printed materials, electronic platforms can include dynamic elements such as audio and video content. While such features can offer new and effective ways of educating users, the nature of this medium also gives rise to potential accessibility barriers. People who may be particularly vulnerable to such barriers include:

- those with disabilities
- those who are unfamiliar with the technologies necessary to benefit from this medium

In the absence of Health Canada guidance on this topic, you should observe established and internationally recognized digital accessibility standards, such as the World Wide Web Consortium's (WC3) Web Content Accessibility Guidelines (WCAG). WCAG compliance can:

- improve accessibility to electronic content
- address many of the considerations necessary to achieve clear and understandable electronic labels

You should continue to express any electronic information in plain language.

Protection of personal information

Guideline 6: Protect any personal information collected through the platform

Any personal information collected by interacting with an electronic platform is subject to the Personal Information Protection and Electronic Documents Act (PIPEDA) (https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/), the federal privacy law for private-sector organizations. PIPEDA sets the ground rules for how businesses should handle personal information in the course of commercial activity. There are a number of requirements associated with PIPEDA. In general, organizations must obtain an individual's consent when they collect, use or disclose that individual's personal information. In addition, personal information can only be used for the purposes for which it was collected.

Maintenance

Guideline 7: Maintain full control over the platform

You are responsible for ensuring that your electronic platform is compliant with all federal requirements. As such, you should maintain complete control over the platform including any information linked to it. This means ensuring that the platform does not link to third-party platforms that:

- are beyond your control
- may be or become non-compliant

In some cases, you may choose to contract the services of a third party to host your platform. Contracting a third party to host the platform does not change your regulatory obligations, regardless of the platform's host or location, and regardless of any agreements between you and the third party.

2.3 Submission and Assessment

2.3.1 Submission

Pre-submission meeting

You are encouraged to indicate the inclusion of electronic labelling materials if you request a pre-submission meeting prior to filing a submission. You can ask specific submission-related questions about with electronic labels in writing to the designated Health Canada regulatory project manager or senior regulatory affairs officer.

Initial request to incorporate a link to an electronic platform

You can make the initial request to incorporate a link to an electronic platform on a prescription drug label through existing submission pathways including a prescription drug's:

- initial application for market authorization ((A)NDS or DINA/DINB)
- the post-market application procedure (S(A)NDS or DINA/DINB)

You cannot make a request using:

- a Level III Annual Notification
- Post-Authorization Division 1 Change (PDC)
- an administrative submission pathway

Like other submissions requiring an assessment of prescription drug labels, you are required to submit mock-ups of physical and electronic labels at the time of initial filing. You must provide final label mock-ups during the review process, before the issuance of the NOC/DIN. You do not need to submit non-labelling materials on an electronic platform (for example, general disease information).

Mock-ups of physical labels, such as inner or outer labels with a newly incorporated link to an electronic platform, should be:

- editable
- actual size
- in full colour

For acceptable file formats, please refer to the electronic Common Technical Document (eCTD) and non-eCTD guidance documents (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/filing-submissions-electronically.html).

Mock-ups of electronic labels consist only of those parts of the platform that speak directly to topics covered by the drug label (that is, the PM). Mock-ups of electronic labels should reflect the format of the electronic material in its final state. For example, if the platform contains an electronic image depicting the administration of the drug, the corresponding mock-up should be submitted as an image file. All forms of non-text media which constitute an electronic label should also be accompanied by a written transcript, or alternative text in the case of an image, to facilitate the review. Non-text media includes:

- audio
- video
- images

For certain media formats, such as videos or interactive media, we recognize that it may not always be feasible for you to provide electronic label mock-ups that reflect the final format of the electronic material. This may not be feasible either at the time of filing or before the issuance of a NOC/DIN. In such circumstances, we will accept the following materials, which when taken together, would be considered to represent the important components of a mock-up:

- a storyboard or series of illustrations depicting the media sequence
- a written description for each segment of a media sequence, as an accompaniment to the storyboard
- a written transcript of any text or audio-based information embedded within each media sequence

For audio-based information without a visual or interactive component, we will accept a written transcript as a mock-up in lieu of an audio file.

At the time of initial filing, in addition to mock-ups, you are also asked to submit a:

- completed Labels and Packages Certification Form for Prescription Drugs
- a Note to Reviewer in section 1.3.2

The Note to Reviewer should provide a written overview of the platform, including:

- its intent
- its audience type
- a general description of the content and its format
- the virtual location of the platform (for example, the URL).

You are also asked to include a wireframe (a visual schematic) that:

- illustrates the general layout of the platform
- identifies which information on your website forms part of the label

While we will not review the design and format of the platform for authorization purposes, the latter information provides important contextual information in order to enhance the review of electronic labels.

In addition to these requirements, we strongly encourage you to submit all electronic materials to an independent advertising agency for preclearance prior to launching an electronic platform.

The Note to Reviewer should also briefly describe:

- what measures you have taken to avoid potential violations to federal advertising laws
- whether you have submitted or will submit electronic materials to an independent advertising agency for preclearance

Request to make changes to an already approved electronic label

Like printed labels, post-market changes to electronic labels require the filing of the appropriate submission type using the same principles outlined in Health Canada guidance documents, including:

- Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs
- Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document
- Post-Notice of Compliance (NOC) Changes: Quality Document
- Post-Drug Identification Number (DIN) Changes

However, you only need to submit content-related changes for authorization. You do not need to submit design and format related changes that do not have any impact on the content of electronic labels. You should note that content-related changes are not limited to text-based content. For example, a change in the way that non-text based elements convey drug information would be considered a content-based change.

You must provide mock-ups of affected electronic labels at the time of filing, and submit updated copies prior to approval of the submission. Any change to electronic label content must be consistent with the most current approved version of the PM.

We strongly encouraged you to submit all electronic materials to an independent advertising agency for preclearance before implementing any subsequent changes to the platform.

Submitting files in eCTD and non-eCTD formats

For more information on how to prepare submissions in eCTD format, refer to the:

- Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/ectd/preparation-drug-submissions-electronic-common-technical-document.html)

- Validation rules for regulatory transactions provided to Health Canada in the electronic Common Technical Document (eCTD) format (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/ectd/notice-validation-rules-regulatory-transactions-submitted-health-canada-electronic-common-technical-document-format-2016-12-1.html)

For more information on how to prepare submissions in non-eCTD format, refer to the:

- Guidance Document: Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" Format (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/common-technical-document/updated-guidance-document-preparation-regulatory-activities-non-ectd-electronic-only-format.html)
- Validation Rules for regulatory transactions filed in non-eCTD format (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/common-technical-document/notice-validation-rules-non-ectd-electronic-only-format.html).

You should submit mock-ups of electronic labels that are represented in different formats as separate files in section 1.3.2 of an eCTD format or non-eCTD electronic only format submission.

Health Canada performance standards and fees for the review of submissions will apply.

2.3.2 Assessment

We will assess physical label mock-ups by reviewing any words or symbols associated with the newly incorporated link, as well as its impact on the overall design and format of the label.

We will assess electronic label mock-ups by reviewing content elements, including information manifested as text as well as non-text formats. Specifically, we will ensure that:

- electronic labels are expressed in plain language
- drug information is consistent with the product's approved PM

As part of the pre-market review process, we will not assess:

- the design and format of electronic labels
- the platform in which they are contained
- any non-labelling material on the electronic platform

If we become aware of contraventions to labelling or advertising regulatory requirements following approval, we will make an assessment to determine the most appropriate type of intervention.

Appendix A – Glossary of abbreviations

(A)NDS

(Abbreviated) New Drug Submission

CDSA

Controlled Drugs and Substances Act

DIN

Drug Identification Number

DINA

Application for a Drug Identification Number

DINB

Drug Identification Number application for a biological product

eCTD

Electronic Common Technical Document

FDA

Food and Drugs Act

FDR

Food and Drug Regulations

IEC

International Electrotechnical Commission

ISO

International Organization for Standardization

NDS

New Drug Submission

NOC

Notice of Compliance

PDC

Post-Authorization Division 1 Change

PIPEDA

Personal Information Protection and Electronic Documents Act

PLL

Plain Language Labelling

500 PM

501 Product Monograph

502 S(A)NDS

503 Supplement to an (Abbreviated) New Drug Submission

504 SEM

505 Search Engine Marketing

506 SEO

507 Search Engine Optimization

508 SNDS

509 Supplement to a New Drug Submission

510 TMA

511 Terms of Market Authorization

512 URL

513 Uniform Resource Locator

514 WCAG

515 Web Content Accessibility Guidelines

516 W3C

517 World Wide Web Consortium