

Drug Intake, Review, Evaluation, Contracts, Transactions (DIRECT) ‘User Guide’

Drug Benefits Management Unit

Health Programs and Delivery Division

Ministry of Health

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What is DIRECT?

DIRECT (Drug Intake, Review, Evaluation, Contracts, Transactions) is a web portal for manufacturers and vendors to submit and manage requests for drug funding under the Ontario Public Drug Programs.

DIRECT provides numerous improvements to help you manage your submissions.

Each manufacturer/vendor registered in DIRECT can:

- View a list of their submissions that have been entered via the DIRECT portal
- Search their submission list based on submission primary file number or product name
- View and track submissions with the following statuses:
 - Additional Information Submitted
 - NDSS Letter Issued
 - Recommendation Letter Issued
 - Reconsideration
 - Saved
 - Submitted
 - Withdrawn
- View a PDF summary of submission data provided to the ministry
- View ministry announcements
- Maintain details for their organization's primary contacts

DIRECT allows manufacturer(s)/vendor(s) to:

- Create new submissions by entering relevant information and uploading files to satisfy submission requirements for:
 - Biosimilar Products
 - Multiple Source Drug Products
 - Single Source Drug Products
 - Nutrition Products
 - Continuous Glucose Monitoring (CGM) Products
 - Diabetic Test Agents (DTA)
 - Valved Holding Chambers (VHC)
- Access relevant submission guidelines based on selection of submission category and product type
- Save a submission as 'draft'
- Delete a 'draft' submission when/if it is no longer required
- Use the integrated submission form (Guided Data Entry) to reduce the occurrence of incomplete submissions

- Submit additional information in cases where an NDSS Letter is issued deeming the submission incomplete
- Submit a notification of change for existing products for the following reasons:
 - Drug Identification Number (DIN) Change
 - Drug Product Name Change
 - Product Monograph Change
 - Formulation Change
 - Ownership Change
 - Distributor Change
 - Organization Name Change
 - Product Discontinuation
 - Price Change
 - Product Change
 - Change in Advertising Policy
 - Change in Food and Drug Regulation Classification
 - Change to Label

**NOTE THE FOLLOWING:**

- DIRECT does not currently provide role-based access within an organization such as ‘creator’ and ‘submitter’, or the ability to restrict user access to select submissions within an organization
- The ministry continues to provide all NDSS Letters and Recommendation Letters via email
- Legacy drug submissions are not visible in DIRECT
- Drug submissions received via email are not visible in DIRECT

Symbols Used in the Guide



This caution symbol indicates important information about DIRECT that you should be aware of.



This icon highlights important items that may be of interest to you.



This icon highlights tips and tricks that will help you in your use of DIRECT and may facilitate your navigation through the platform.

About This Guide

The guide provides a step-by-step approach to using DIRECT from logging in through to the submission and tracking of a submission status. It is designed to be used by manufacturers and vendors. This guide refers to features and functions implemented for this current release of DIRECT and will be updated as new functionality is implemented.



Note that all screenshots and examples shown in this document use fake data. All drug names, indications, active ingredients, dosages, manufacturer names, and user names are fictional.

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Chapter 1 – Getting Started in DIRECT

This chapter provides the instructions for logging into DIRECT. It also includes step-by-step details on how to manage contacts and add additional users as needed (see [Chapter 1.2](#) for details).

1.1. How to Log In to DIRECT

The following steps highlight the procedures a manufacturer or vendor follows to log into the DIRECT portal.

1.1.1. The DIRECT project team will provide a URL to access DIRECT, and the **Welcome** screen below will display.



The latest version of Chrome, MS Edge, Opera, Firefox, or Safari are the recommended browsers for accessing DIRECT. Other browsers are not supported and may lead to unexpected behaviour including the inability to log in.

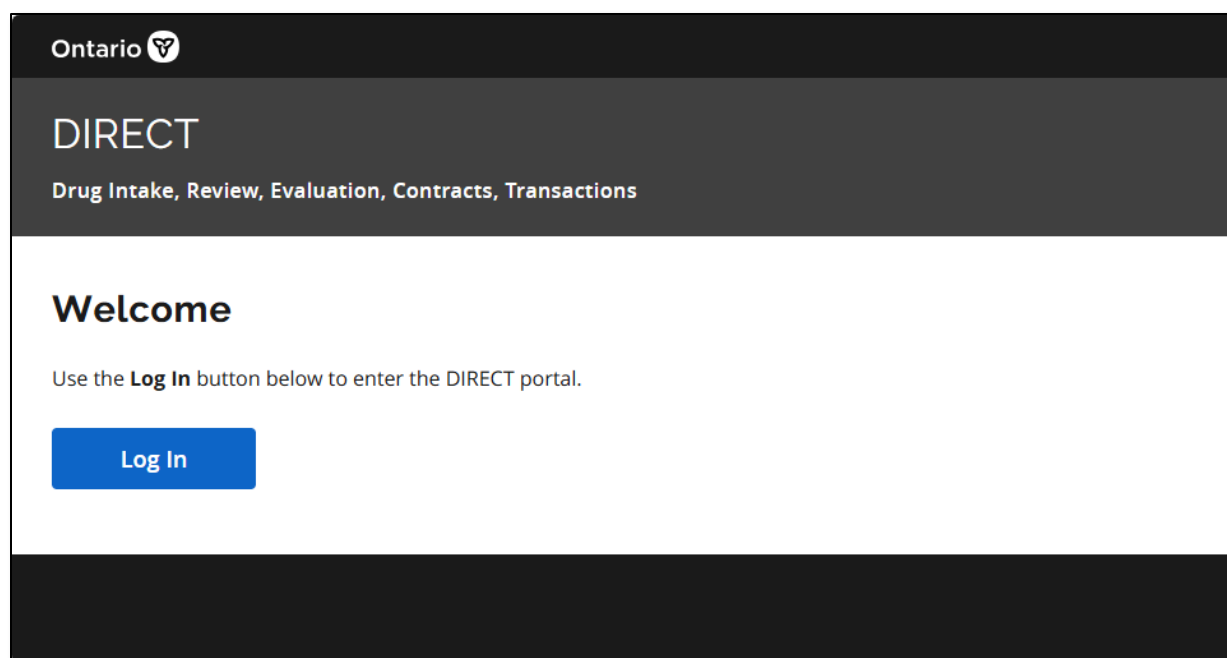


Figure 1 - Image of the DIRECT Log In Button on the Ministry's DIRECT Website

1.1.2. Select the **<Log In>** button and the **Submissions** screen displays (shown below), and you can begin to create submissions.

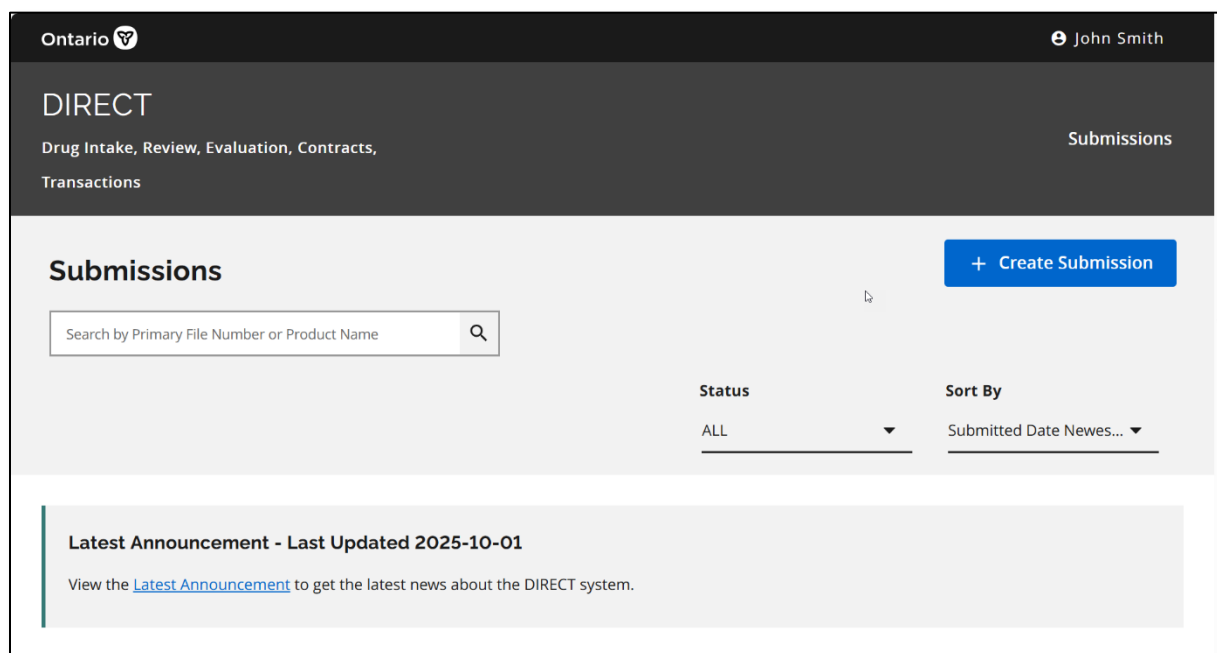


Figure 2 - Image of the Submissions Screen



Note that the **DIRECT Terms of Use** policy displays under these circumstances for each user:

- The first time a user logs into DIRECT
- The **DIRECT Terms of Use** policy has changed
- 90 calendar days or more have passed since a user last accepted the **DIRECT Terms of Use** policy

1.2. How to Manage Your Organization's Contact List

All users can add new contacts and edit details for existing contacts under their organization's list of contacts.



Important: All organizations and new users that require access to DIRECT must be onboarded individually. Manufacturers cannot register or provide system access to vendors, and vendors cannot register or provide access on behalf of manufacturers. Each organization must contact DIRECT@ontario.ca to be authenticated and granted access to DIRECT. **Users can only manage contacts' details within their own organization.** Vendors should contact DIRECT@ontario.ca if the manufacturer they are submitting on behalf of is not visible in the system.

- 1.2.1. Log in to DIRECT and click on your name in the top left corner of the screen, then select the <Manage Contact List> link.

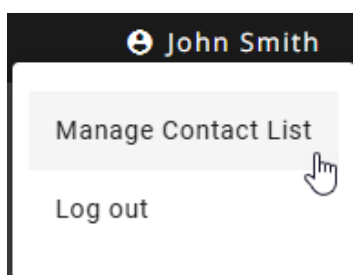


Figure 3 – Screenshot of the Manage Contact List Link

- 1.2.2. The **Individual Contacts** list for your organization is displayed.

Individual Contacts

VitalCure Medications

The ministry requires written notification in order to change a primary contact, or any other information related to contact information (e.g., address, telephone number, e-mail address etc.). Please also note any active submissions that would be affected by this change. It is the manufacturer's responsibility to keep this information current and accurate. Please notify the ministry within 1 business day if the primary contact has changed. Failure to do so may delay the submission review.

[+ Add Contact](#)

Smith, John

Title

Director

Phone Number

4164564567

Email

john@vitalcure.ca

Address

500 Main Street



Primary

[View/Edit](#)

Figure 4 – Screenshot of the Individual Contacts List

- 1.2.3. Note that the contact shown in the screenshot above is selected as the *Primary contact* for this organization. To view or change this contact's information, click the **<View/Edit>** button.



Note the following requirements if your organization wishes to change a primary contact:

"The ministry requires written notification in order to change a primary contact, or any other information related to contact information (e.g., address, telephone number, e-mail address etc.). Please also note any active submissions that would be affected by this change. It is the manufacturer's responsibility to keep this information current and accurate. Please notify the ministry within 1 business day if the primary contact has changed. Failure to do so may delay the submission review".

- 1.2.4. To add a new contact for your organization, select the **<+ Add Contact>** link. The **Contact Details** Pop-up Window opens. Enter all required details for the new contact, then select the **<Add >** button.

Contact Details

Personal

Prefix (optional)

Select ▼

Job Title (required)

Chief Scientific Officer (CSO)

First Name (optional)

Enter the first name of the contact

jennifer

Middle Name (optional)

Enter the middle name of the contact

Last Name (required)

Enter the last name of the contact

Matheson

Contact

Primary Phone Number (required)

Enter the phone number with the area code

5554447777

Extension (optional)

Enter the phone number extension

Cancel

Add

Figure 5 – Screenshot of the Contact Details Pop-up Window

1.2.5. The **Individual Contacts** screen displays the new contact.

Individual Contacts

VitalCure Medications

The ministry requires written notification in order to change a primary contact, or any other information related to contact information (e.g., address, telephone number, e-mail address etc.). Please also note any active submissions that would be affected by this change. It is the manufacturer's responsibility to keep this information current and accurate. Please notify the ministry within 1 business day if the primary contact has changed. Failure to do so may delay the submission review.

[+ Add Contact](#)

Matheson, Jennifer

Title
Chief Scientific Officer
(CSO)

Phone Number
5554447777

Email
Jenn@vitalcure.ca

Address
500 Main Street

☐ Primary

[View/Edit](#)

Smith, John

Title
Director

Phone Number
4164564567

Email
john@vitalcure.ca

Address
500 Main Street

☒ Primary

[View/Edit](#)

Figure 6 – Screenshot of the Individual Contacts screen

- 1.2.6. The new contact has been successfully added for this organization. Users can view/edit details by selecting the **<View/Edit>** button, and they can select the **Primary** checkmark, depending on the situation. (See the note above regarding the process, if your organization wishes to change a primary contact.)



If the new contact requires access to DIRECT, contact the ministry (DIRECT@ontario.ca)

including the name and email of new contact(s).

Chapter 2 – Key Features in DIRECT

This chapter outlines the key features of DIRECT that users should be familiar with, including the options available on the Submissions Screen, how to access the latest ministry announcements, general navigation guidelines, and the requirements and parameters for uploading files.

2.1. The Submissions Screen

This section describes the key features of the **Submissions** screen. On initial log in, once you have accepted the '**Terms of Use**' policy, you will be directed to the **Submissions** screen. On this screen you can view, filter, sort and search for submissions your organization is working on, or has submitted through DIRECT, and you can create a new submission. You can also view the ministry's latest DIRECT-related announcements.

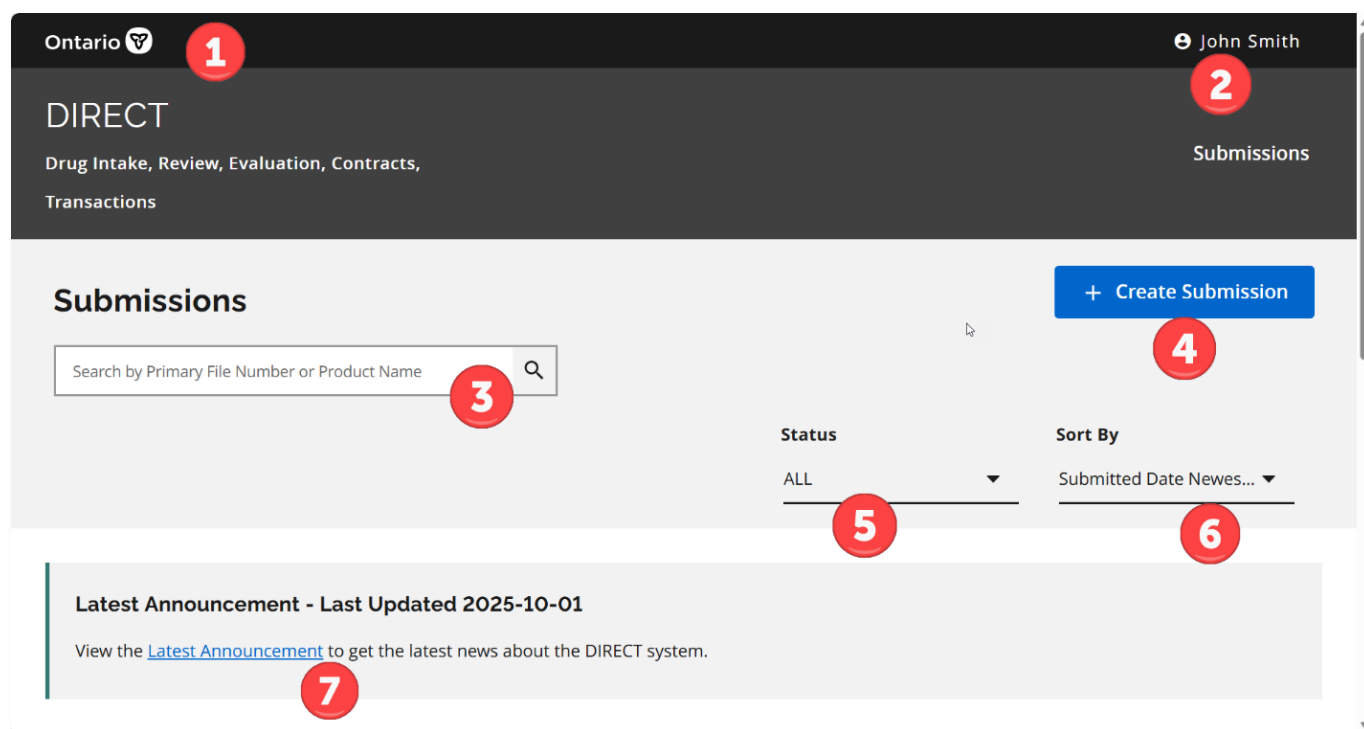


Figure 7 - Image of the Submissions Screen

Submissions Screen Descriptions:

Item	Description
1. Ontario logo	Link opens the Ontario government website in a separate tab.
2. Username link	Provides option to manage organization Contact List , and to Log out.
3. Submissions Search field	Search for organization's submissions submitted via DIRECT, by Primary File Number or Product Name.
4. <+Create Submission> button	Use to begin a new submission.
5. Status filter	Use drop-down to view list of submissions by status.
6. Sort by filter	Use drop-down to sort submissions by date submitted, Status, Primary File Number, etc.
7. Latest Announcement	Provides updates on DIRECT, ministry notices and tips for using DIRECT, including links to online support resources.



When exiting DIRECT, it is recommended that you always select your username at the top of the screen, to click on the **<Log out>** link to log out, to ensure your DIRECT session ends. As an additional precaution, it is recommended that you close your browser after you log out of DIRECT.

2.2. Ministry Announcements

The **Latest Announcements** section provides updates on DIRECT, as well as ministry notices related to DIRECT and tips for using DIRECT, including links to online support resources. Announcements are updated regularly. You can view all the information in this section by clicking the arrow on the right side of the screen and scrolling down, as shown below:

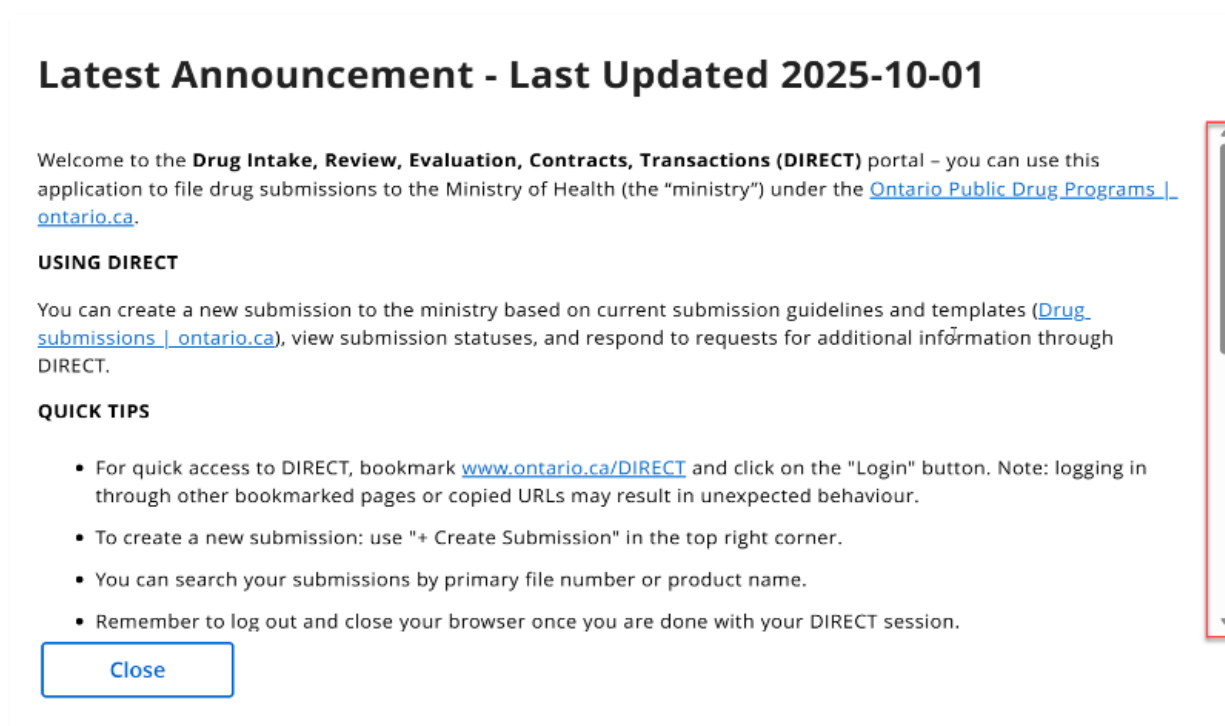


Figure 8 – Image of the Latest Announcement Section

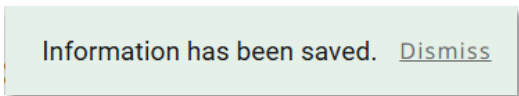
2.3. General Navigation

The following information may help you navigate efficiently within DIRECT, and ensure information entered is saved to the portal.



DIRECT does not automatically save your data, so it is important that you save as you go by clicking the **<Save>** button periodically. The **<Save>** button is available and “floats” at the bottom of every screen. A notification will pop-up on the screen informing you that your data has been saved. Clicking **Dismiss** will close the notification or leave it to close automatically after a few seconds.

Note that *saved* submissions can be found on the **Submissions List** by applying the filter status of *Saved*. [See Section 4.2](#) for more details about the filter feature.

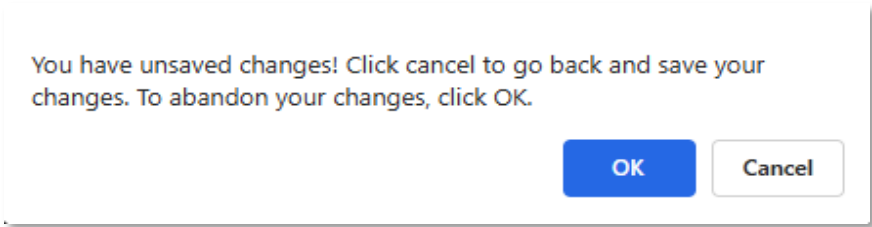
A light green rectangular notification box with a thin border. It contains the text "Information has been saved." followed by a blue, underlined link "Dismiss".

Information has been saved. [Dismiss](#)

Figure 9 - Image of the Information Saved Message



If you attempt to leave the submission without saving, the pop-up below will appear:

A white rectangular dialog box with a thin border. It contains the text "You have unsaved changes! Click cancel to go back and save your changes. To abandon your changes, click OK." and two buttons at the bottom right: a blue "OK" button and a white "Cancel" button with a grey border.

You have unsaved changes! Click cancel to go back and save your changes. To abandon your changes, click OK.

OK

Cancel

Figure 10 - Image of the Unsaved Changes Message

Clicking **OK** will exit the submission, and any information entered since the last time you saved the request will be lost. Clicking **Cancel** will close the pop-up and return you to the request, so you can

save before exiting.

A floating <↑**Top**> button displays at the bottom of screens and can be selected to quickly navigate to the top of the screen.

Clicking the <**More Actions**> link, available on some screens, provides an option to view the relevant Submission Guidelines, and an option to delete the current submission, if it is in a draft status.

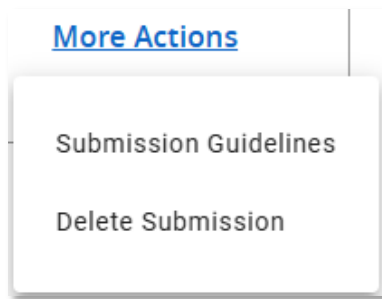


Figure 11 - Image of the More Actions Link

2.4. File Upload Messages

This section highlights the three main scenarios to be aware of when adding attachments (file uploads) in DIRECT.

- 1) **File Type is Invalid:** Only specific file types can be uploaded to DIRECT. Other file types are not supported, and an error message will display if you attempt to upload them.
- 2) **File Size is Too Large:** There is a limit of 200MB per individual file attachment. Files that exceed the limits will result in an upload failure and an error message will display. Compressed file archives (i.e., .ZIP, .7Z, .TAR) have additional rules.
- 3) **Timeout messaging:** Due to large files and/or slow internet connections, you may experience timeout messaging.

Scenario 1: File Type is Invalid

The following file types can be uploaded to DIRECT:

- .DOC, .DOCX, .TXT, .MSG, .RTF
- .PPT, .PPTX
- .XLS, .XLSM, .XLSB, .XLSX, .CSV
- .ZIP, .7Z, .TAR
- TIF, .TIFF, .GIF, .PDF

The following error message displays when a user is attempting to upload a file type that is not supported by DIRECT:

“Upload failure: File type is invalid. Refer to user guide for acceptable file types.

If the file type is not acceptable, please note the affected file in the “Supplemental Information” section and contact the ministry (DIRECT@ontario.ca) including the Primary File Number which is provided after submitting.”

Scenario 2: File Size is Too Large

The following messages display when a user is attempting to upload a file that is too large.

A: Attachment Exceeds 200MB

There is a limit of 200MB per file attachment. The following message displays:

“Upload failure: Attachment too large (max: 200MB). Please consider uploading a compressed ZIP file to reduce the size. If the file is still too large, note the affected file in the “Supplemental Information” section and contact the ministry (DIRECT@ontario.ca) including the Primary File Number which is provided after submitting.”

B: Individual File Within Compressed File Exceeds 500MB

There is a limit of 500MB per file when extracted. The following message displays:

“Upload failure: One or more files inside the compressed archive are too large (max: 500MB). Please note the affected file in the “Supplemental Information” section and contact the ministry (DIRECT@ontario.ca), including the Primary File Number which is provided after submitting.”

C: Total Size for All Files Within Compressed File Attachment Exceeds 1GB

There is a limit of 1GB when all files are extracted. The following message displays:

“Upload failure: The total size of all files inside the compressed archive is too large (max: 1GB). Please consider uploading multiple ZIP files.”

Scenario 3: Timeout messaging

There are timeout restrictions when adding an attachment, due to large files and/or slow internet connections. The following message displays when there is a system timeout:

“Upload failure: Upload timed out due to file size (max: 200MB) or internet connection. Please check the file size and your network connection, refresh your browser and try again. If the file is

too large, consider compressing it into a ZIP file before uploading. If the file remains too large or the issue persists, note the affected file in the “Supplemental Information” section and contact the ministry (DIRECT@ontario.ca) including the Primary File Number which is provided after submitting.”

Chapter 3 – Create a New Submission

This chapter describes how to create submissions in DIRECT. Submissions include the following submission categories: Drug Submissions, Non-Drug Submissions, and Notice of Change. DIRECT has been designed to be “user friendly” with a “guided data entry” feature that presents appropriate questions and options, based on the ministry’s guidelines. Users are directed to provide specific information or files to meet submission requirements and reduce the occurrence of incomplete submissions or delays.

Users will find that the process to create a submission using the “guided data entry” feature works the same way in DIRECT for the different submission categories, therefore, to be concise, this chapter will focus on two of the main new drug submissions, **Single Source Drug Product**, and **Multiple Source Drug Product**. This chapter also highlights the processes for creating and submitting a **Notice of Change**, and **Adding Additional Information**.

3.1. Submission Types that Can Be Entered Via DIRECT

This section provides an overview of the submissions that can be made for different product types via DIRECT.

The following diagram shows the options within DIRECT, for entering Drug Submissions:

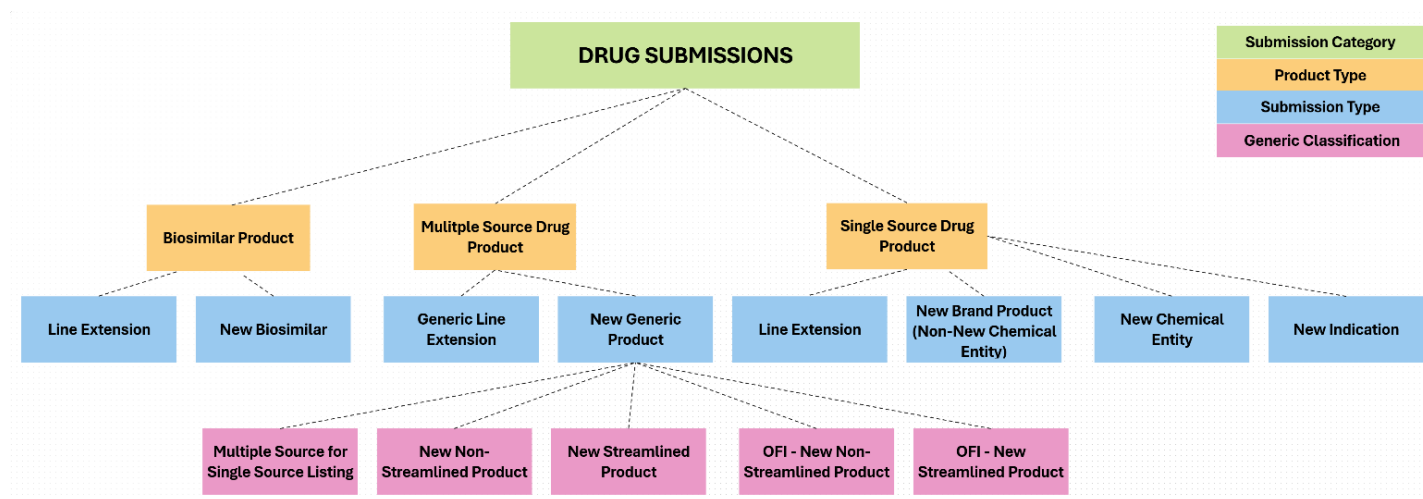


Figure 12 – Diagram of Options for Drug Submissions

The following diagram shows the options within DIRECT for entering Non-Drug Submissions:

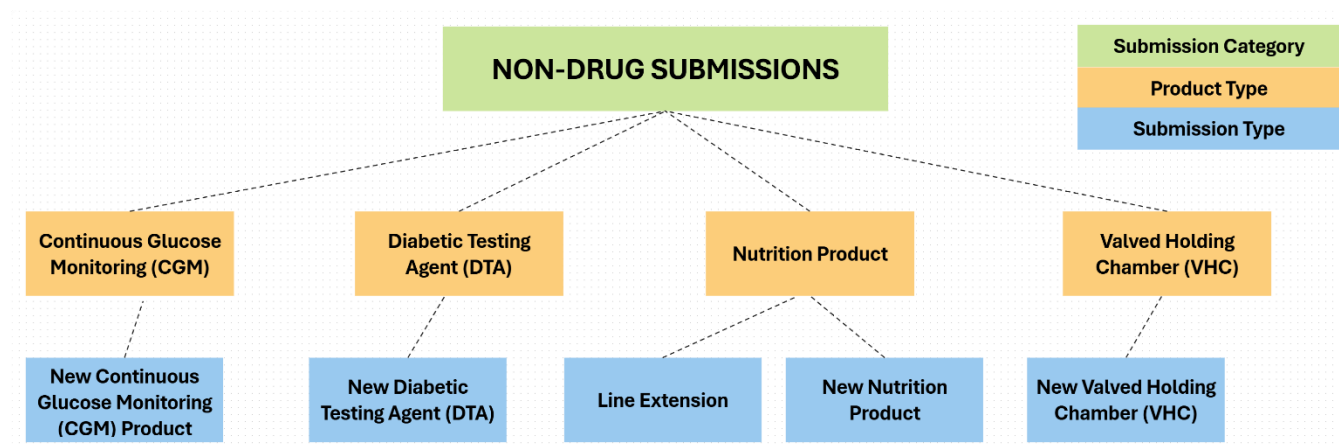


Figure 13 – Diagram of Options for Non-Drug Submissions

The following diagram shows the options within DIRECT for entering Notice of Change Submissions:

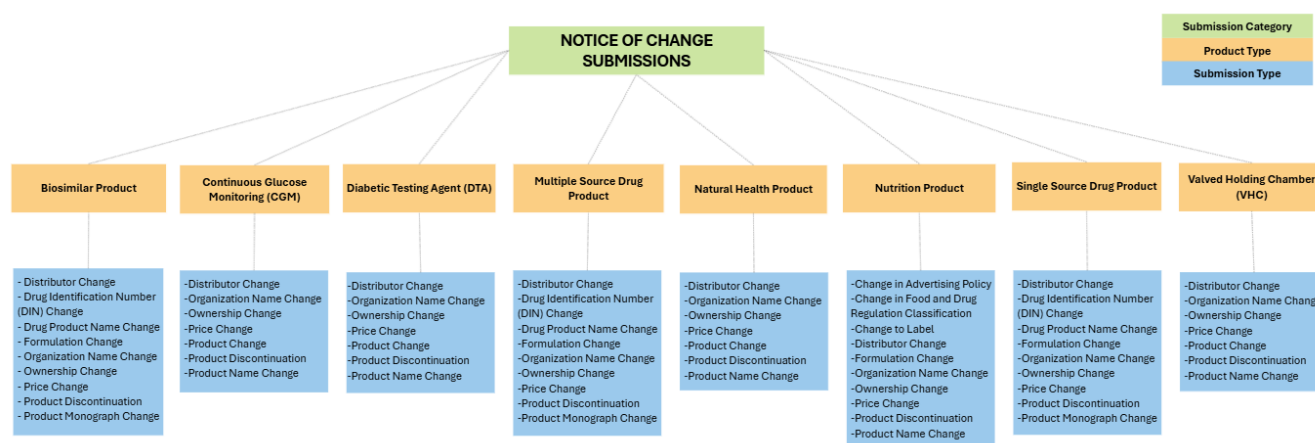


Figure 14 – Diagram of Options for Notice of Change Submissions

3.2. Submission Types that Cannot Be Entered Via DIRECT

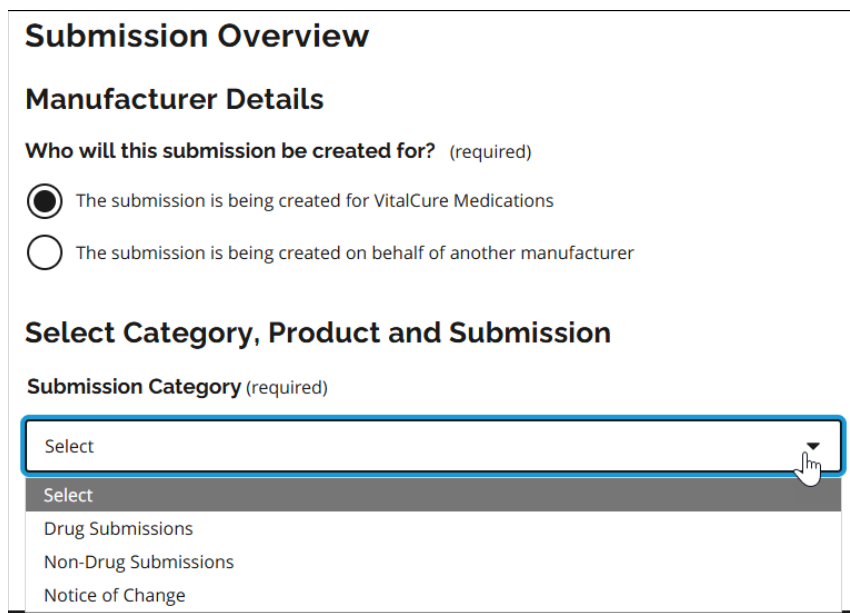
A new submission for the following product types are not available via DIRECT at this time and must be submitted via email:

- Natural Health Products
- Over-The-Counter (OTC) Products

3.3. How to Create a New Drug Submission for a Single Source Drug Product

The following steps outline the process for creating a new submission for a new chemical entity by a manufacturer user.

- 3.3.1. Log in to DIRECT and click on the **<+ Create Submission>** button. The **Submission Overview** screen displays.



The screenshot shows the 'Submission Overview' screen. It has two main sections. The first section, 'Manufacturer Details', contains a question 'Who will this submission be created for?' with a '(required)' label. There are two radio buttons: the first is selected and labeled 'The submission is being created for VitalCure Medications', and the second is unselected and labeled 'The submission is being created on behalf of another manufacturer'. The second section, 'Select Category, Product and Submission', contains a label 'Submission Category (required)' and a dropdown menu. The dropdown menu is open, showing a list of options: 'Select' (highlighted), 'Drug Submissions', 'Non-Drug Submissions', and 'Notice of Change'. A mouse cursor is pointing at the dropdown arrow.

Figure 15 – Screenshot of the Submission Overview screen

- 3.3.2. Select the default radio button to indicate the submission is being created for your organization.



See [Section 3.7](#) for details if the submission is being created on behalf of the Notice of Compliance (NOC) or Drug Identification Number (DIN) holder (e.g., the submission is being created by a vendor).

- 3.3.3. Click the **Submission Category** drop-down and select the value, '*Drug Submissions*'.
(Note that *Product Types* for Drug Submissions include the following options: Biosimilar Product, Multiple Source Drug Product, and Single Source Drug Product.)
- 3.3.4. Click the **Product Type** drop-down and select the value, '*Single Source Drug Product*'.

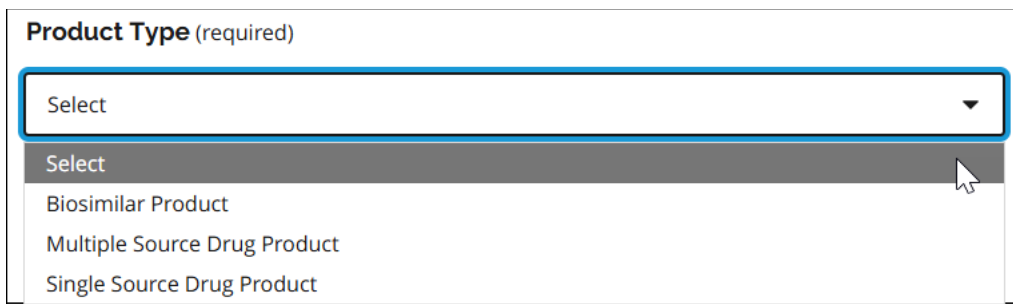


Figure 16 – Screenshot of the Product Type drop-down field

- 3.3.5. Click the **Submission Type** drop-down and select the value 'New Chemical Entity'. (Note that Submission Types for Single Source Drug Product Submissions include the following options: Line Extension, New Brand Product (Non-New Chemical Entity), New Chemical Entity, and New Indication.)

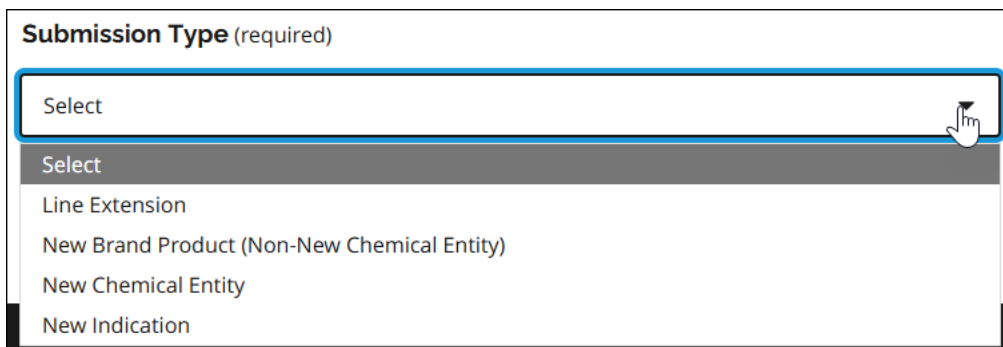


Figure 17 – Screenshot of the Submission Type drop-down field

- 3.3.6. Select the **<Applicable Guidelines>** link, if desired, and the relevant Guidelines open in PDF format in a separate tab, or they are downloaded to your Downloads folder, as a PDF document that can be opened and viewed.

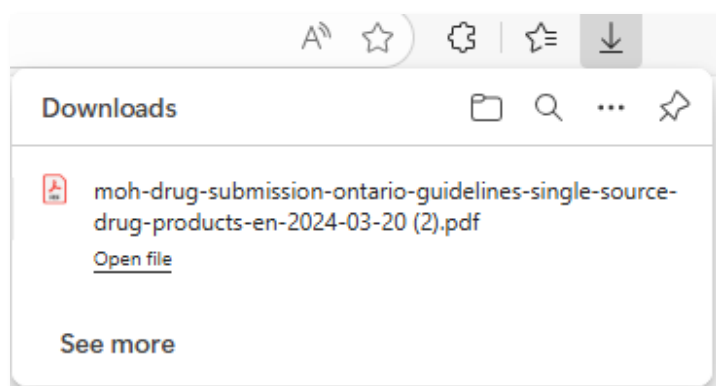
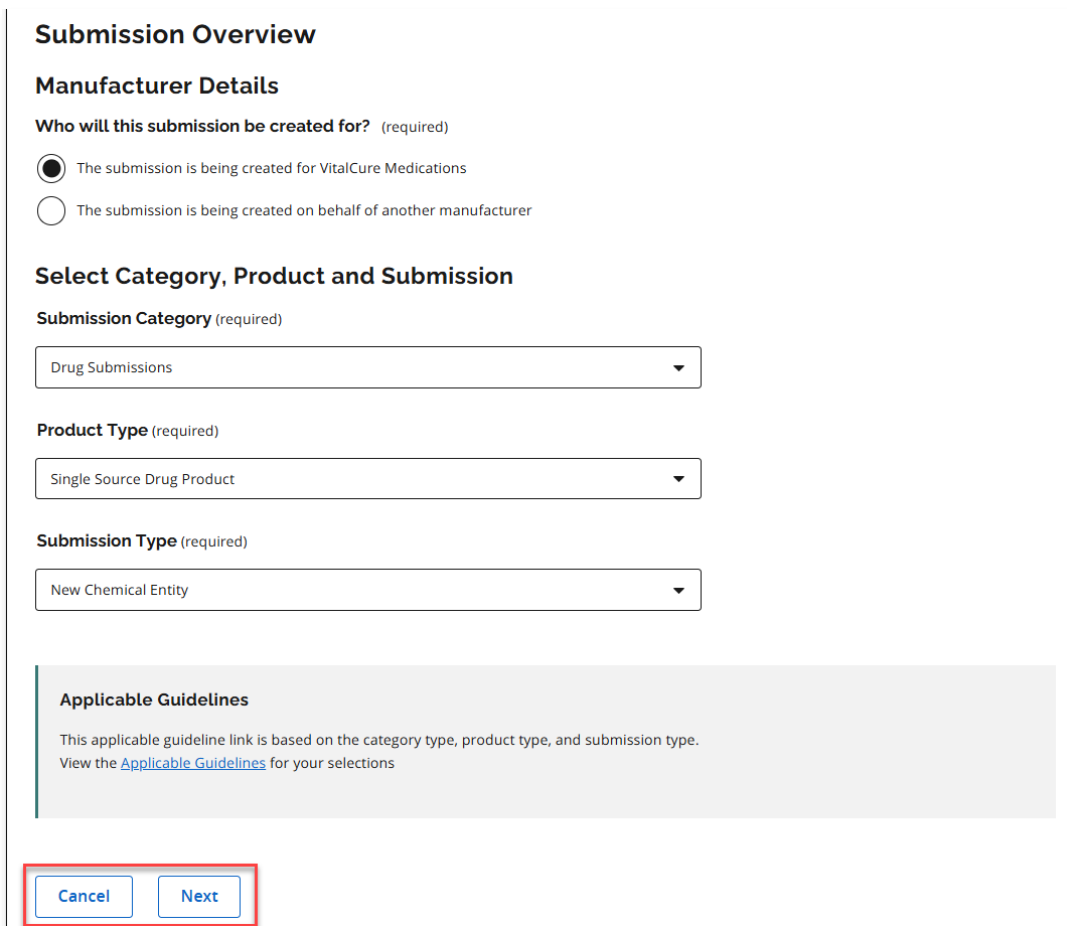


Figure 18 – Screenshot of a Downloaded Guidelines document as a PDF

- 3.3.7. Click the **<Cancel>** button to remove all selections on the screen, and return to the **Submissions** home screen, or click the **<Next>** button to continue to create the submission.



Submission Overview

Manufacturer Details

Who will this submission be created for? (required)

☒ The submission is being created for VitalCure Medications

☐ The submission is being created on behalf of another manufacturer

Select Category, Product and Submission

Submission Category (required)

Drug Submissions ▼

Product Type (required)

Single Source Drug Product ▼

Submission Type (required)

New Chemical Entity ▼

Applicable Guidelines

This applicable guideline link is based on the category type, product type, and submission type.
View the [Applicable Guidelines](#) for your selections

[Cancel](#) [Next](#)

Figure 19 – Screenshot of the Submission Overview screen

- 3.3.8. After clicking the **<Next>** button, the **Manufacturer Details** screen displays and is bolded in the left menu. Users must provide information in the *required* fields in each of the screens shown in the left menu, before submitting.

DIRECT

Drug Intake, Review, Evaluation, Contracts, Transactions

Back to Submissions

Manufacturer Details

Product Details

Submission Details

Health Canada Documentation

Clinical Evidence/Studies

Financial Impact Analysis

Pharmacoeconomic Analysis

Supplemental Information

Attestations

Review

No Product Assigned

Submission Category

Drug Submissions

Submission Type

New Chemical Entity

Product Type

Single Source Drug Product

More Actions

Manufacturer Information

VitalCure Medications

Address

Toronto, Ontario, Canada

Primary Contact Information

Select a Primary Contact for

Save

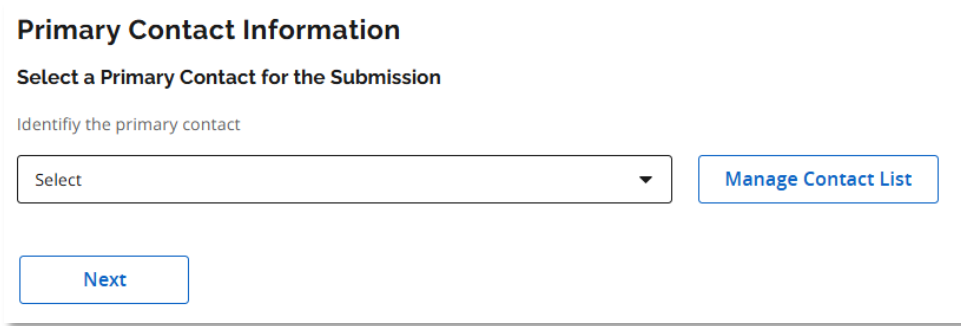
Identify the primary contact

Figure 20 – Screenshot of the Manufacturer Details screen



Note that if required information cannot be provided due to exceptional circumstances, please see [Section 3.3.58](#) for more information about entering a rationale.

3.3.9. Scroll down to the **Primary Contact Information** section and click on the **Primary Contact** drop-down and select the *'Primary Contact'* value.



Primary Contact Information

Select a Primary Contact for the Submission

Identify the primary contact

Select ▼

Manage Contact List

Next

Figure 21 – Screenshot of the Primary Contact Information section

3.3.10. Note that the Primary Contact for the organization displays with “*Primary*” in brackets, in the drop-down. Users can select the **<Manage Contact List>** button to view/edit/add contacts. (See [Section 1.2](#) How to Manage an Organization’s Contact List, for more details.)

3.3.11. The selected contact’s information displays (company, job title, email). Click the **<Next>** button.



- ✓ Manufacturer Details
- Product Details**
- Submission Details
- Health Canada Documentation
- Clinical Evidence/Studies
- Financial Impact Analysis
- Pharmacoeconomic Analysis
- Supplemental Information
- Attestations
- Review

Figure 22 – Screenshot of the Left Menu Tabs on the Product Details screen

3.3.12. The **Product Details** screen displays and is bolded in the left menu.



Note that after completing the required details on the **Manufacturer Details** screen, there is now a green checkmark beside *Manufacturer Details*, in the Left Menu. DIRECT guides users as screens are completed, using green checkmarks as a visual indicator that required details have been entered.

3.3.13. Click in the **Product Name** field and enter the product name.



The screenshot shows a form field for 'Product Name' with a '(required)' label. Below the label is a placeholder text 'Please enter the product name'. The input field contains the text 'Osteonix'.

Figure 23 – Screenshot of the Product Name field on the Product Details screen

3.3.14. Click in the **Active Ingredient(s)** field and enter the active ingredient(s) as it appears in Health Canada documentation.



The screenshot shows a form field for 'Active Ingredient(s)' with a '(required)' label. Below the label is a placeholder text 'Please enter the product's active ingredient(s) as it appears in Health Canada documentation'. The input field contains the text 'Hepatryl succinate'.

Figure 24 – Screenshot of the Active Ingredient(s) field on the Product Details screen

3.3.15. If appropriate, click in the **Identifier Type** drop-down field and select the value '*Drug Identification Number*'. (Note, this field is 'optional' in some situations, for example in the case of a pre-NOC where the DIN has not yet been issued.)

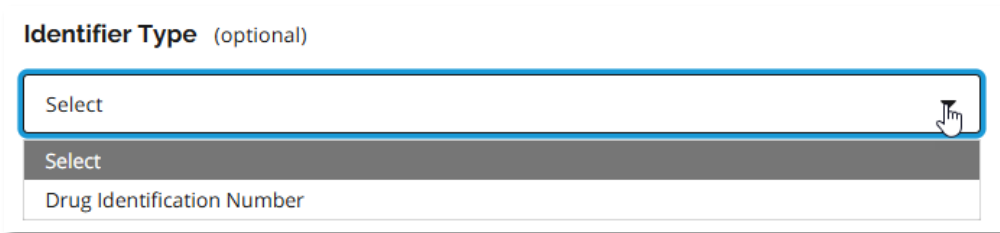


Figure 25 – Screenshot of the Identifier Type drop-down field on the Product Details screen

3.3.16. The **Identifier** field displays, if the Identifier Type was selected, enter the unique identifier assigned by Health Canada for the identifier type selected.



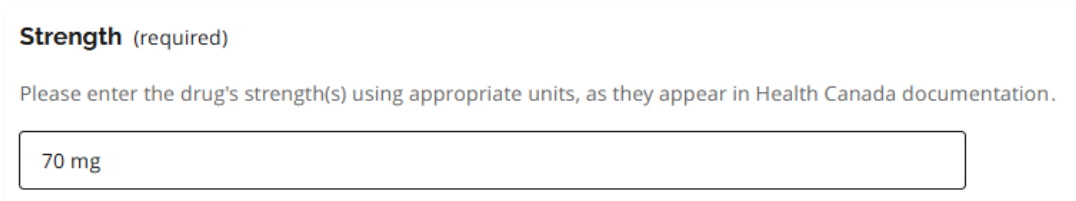
Figure 26 – Screenshot of the Identifier field on the Product Details screen

3.3.17. Click the **Dosage Form** drop-down and select the applicable value. Note that if the correct value cannot be located in the drop-down, choose 'Other' and you will be able to enter the value as free text.



Figure 27 – Screenshot of the Dosage Form drop-down field on the Product Details screen

3.3.18. Click in the **Strength** field and enter the drug's strength(s) using appropriate units and formatting, as they appear in Health Canada documentation (e.g., 500 mg, 10 mg/mL, 250 mcg/0.5 mL, 1 g/actuation).



Strength (required)

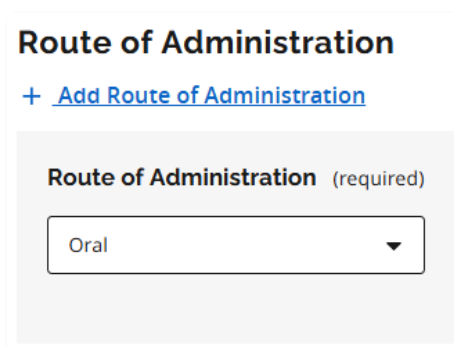
Please enter the drug's strength(s) using appropriate units, as they appear in Health Canada documentation.

70 mg

Figure 28 – Screenshot of the Strength field on the Product Details screen

3.3.19. Click in the **Route of Administration** drop-down field and select the applicable value.

Note that if the correct value cannot be located in the drop-down, choose 'Other' and you will be able to enter the value as free text.



Route of Administration

[+ Add Route of Administration](#)

Route of Administration (required)

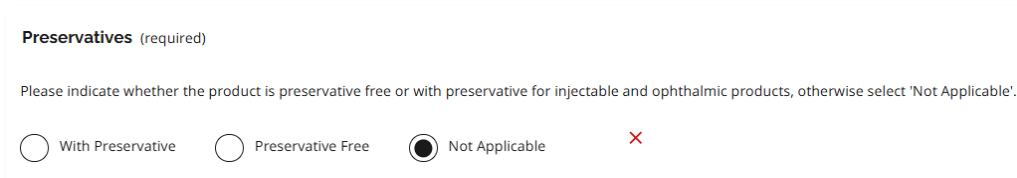
Oral ▼

Figure 29 – Screenshot of the Route of Administration drop-down field on the Product Details screen



Note that multiple routes of administration can be added, if necessary, by selecting the **<+ Add Route of Administration>** link.

3.3.20. Select the required radio button in the **Preservatives** field to indicate whether the product is preservative free or with preservative for injectable and ophthalmic products, otherwise select 'Not Applicable'.



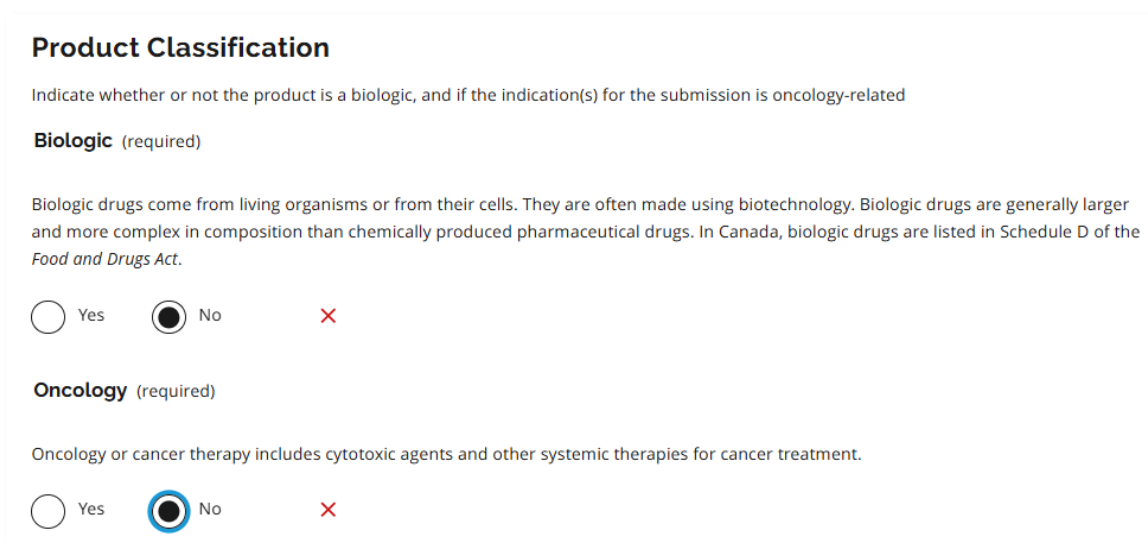
Preservatives (required)

Please indicate whether the product is preservative free or with preservative for injectable and ophthalmic products, otherwise select 'Not Applicable'.

☐ With Preservative ☐ Preservative Free ☒ Not Applicable ✗

Figure 30 – Screenshot of the Preservative field on the Product Details screen

3.3.21. Select the required radio buttons in the **Product Classification** section to indicate if the product is a biologic, and if the indication(s) for the submission is oncology-related.



Product Classification

Indicate whether or not the product is a biologic, and if the indication(s) for the submission is oncology-related

Biologic (required)

Biologic drugs come from living organisms or from their cells. They are often made using biotechnology. Biologic drugs are generally larger and more complex in composition than chemically produced pharmaceutical drugs. In Canada, biologic drugs are listed in Schedule D of the *Food and Drugs Act*.

☐ Yes ☒ No ✗

Oncology (required)

Oncology or cancer therapy includes cytotoxic agents and other systemic therapies for cancer treatment.

☐ Yes ☒ No ✗

Figure 31 – Screenshot of the Product Classification section on the Product Details screen

3.3.22. Enter the required details in the **Packaging and Pricing** section. Click the **Package Type** drop-down and select the package type. If the specific package type is not included in the drop-down list, select “Other” and enter the information as it appears in Health Canada documentation.

Packaging and Pricing

[+ Add additional packaging](#)

Package Type (required)

Please select the package type for the product from the drop-down list below. If the specific package type is not included in the drop-down list, select "Other" and enter the information as it appears in Health Canada documentation.

Package Size (required)

Please include package size(s), as it appears in Health Canada documentation (e.g., 30 tablets, 100 mL, 1 prefilled syringe, 5 vials)

[+ Add Price](#)

Price Type (required)

Price (required)

Unit (required)

Please enter the unit based on the selected price type (e.g., use tablet, gram, mL, etc. for smallest units; use bottle, kit, pre-filled syringe, etc. for package sizes)

[Back](#) [Next](#) [Save](#)

Figure 32 – Screenshot of the Product Classification section on the Product Details screen



Note that multiple packaging with multiple pricing per each package can be added.

3.3.23. Select the **Package Size** field and enter details. Include package size(s), as it appears in Health Canada documentation.

3.3.24. Click the **Price Type** drop-down and select the appropriate value.

3.3.25. Select the **Price** field and enter details. Note that the value should be to 4 decimal points.

3.3.26. Select the **Unit** field and enter the appropriate unit based on the selected price, then click the **<Next>** button to continue to create the submission.

3.3.27. The **Submission Details** screen displays and is bolded in the left menu.

3.3.28. Scroll down to the **Requested Funding/Listing/Program** section and select the appropriate value. Multiple values can be selected, if appropriate.



Submission Details

Requested Funding/Listing/Program (required)

☐ Exceptional Access Program (EAP)

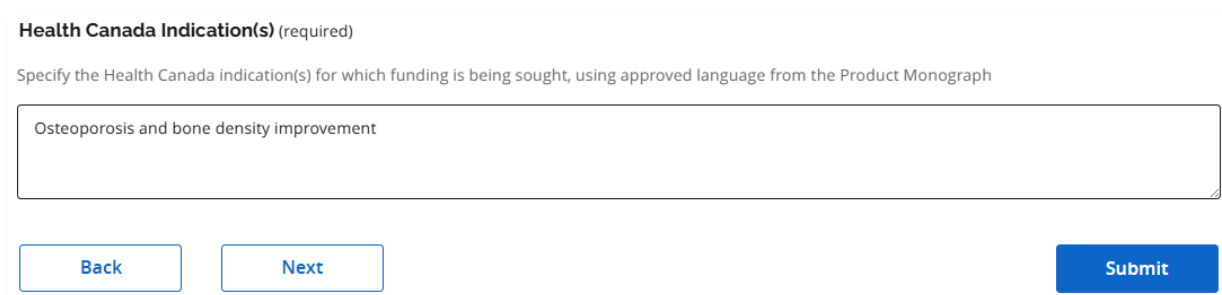
☒ General Benefit (GB)

☐ Limited Use (LU)

☐ New Drug Funding Program (NDFP)

Figure 33 – Screenshot of the Requested Funding/Listing/Program section

3.3.29. Select the **Health Canada Indication(s)** field and enter the details, then click the **<Next>** button to continue to create the submission.



Health Canada Indication(s) (required)

Specify the Health Canada indication(s) for which funding is being sought, using approved language from the Product Monograph

Osteoporosis and bone density improvement

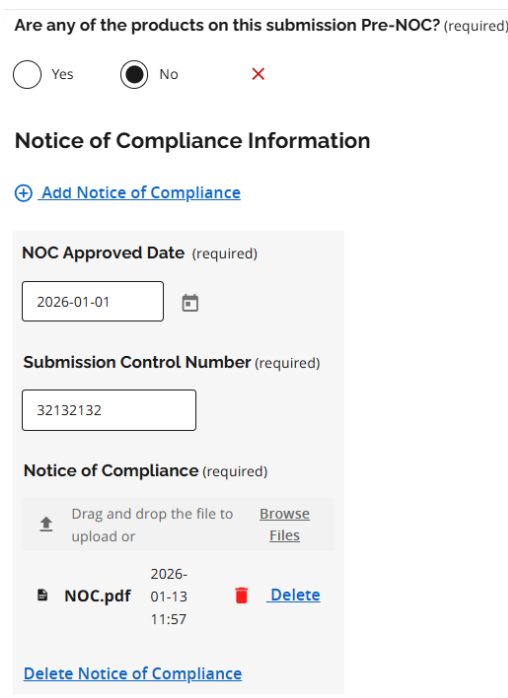
[Back](#) [Next](#) [Submit](#)

Figure 34 – Screenshot of the Health Canada Indication(s) field

3.3.30. The **Health Canada Documentation** screen displays and is bolded in the left menu.

3.3.31. Select the appropriate radio button for the question: *Are any of the products on this submission Pre-NOC?*

3.3.32. If selecting 'No' to the question: *Are any of the products on this submission Pre-NOC?* select the **<Add Notice of Compliance>** link.



Are any of the products on this submission Pre-NOC? (required)

☐ Yes ☒ No ☐

Notice of Compliance Information

[+ Add Notice of Compliance](#)

NOC Approved Date (required)

2026-01-01 

Submission Control Number (required)

32132132

Notice of Compliance (required)

 Drag and drop the file to upload or [Browse Files](#)

 **NOC.pdf** 2026-01-13 11:57  [Delete](#)

[Delete Notice of Compliance](#)

Figure 35 – Screenshot of the Notice of Compliance section

3.3.33. Enter the appropriate date in the **NOC Approved Date** field and enter the value in the **Submission Control Number** field. Then, upload the Notice of Compliance file by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.

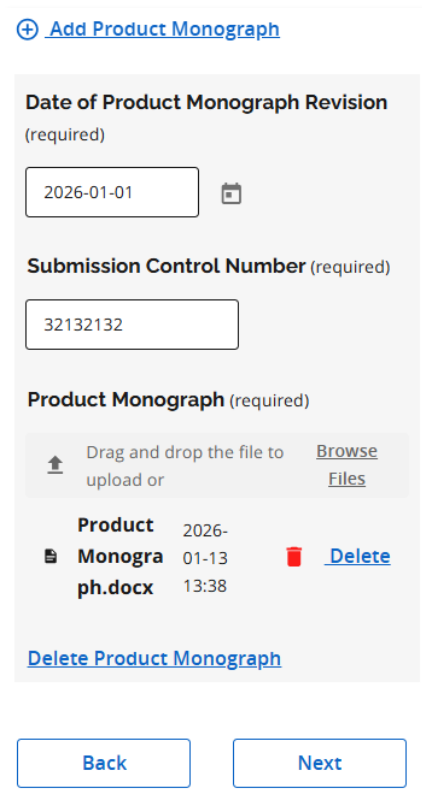


Important: Refer to [Section 2.4](#) for information related to file uploads.

3.3.34. In the **Product Monograph Information** section, provide the current Product Monograph approved by Health Canada and enter its date and submission control number. If Health Canada has not approved a Product Monograph for the drug product (e.g., it is an “old” drug that received a DIN but no NOC), please provide the information outlined in the Guidelines (see “If No Product Monograph Has Been Approved”). All supporting documents should be submitted via the Supplemental Information page.

3.3.35. Select the **<Add Product Monograph>** link. Enter the appropriate date in the **Date of Product Monograph Revision** field and enter the value in the **Submission Control Number** field.

3.3.36. Upload the Product Monograph file by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.



[+ Add Product Monograph](#)

Date of Product Monograph Revision (required)

2026-01-01 

Submission Control Number (required)

32132132

Product Monograph (required)

 Drag and drop the file to upload or [Browse Files](#)

Product	Monograph	File Name	Size	Actions
2026-	01-13	Monograph.docx	13:38	 Delete

[Delete Product Monograph](#)

[Back](#) [Next](#)

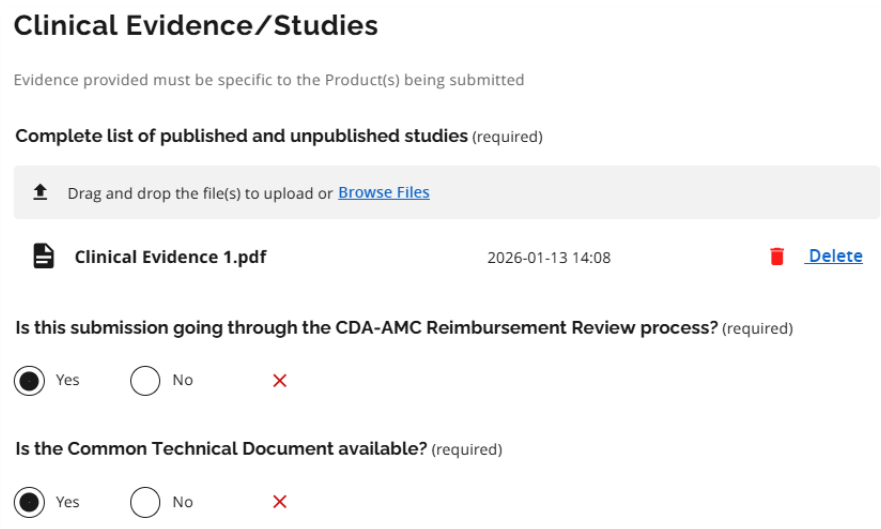
Figure 36 – Screenshot of the Product Monograph section

3.3.37. Click the **<Next>** button to continue to create the submission.

3.3.38. The **Clinical Evidence / Studies** screen displays and is bolded in the left menu. Note that evidence provided must be specific to the Product(s) being submitted.

3.3.39. Upload file(s) in the **Complete list of published and unpublished studies** field by

dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.



Clinical Evidence/Studies

Evidence provided must be specific to the Product(s) being submitted

Complete list of published and unpublished studies (required)

 Drag and drop the file(s) to upload or [Browse Files](#)

 Clinical Evidence 1.pdf	2026-01-13 14:08	 Delete
--	------------------	--

Is this submission going through the CDA-AMC Reimbursement Review process? (required)

☒ Yes ☐ No ✗

Is the Common Technical Document available? (required)

☒ Yes ☐ No ✗

Figure 37 – Screenshot of the Clinical Evidence / Studies section

3.3.40. Select the appropriate radio buttons for the following questions: “Is this submission going through the CDA-AMC Reimbursement Review process?” And “Is the Common Technical Document available?”

3.3.41. If selecting ‘Yes’ to the question: *Is the Common Technical Document available?* the **Common Technical Document(s)** section displays.

Common Technical Document(s)

Module Section 2.5: Clinical Overview (required)

Drag and drop the file(s) to upload or [Browse Files](#)

 Clinical Overview.pdf	2026-01-13 14:15	 Delete
---	------------------	--

Module Section 2.7.1: Biopharmaceutical Studies and Associated Analytical Methods (required)

Drag and drop the file(s) to upload or [Browse Files](#)

 Biopharmaceutical Studies and Associated Analytical Methods.pdf	2026-01-13 14:15	 Delete
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Module Section 2.7.3: Clinical Efficacy (required)

Drag and drop the file(s) to upload or [Browse Files](#)

 Clinical Efficacy.pdf	2026-01-13 14:15	 Delete
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Module Section 2.7.4: Clinical Safety (required)

Drag and drop the file(s) to upload or [Browse Files](#)

 Clinical Safety.pdf	2026-01-13 14:15	 Delete
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Module Section 5.2: Tabular Listing of All Clinical Studies (required)

Drag and drop the file(s) to upload or [Browse Files](#)

 Tabular Listing of All Clinical Studies.pdf	2026-01-13 14:15	 Delete
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Supporting Document(s) (optional)

Drag and drop the file(s) to upload or [Browse Files](#)

 Supporting Document(s).pdf	2026-01-13 14:15	 Delete
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[Back](#) [Next](#)

Figure 38 – Screenshot of the Common Technical Document(s) section

3.3.42. Upload the Common Technical Document(s) file(s) in the required fields by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.

3.3.43. Click the **<Next>** button to continue to create the submission.

3.3.44. The **Financial Impact Analysis** screen displays and is bolded in the left menu. Provide an estimate of the net costs to the OPDP in a three-year period.

In assessing financial impact, the ministry is interested in yearly expenditures (drug costs only) for the product(s) under consideration. Drug costs should exclude upcharge (mark-up) and dispensing fee.

Financial Impact Analysis

Please provide an estimate of the net costs to the OPDP in three-year period.

In assessing financial impact, the ministry is interested in yearly expenditures (drug costs only) for the product(s) under consideration. Drug costs should exclude upcharge (mark-up) and dispensing fee.

Budget Impact Analysis Report (required)

⬆ Drag and drop the file(s) to upload or [Browse Files](#)

	Budget Impact Analysis Report.pdf	2026-01-13 14:40	 Delete
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Budget Impact Analysis Model (required)

⬆ Drag and drop the file(s) to upload or [Browse Files](#)

	Budget Impact Analysis Model.pdf	2026-01-13 14:40	 Delete
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OPDP Financial Impact Analysis Summary (required)

Please refer to the Drug Submissions website for the most recent template.

⬆ Drag and drop the file(s) to upload or [Browse Files](#)

	OPDP Financial Impact Analysis Summary.pdf	2026-01-13 14:40	 Delete
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[Back](#)
[Next](#)

[Submit](#)

Figure 39 – Screenshot of the Financial Impact Analysis section

3.3.45. Upload the Financial Impact Analysis file(s) in the required fields by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.

3.3.46. Click the **<Next>** button to continue to create the submission.

3.3.47. The **Pharmacoeconomic Analysis** screen displays and is bolded in the left menu.

Pharmacoeconomic Analysis

Pharmacoeconomic Analysis Report (required)

 Drag and drop the file(s) to upload or [Browse Files](#)

 Pharmacoeconomic Analysis Report.pdf	2026-01-13 14:52	 Delete
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Pharmacoeconomic Analysis Model (required)

 Drag and drop the file(s) to upload or [Browse Files](#)

 Pharmacoeconomic Analysis Model.pdf	2026-01-13 14:52	 Delete
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Pharmacoeconomic Analysis Summary (required)

Please refer to the Drug Submissions website for the most recent template.

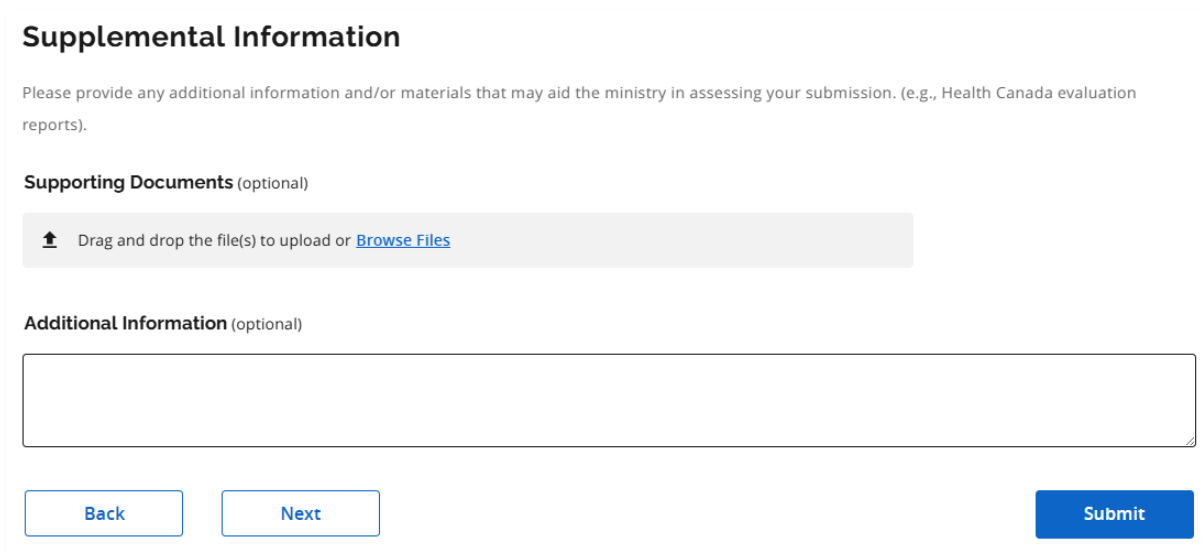
 Drag and drop the file(s) to upload or [Browse Files](#)

 Pharmacoeconomic Analysis Summary.docx	2026-01-13 14:52	 Delete
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[Back](#) [Next](#)

Figure 40 – Screenshot of the Pharmacoeconomic Analysis section

- 3.3.48. Upload the Pharmacoeconomic Analysis files in the required fields by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.
- 3.3.49. Click the **<Next>** button to continue to create the submission.
- 3.3.50. The **Supplemental Information** screen displays and is bolded in the left menu. This optional screen is available to provide any additional information and/or materials that may aid the ministry in assessing your submission. (e.g., Health Canada evaluation reports).



Supplemental Information

Please provide any additional information and/or materials that may aid the ministry in assessing your submission. (e.g., Health Canada evaluation reports).

Supporting Documents (optional)

 Drag and drop the file(s) to upload or [Browse Files](#)

Additional Information (optional)

[Back](#) [Next](#) [Submit](#)

Figure 41 – Screenshot of the Supplemental Information screen

- 3.3.51. Upload any supporting documents by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if desired.
- 3.3.52. Select the **Additional Information** field and enter supplemental information, if desired.
- 3.3.53. Click the **<Next>** button to continue to create the submission.
- 3.3.54. The **Attestations** screen displays and is bolded in the left menu.

Attestations

- ☒ Pursuant to the requirements under the Ontario Drug Benefit Act and Drug Interchangeability and Dispensing Fee Act (as applicable) but subject to the limitation concerning confidential pricing information set out below, I confirm that the Manufacturer authorizes His Majesty the King in right of Ontario as represented by the Executive Officer of Ontario Public Drug Programs of the Ministry of Health (the "Ministry"), both during and after the Ministry's Product evaluation process, to:
- to collect and use information pertaining to the Product and the Manufacturer in the possession of Health Canada, the government of any province or territory in Canada, the Patented Medicine Prices Review Board, Canada's Drug Agency, or Ontario Health (the "Public Organizations"); and
 - disclose information pertaining to the Product and the Manufacturer in the possession of the Ministry to any of the Public Organizations.
- Despite the foregoing, neither the Manufacturer nor the Ministry will disclose to any of the Public Organizations any confidential pricing or commercial terms in respect of the Product that are specific to Ontario Public Drug Programs unless the other party has been notified and has authorized the disclosure in writing.
- ☒ I confirm that that the manufacturer is able to supply the Product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the Product
- ☒ I confirm that the Manufacturer hereby represents and warrants that the Manufacturer has not provided a rebate, as defined in subsection 12.1(14) of the Drug Interchangeability and Dispensing Fee Act (DIDFA) and subsection 11.5(15) of the Ontario Drug Benefit Act (ODBA), to any of the persons listed in subsection 11.5(1) of the ODBA and 12.1(1) of the DIDFA,), as applicable, with respect to the Product contrary to the ODBA and/or DIDFA since Health Canada approved the Product for sale in Canada.

[Back](#)[Next](#)[Submit](#)

Figure 42 – Screenshot of the Attestations screen

3.3.55. Review and click to select checkmarks for each attestation, if appropriate, then click the **<Next>** button to review all information provided for the submission, before submitting.



Note that you can choose to click the **<Submit>** button from this screen to submit, but it is recommended to first review information on the **Review** screen, which summarizes your submission and highlights any required information that must still be provided before submitting. **It is highly recommended to review all information before submitting, because you cannot edit a submission through DIRECT after it is submitted.**

3.3.56. The **Review** screen displays and is bolded in the left menu.

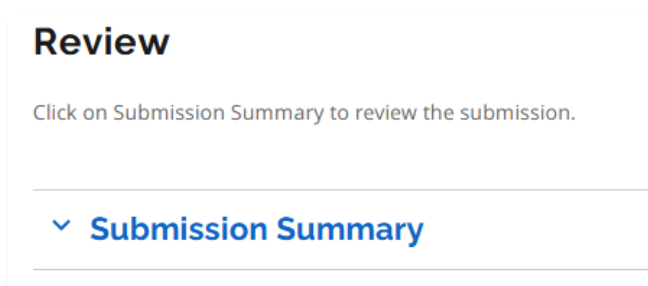


Figure 43 – Screenshot of the Submission Summary Link on the Review screen

3.3.57. Click the <Submission Summary> link to expand the screen to show all information that has been entered for the submission, including all attachments. Any required information that has been missed will be highlighted.

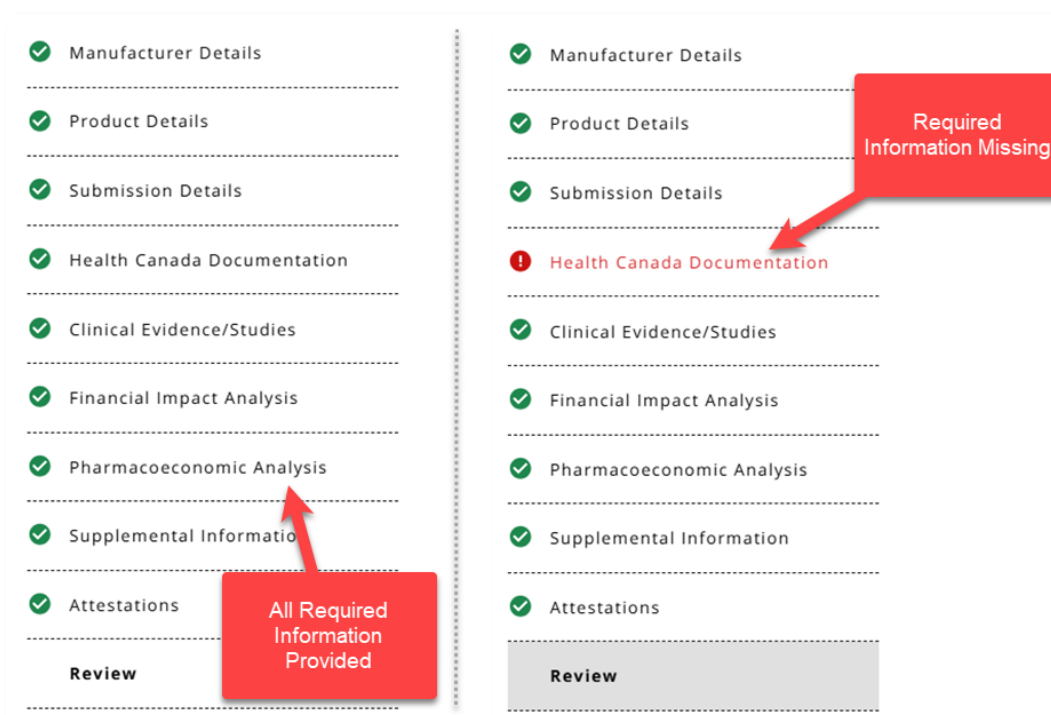


Figure 44 – Screenshot of the Left Menu Shown with All Required Information Provided (Left) and Required Information Missing (Right)



Note that information that has been flagged as 'missing' appears in red font in the Left Menu, as shown in the above screenshot. You can jump to the area missing information by clicking on the flagged area.

3.3.58. If all required information for the submission has been entered, green checkmarks appear for each page in the Left Menu.

3.3.59. If required information for the submission has not been entered, when you click the **<Submit>** button, a Rationale Required window (shown below) displays, and a red exclamation mark appears for each page missing information in the Left Menu. You can provide an explanation and continue to submit the submission, or you can edit the submission and enter the missing information.

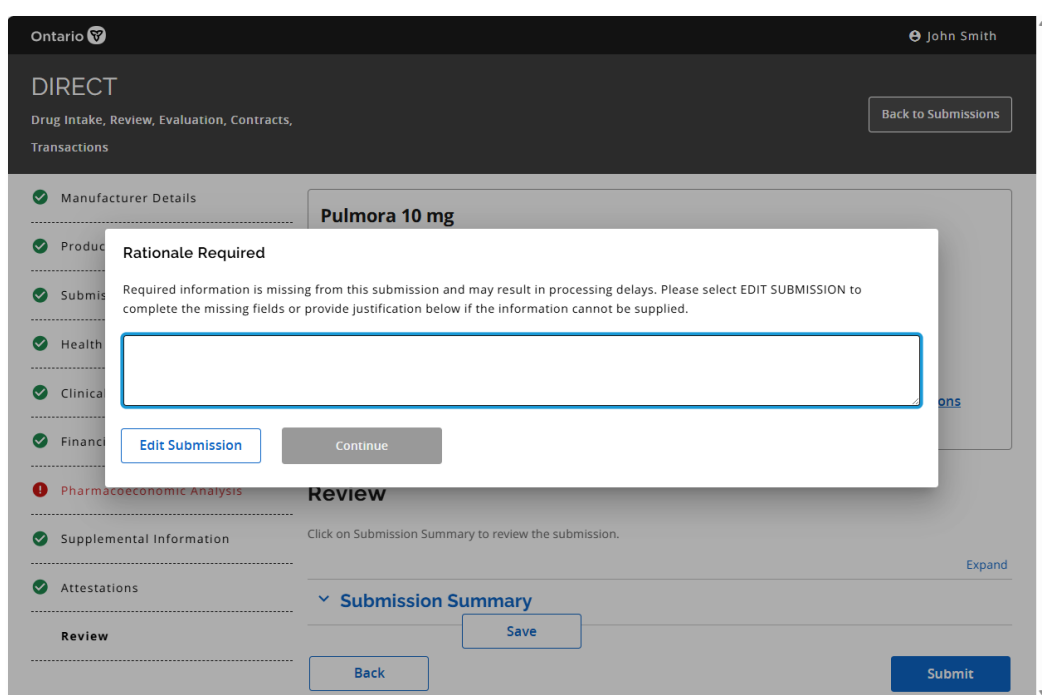


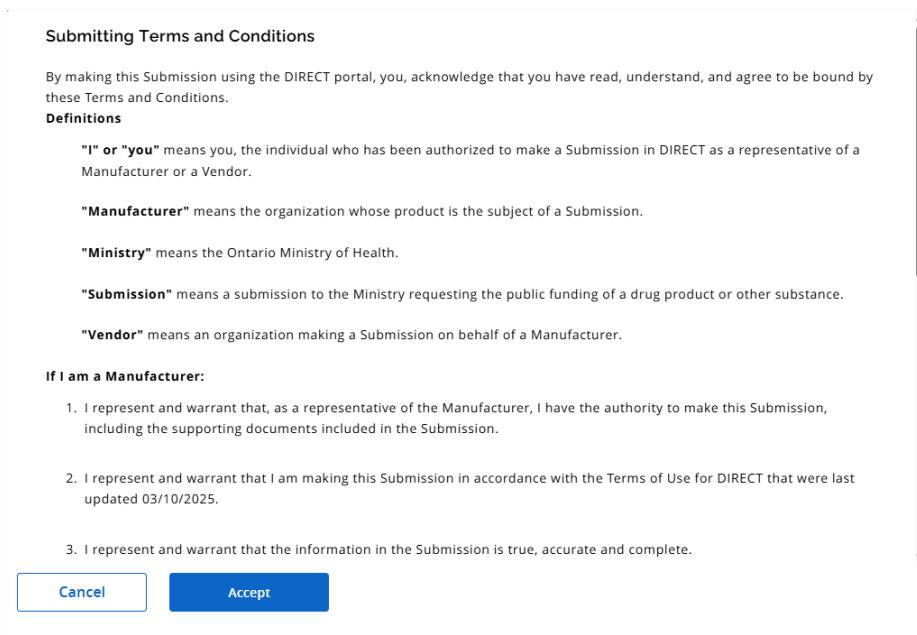
Figure 45 – Screenshot of the Rationale Required Window



Note that some fields are noted as *Optional*, while others are *Required*. Certain *required* fields are mandatory to submit a submission, for example the Primary Contact for your organization must be selected. Other *required* fields are also necessary; however, it is recognized that at times you may be unable to provide details for a required field (e.g., it cannot be provided due to exceptional circumstances). If information that is required is not provided, the submission may be deemed incomplete.

3.3.60. Click the **<Submit>** button. DIRECT validates responses and highlights any items requiring review/update.

3.3.61. The **Submitting Terms and Conditions** display, providing definitions and statements for manufacturers and vendors.



Submitting Terms and Conditions

By making this Submission using the DIRECT portal, you, acknowledge that you have read, understand, and agree to be bound by these Terms and Conditions.

Definitions

"I" or "you" means you, the individual who has been authorized to make a Submission in DIRECT as a representative of a Manufacturer or a Vendor.

"Manufacturer" means the organization whose product is the subject of a Submission.

"Ministry" means the Ontario Ministry of Health.

"Submission" means a submission to the Ministry requesting the public funding of a drug product or other substance.

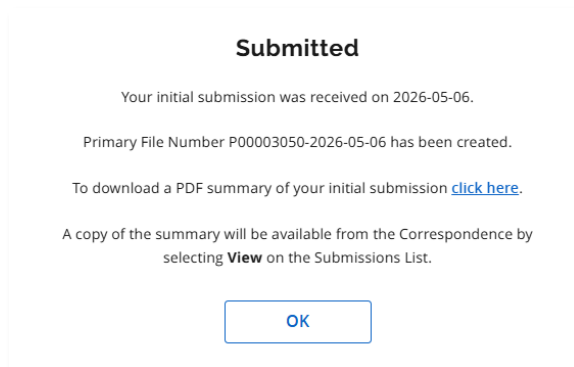
"Vendor" means an organization making a Submission on behalf of a Manufacturer.

If I am a Manufacturer:

1. I represent and warrant that, as a representative of the Manufacturer, I have the authority to make this Submission, including the supporting documents included in the Submission.
2. I represent and warrant that I am making this Submission in accordance with the Terms of Use for DIRECT that were last updated 03/10/2025.
3. I represent and warrant that the information in the Submission is true, accurate and complete.

Figure 46 – Screenshot of the Submitting Terms and Conditions

3.3.62. Scroll to review the complete terms and conditions, and if desired, click the **<Accept>** button.



Submitted

Your initial submission was received on 2026-05-06.

Primary File Number P00003050-2026-05-06 has been created.

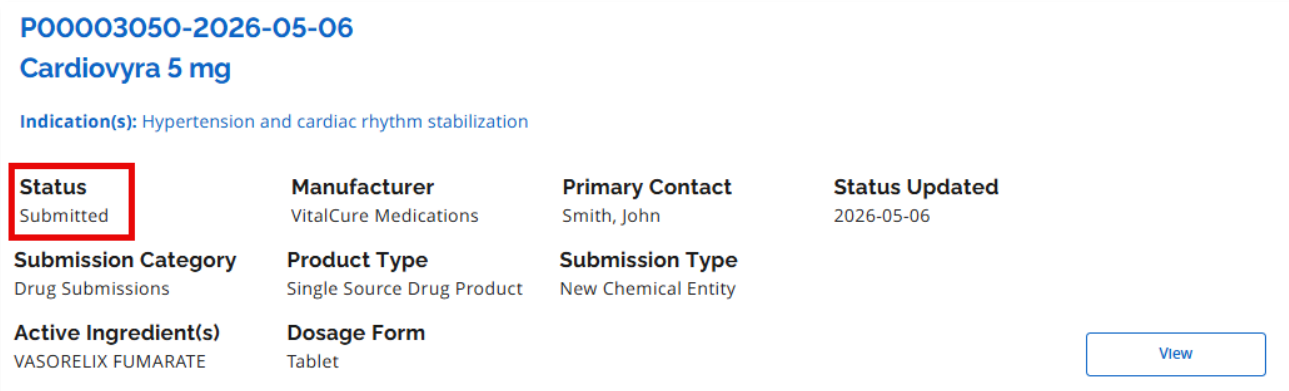
To download a PDF summary of your initial submission [click here](#).

A copy of the summary will be available from the Correspondence by selecting **View** on the Submissions List.

Figure 47 – Screenshot of the Submitted Message

3.3.63. A pop-up message indicates the submission has been successfully submitted. The initial submission date is provided, along with the 'Primary File Number' that has been generated. A PDF summary of the submission can be downloaded by selecting the **<click here>** link, and a copy is available anytime by selecting the **<View>** button in the **Correspondence** section for the submission, on the Submissions List.

3.3.64. Select the **<OK>** button to return to the submission list. The submission now appears in the submission list with a status of 'Submitted'.



P00003050-2026-05-06
Cardiovyra 5 mg

Indication(s): Hypertension and cardiac rhythm stabilization

Status Submitted	Manufacturer VitalCure Medications	Primary Contact Smith, John	Status Updated 2026-05-06
Submission Category Drug Submissions	Product Type Single Source Drug Product	Submission Type New Chemical Entity	
Active Ingredient(s) VASORELIX FUMARATE	Dosage Form Tablet		View

Figure 48 – Screenshot of the submission with a status of submitted in the Submission List

You have successfully submitted the submission to the ministry. You can expect the *status* of the submission to change after the ministry has completed their screening.

3.4. How to Create a New Drug Submission for a Multiple Source Drug Product

The following steps outline the process for creating a new submission for a multiple source drug product, specifically a new streamlined product.

3.4.1. Log in to DIRECT and click on the **<+ Create Submission>** button. The **Submission Overview** screen displays.

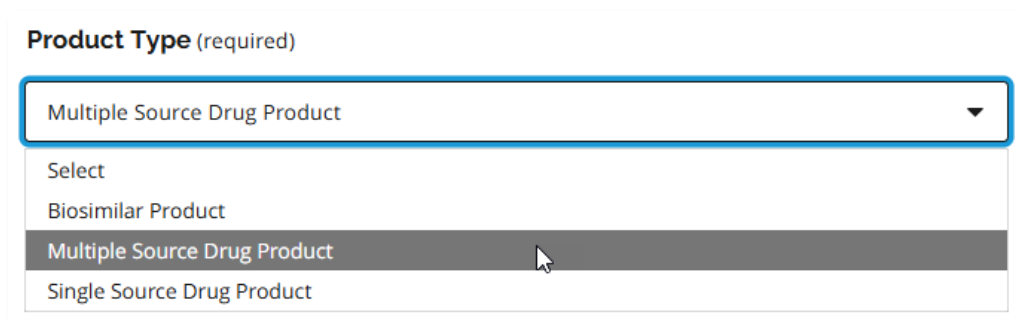
3.4.2. Select the default radio button to indicate the submission is being created for your

organization. (See [Section 3.7](#) for details about creating a submission on behalf of another manufacturer, i.e., as a ‘vendor’.)

3.4.3. Click the **Submission Category** drop-down and select the value, ‘*Drug Submissions*’.

(Note that *Product Types* for Drug Submissions include the following options: Biosimilar Product, Multiple Source Drug Product, and Single Source Drug Product.)

3.4.4. Click the **Product Type** drop-down and select the value, ‘*Multiple Source Drug Product*’.



The screenshot shows a form field titled "Product Type (required)". The drop-down menu is open, displaying four options: "Select", "Biosimilar Product", "Multiple Source Drug Product", and "Single Source Drug Product". The option "Multiple Source Drug Product" is highlighted with a dark grey background and a mouse cursor is pointing at it.

Figure 49 – Screenshot of the Product Type drop-down field

3.4.5. Click the **Submission Type** drop-down and select the value ‘*New Chemical Entity*’. (Note that *Submission Types* for Multiple Source Drug Product Submissions include the following options: Generic Line Extension, and New Generic Product.)



The screenshot shows a form field titled "Submission Type (required)". The drop-down menu is open, displaying four options: "Select", "Select", "Generic Line Extension", and "New Generic Product". The option "New Generic Product" is highlighted with a dark grey background.

Figure 50 – Screenshot of the Submission Type drop-down field

3.4.6. Click the **Generic Classification** drop-down and select the value '*New Streamlined Product*'. (Note that *Generic Classification Types* for New Generic Product Submissions include the following options: Multiple Source for Single Source Listing, New Non-Streamlined Product, New Streamlined Product, OFI – New Non-Streamlined Product, and OFI – New Streamlined Product.)

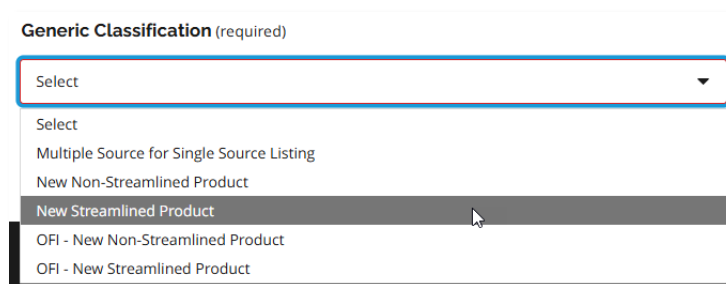


Figure 51 – Screenshot of the Submission Type drop-down field



Note the following information displays:

“A submission is streamlined if it relates to a multiple source (i.e., generic) product that has received a Notice of Compliance with a declaration of equivalence (DOE) from Health Canada with the brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.

A submission is also streamlined if it relates to a pseudogeneric product – i.e., a generic product with the same dosage form, strength, formula, manufacturing process, and raw material testing standards, as the product with which it seeks to be designated as interchangeable. A generic product cross-referenced to another listed generic product does not qualify as a pseudogeneric drug product.

Submissions for pseudogeneric or cross-referenced drug products are not currently accepted through the portal. Please email these submissions to the Drug Submissions Group at:

DrugSubmissions.MOH@ontario.ca.

- 3.4.7. Select the **<Applicable Guidelines>** link, if desired, and the relevant Guidelines open in PDF format in a separate tab, or they are downloaded to your Downloads folder, as a PDF document that can be opened and viewed.

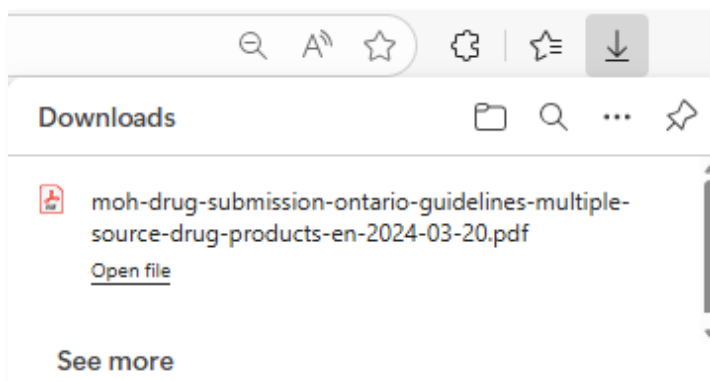


Figure 52 – Screenshot of a Downloaded Guidelines document as a PDF

- 3.4.8. The **Submissions Overview** screen displays. Click the **<Cancel>** button to remove all selections on the screen, and return to the **Submissions** home screen, or click the **<Next>** button to continue to create the submission.

Submission Overview

Manufacturer Details

Who will this submission be created for? (required)

- ☒ The submission is being created for VitalCure Medications
- ☐ The submission is being created on behalf of another manufacturer

Select Category, Product and Submission

Submission Category (required)

Drug Submissions

Product Type (required)

Multiple Source Drug Product

Submission Type (required)

New Generic Product

Generic Classification (required)

New Streamlined Product



A submission is streamlined if it relates to a multiple source (i.e., generic) product that has received a Notice of Compliance with a declaration of equivalence (DOE) from Health Canada with the brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.

A submission is also streamlined if it relates to a pseudogeneric product – i.e., a generic product with the same dosage form, strength, formula, manufacturing process, and raw material testing standards, as the product with which it seeks to be designated as interchangeable. A generic product cross-referenced to another listed generic product does not qualify as a pseudogeneric drug product.

Submissions for pseudogeneric or cross-referenced drug products are not currently accepted through the portal. Please email these submissions to the Drug Submissions Group at DrugSubmissions.MOH@ontario.ca.

Applicable Guidelines

This applicable guideline link is based on the category type, product type, and submission type. View the [Applicable Guidelines](#) for your selections

Cancel

Next

Figure 53 – Screenshot of the Submission Overview screen

- 3.4.9. After clicking the <Next> button, the **Manufacturer Details** screen displays and is bolded in the left menu.

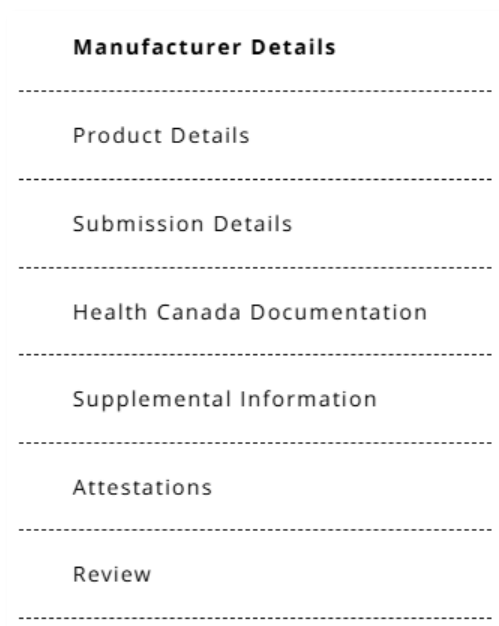


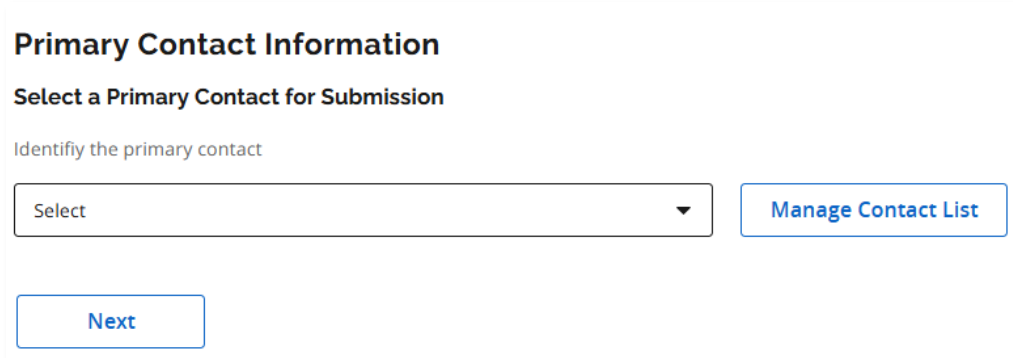
Figure 54 – Screenshot of the Left Menu Tabs on the Manufacturer Details screen

3.4.10. Users must provide information in the *required* fields in each of the screens shown in the left menu, before completing a submission.



Note that if you submit the submission and have not provided all the required information, you will be prompted to provide a rationale for why you cannot provide the information. You can provide an explanation and continue to submit the submission. See [Section 3.5.38](#) for more information about entering a rationale.

3.4.11. Scroll down to the **Primary Contact Information** section and click on the **Primary Contact** drop-down and select the '*Primary Contact*' value.



Primary Contact Information

Select a Primary Contact for Submission

Identify the primary contact

Select 

[Manage Contact List](#)

[Next](#)

Figure 55 – Screenshot of the Primary Contact Information section

3.4.12. Note that the Primary Contact for the organization displays with “*Primary*” in brackets, in the drop-down. Users can select the **<Manage Contact List>** button to view/edit/add contacts. (See [Section 1.2](#) How to Manage an Organization’s Contact List, for more details.)

3.4.13. The selected contact’s information displays (company, job title, email). Click the **<Next>** button.



- ✓ Manufacturer Details
- Product Details**
- Submission Details
- Health Canada Documentation
- Supplemental Information
- Attestations
- Review

Figure 56 – Screenshot of the Left Menu Tabs on the Product Details screen

3.4.14. The **Product Details** screen displays and is bolded in the left menu.



Note that after completing the required details on the **Manufacturer Details** screen, there is now a green checkmark beside *Manufacturer Details*, in the Left Menu. DIRECT guides users as screens are completed, using green checkmarks as a visual indicator that required details have been entered.

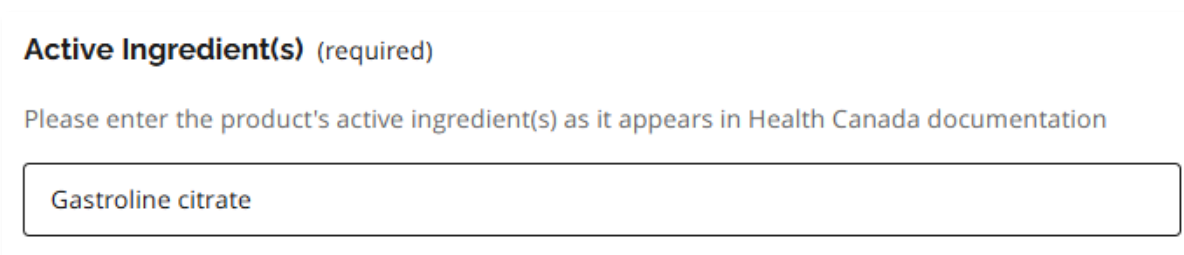
3.4.15. Click in the **Product Name** field and enter the product name.



The screenshot shows a form field titled "Product Name (required)". Below the title is a placeholder text "Please enter the product name". The input field contains the text "Gastroquel".

Figure 57 – Screenshot of the Product Name field on the Product Details screen

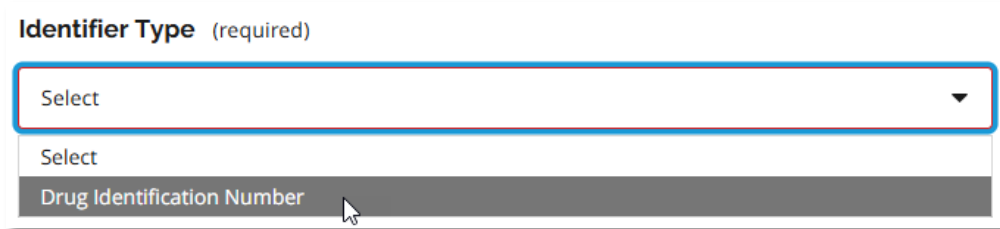
3.4.16. Click in the **Active Ingredient(s)** field and enter the active ingredient(s) as it appears in Health Canada documentation.



The screenshot shows a form field titled "Active Ingredient(s) (required)". Below the title is a placeholder text "Please enter the product's active ingredient(s) as it appears in Health Canada documentation". The input field contains the text "Gastroline citrate".

Figure 58 – Screenshot of the Active Ingredient(s) field on the Product Details screen

3.4.17. Click in the **Identifier Type** drop-down field and select the value '*Drug Identification Number*'.



Identifier Type (required)

Select ▼

Select

Drug Identification Number

Figure 59 – Screenshot of the Identifier Type drop-down field on the Product Details screen

3.4.18. The **Identifier** field displays. Enter the unique identifier assigned by Health Canada for the identifier type selected.



Identifier (required)

Please enter the unique identifier assigned by Health Canada for the identifier type selected above

12345678

Figure 60 – Screenshot of the Identifier field on the Product Details screen

3.4.19. Click the **Dosage Form** drop-down and select the applicable value.



Dosage Form (required)

Tablet ▼

Figure 61 – Screenshot of the Dosage Form drop-down field on the Product Details screen

3.4.20. Click in the **Strength** field and enter the drug's strength(s) using appropriate units, as they appear in Health Canada documentation (e.g., 500 mg, 10 mg/mL, 250 mcg/0.5 mL, 1 g/actuation).

Strength (required)

Please enter the drug's strength(s) using appropriate units, as they appear in Health Canada documentation (e.g., 500 mg, 10 mg/mL, 250 mcg/0.5 mL, 1 g/actuation).

50 mg

Figure 62 – Screenshot of the Strength field on the Product Details screen

3.4.21. Click in the **Route of Administration** drop-down field and select the applicable value.

Multiple routes of administration can be added.

Route of Administration

[+ Add Route of Administration](#)

Route of Administration (required)

Oral

Figure 63 – Screenshot of the Route of Administration drop-down field on the Product Details screen

3.4.22. Select the required radio button in the **Preservatives** field to indicate whether the product is preservative free or with preservative for injectable and ophthalmic products, otherwise select 'Not Applicable'.

Preservatives (required)

Please indicate whether the product is preservative free or with preservative for injectable and ophthalmic products, otherwise select 'Not Applicable'.



With Preservative



Preservative Free



Not Applicable



Figure 64 – Screenshot of the Preservative field on the Product Details screen

3.4.23. Select the required radio buttons in the **Product Classification** section to indicate if the product is a biologic, and if the indication(s) for the submission is oncology-related.

Product Classification

Indicate whether or not the product is a biologic, and if the indication(s) for the submission is oncology-related

Biologic (required)

Biologic drugs come from living organisms or from their cells. They are often made using biotechnology. Biologic drugs are generally larger and more complex in composition than chemically produced pharmaceutical drugs. In Canada, biologic drugs are listed in Schedule D of the *Food and Drugs Act*.

☐ Yes ☒ No ✗

Oncology (required)

Oncology or cancer therapy includes cytotoxic agents and other systemic therapies for cancer treatment.

☐ Yes ☒ No ✗

Figure 65 – Screenshot of the Product Classification section on the Product Details screen

3.4.24. Enter the required details in the **Packaging and Pricing** section. Click the **Package Type** drop-down and select the package type. If the specific package type is not included in the drop-down list, select “Other” and enter the information as it appears in Health Canada documentation.

Package Type (required)

Please select the package type for the product from the drop-down list below. If the specific package type is not included in the drop-down list, select "Other" and enter the information as it appears in Health Canada documentation.

Bottle ▼

Package Size (required)

Please include package size(s), as it appears in Health Canada documentation (e.g., 30 tablets, 100 mL, 1 prefilled syringe, 5 vials)

100 tablets

[+ Add Price](#)

Price Type (required) **Price** (required)

Price per smallest dispensable unit ▼ 5.0000

Unit (required)

Please enter the unit based on the selected price type (e.g., use tablet, gram, ml mL, etc. for smallest units; use bottle, kit, pre-filled syringe, etc. for package sizes)

tablet

[Save](#)

Figure 66 – Screenshot of the Packaging and Pricing section on the Product Details screen

- 3.4.25. Select the **Package Size** field and enter details. Include package size(s), as it appears in Health Canada documentation.
- 3.4.26. Click the **Price Type** drop-down and select the appropriate value.
- 3.4.27. Select the **Price** field and enter details. Note that the value rounds to 4 decimal points.
- 3.4.28. Select the **Unit** field and enter the appropriate unit based on the selected price, then click the **<Next>** button to continue to create the submission.
- 3.4.29. The **Submission Details** screen displays and is bolded in the left menu.
- 3.4.30. Select the checkmark to confirm that this Product does not qualify as a pseudogeneric or cross-referenced drug product, if appropriate.

3.4.31. Select the appropriate radio button for the question: Has a declaration of equivalence (DOE) been received from Health Canada with the brand reference product or another listed interchangeable product with which the Generic Product would be designated as interchangeable?

Submission Details



Please confirm that this Product does not qualify as a pseudogeneric or cross-referenced drug product

Submissions for pseudogeneric or cross-referenced drug products are not currently accepted through the portal. Please email the submissions to DrugSubmissions.MOH@ontario.ca.

Has a declaration of equivalence (DOE) been received from Health Canada with the brand reference product or another listed interchangeable product with which the Generic Product would be designated as interchangeable? (required)

A submission is streamlined if it relates to a multiple source (i.e., generic) product that has received a declaration of equivalence (DOE) from Health Canada with the brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.



Yes



No



Figure 67 – Screenshot of the Submission Details screen



A submission is streamlined if it relates to a multiple source (i.e., generic) product that has received a declaration of equivalence (DOE) from Health Canada with the brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.

3.4.32. Scroll down to the **Requested Funding/Listing/Program** section and select the appropriate value.

Requested Funding/Listing/Program (required)



General Benefit (GB)



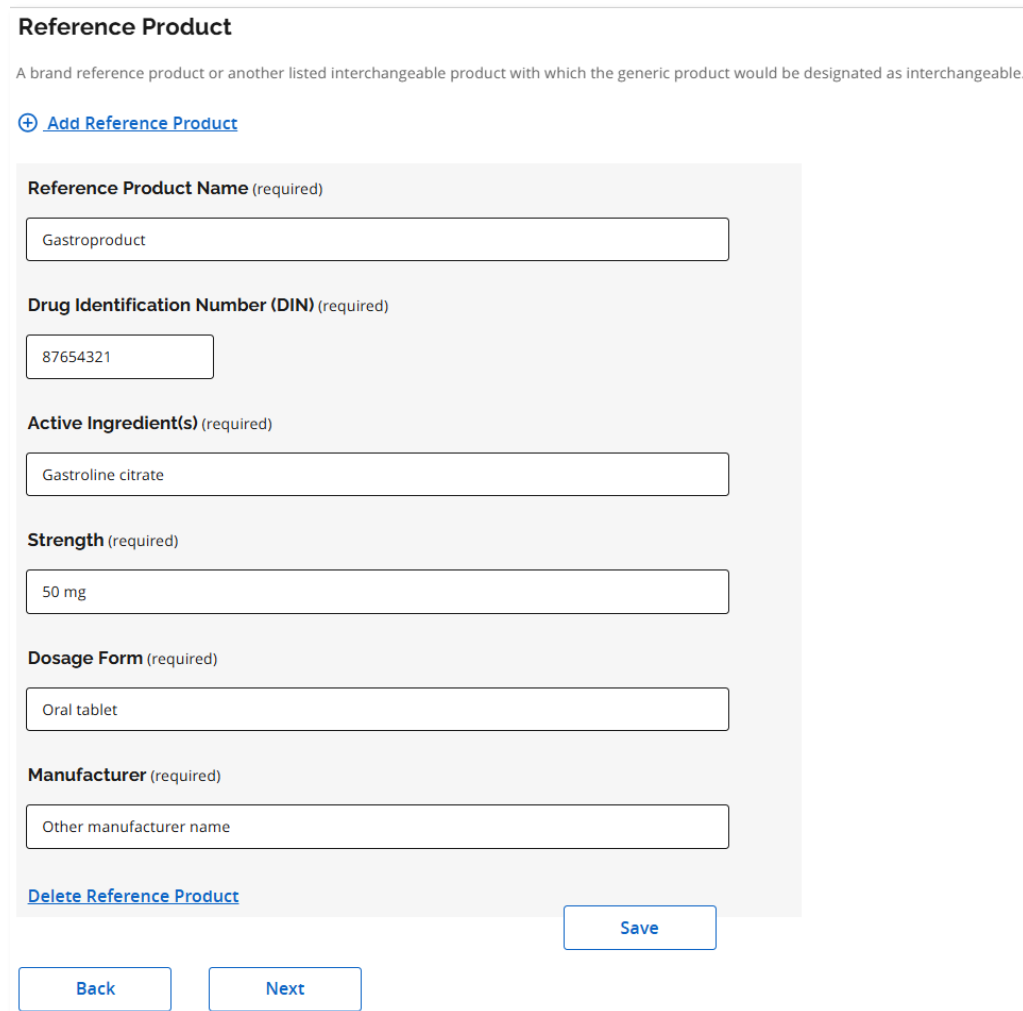
Limited Use (LU)



New Drug Funding Program (NDFP)

Figure 68 – Screenshot of the Requested Funding/Listing/Program section

3.4.33. Select the **<+ Add Reference Product>** link to provide details about the brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.



Reference Product

A brand reference product or another listed interchangeable product with which the generic product would be designated as interchangeable.

[+ Add Reference Product](#)

Reference Product Name (required)

Gastroproduct

Drug Identification Number (DIN) (required)

87654321

Active Ingredient(s) (required)

Gastroline citrate

Strength (required)

50 mg

Dosage Form (required)

Oral tablet

Manufacturer (required)

Other manufacturer name

[Delete Reference Product](#)

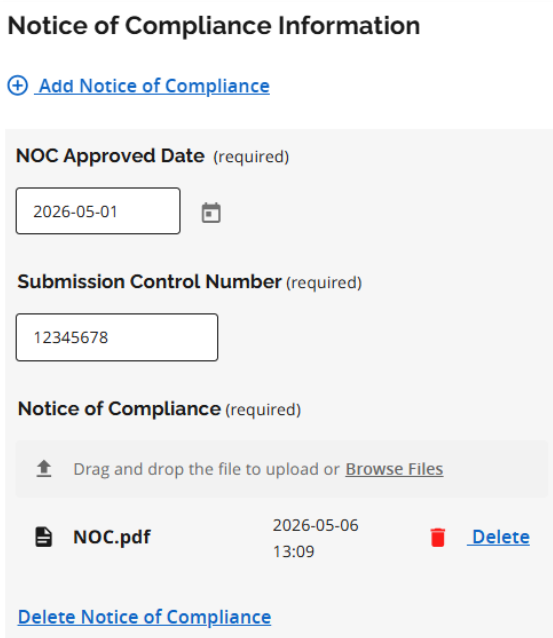
[Save](#)

[Back](#) [Next](#)

Figure 69 – Screenshot of the Reference Product section

3.4.34. Click the **<Next>** button; the **Health Canada Documentation** screen displays and is bolded in the left menu.

3.4.35. Select the **<Add Notice of Compliance>** link.



Notice of Compliance Information

[+ Add Notice of Compliance](#)

NOC Approved Date (required)

2026-05-01

Submission Control Number (required)

12345678

Notice of Compliance (required)

Drag and drop the file to upload or [Browse Files](#)

 NOC.pdf	2026-05-06 13:09	 Delete
--	---------------------	--

[Delete Notice of Compliance](#)

Figure 70 – Screenshot of the Notice of Compliance section

3.4.36. Enter the appropriate date in the **NOC Approved Date** field and enter the value in the **Submission Control Number** field. Then, upload the Notice of Compliance file by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.



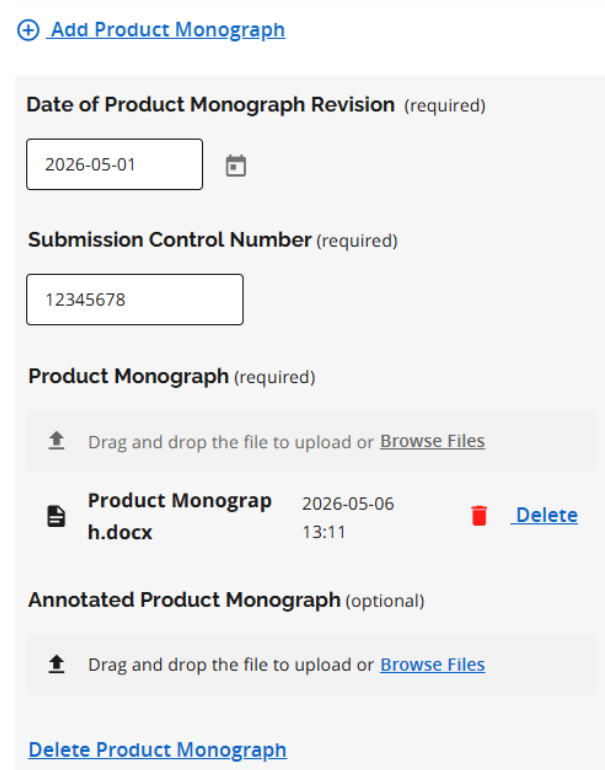
Important: Refer to [Section 2.4](#) for information related to file uploads.

3.4.37. In the **Product Monograph Information** section, provide the current Product Monograph approved by Health Canada and enter its date and submission control number. If Health Canada has not approved a Product Monograph for the drug product (e.g., it is an “old” drug that received a DIN but no NOC), please provide the information outlined in the Guidelines (see “If No Product Monograph Has Been Approved”). All supporting documents should be submitted via the Supplemental Information page.

3.4.38. Select the **<Add Product Monograph>** link. Enter the appropriate date in the **Date of Product Monograph Revision** field and enter the value in the **Submission Control Number** field.

3.4.39. Upload the required *Product Monograph* file by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.

3.4.40. If the Product Monograph has been updated, upload the Annotated Product Monograph file by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.



[+ Add Product Monograph](#)

Date of Product Monograph Revision (required)

2026-05-01 

Submission Control Number (required)

12345678

Product Monograph (required)

 Drag and drop the file to upload or [Browse Files](#)

Product Monograph	Date	Time	Action
 Product Monograph h.docx	2026-05-06	13:11	 Delete

Annotated Product Monograph (optional)

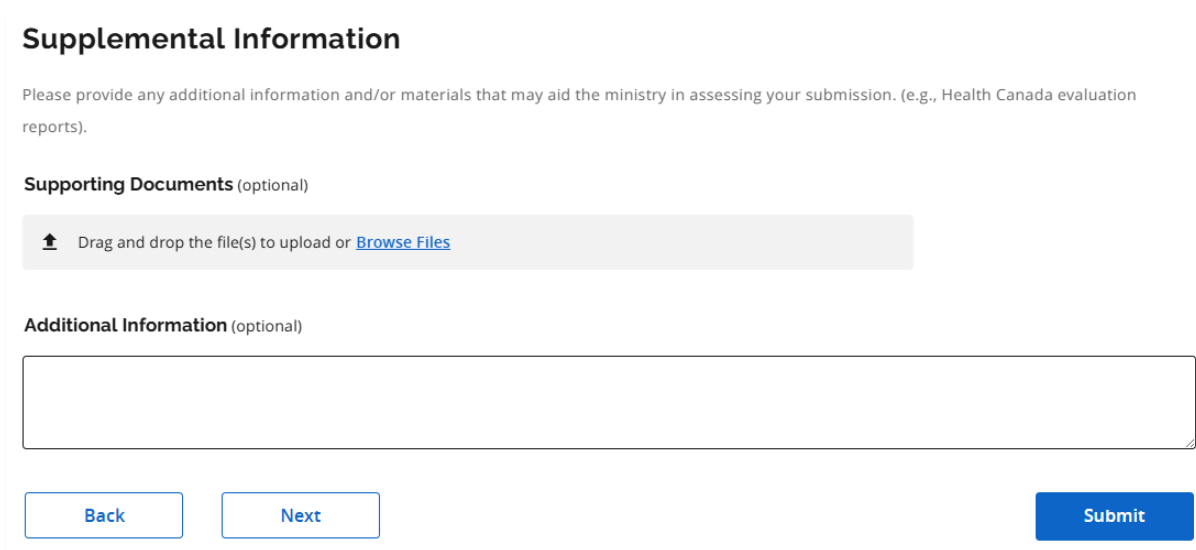
 Drag and drop the file to upload or [Browse Files](#)

[Delete Product Monograph](#)

Figure 71 – Screenshot of the Product Monograph section

3.4.41. Click the **<Next>** button to continue to create the submission.

3.4.42. The **Supplemental Information** screen displays and is bolded in the left menu. This optional screen is available to provide any additional information and/or materials that may aid the ministry in assessing your submission. (e.g., Health Canada evaluation reports).



Supplemental Information

Please provide any additional information and/or materials that may aid the ministry in assessing your submission. (e.g., Health Canada evaluation reports).

Supporting Documents (optional)

 Drag and drop the file(s) to upload or [Browse Files](#)

Additional Information (optional)

[Back](#) [Next](#) [Submit](#)

Figure 72 – Screenshot of the Supplemental Information screen

3.4.43. Upload any supporting documents by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if desired.

3.4.44. Select the **Additional Information** field and enter supplemental information, if desired.

3.4.45. Click the **<Next>** button to continue to create the submission.

3.4.46. The **Attestations** screen displays and is bolded in the left menu.

Attestations

☒ Pursuant to the requirements under the Ontario Drug Benefit Act and Drug Interchangeability and Dispensing Fee Act (as applicable) but subject to the limitation concerning confidential pricing information set out below, I confirm that the Manufacturer authorizes His Majesty the King in right of Ontario as represented by the Executive Officer of Ontario Public Drug Programs of the Ministry of Health (the "Ministry"), both during and after the Ministry's Product evaluation process, to:

- a. to collect and use information pertaining to the Product and the Manufacturer in the possession of Health Canada, the government of any province or territory in Canada, the Patented Medicine Prices Review Board, Canada's Drug Agency, or Ontario Health (the "Public Organizations"); and
- b. disclose information pertaining to the Product and the Manufacturer in the possession of the Ministry to any of the Public Organizations.

Despite the foregoing, neither the Manufacturer nor the Ministry will disclose to any of the Public Organizations any confidential pricing or commercial terms in respect of the Product that are specific to Ontario Public Drug Programs unless the other party has been notified and has authorized the disclosure in writing.

☒ I confirm that the manufacturer is able to supply the Product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the Product

☒ I confirm that the Manufacturer hereby represents and warrants that the Manufacturer has not provided a rebate, as defined in subsection 12.1(14) of the Drug Interchangeability and Dispensing Fee Act (DIDFA) and subsection 11.5(15) of the Ontario Drug Benefit Act (ODBA), to any of the persons listed in subsection 11.5(1) of the ODBA and 12.1(1) of the DIDFA, as applicable, with respect to the Product contrary to the ODBA and/or DIDFA since Health Canada approved the Product for sale in Canada.

☒ I confirm that the Manufacturer hereby represents and warrants that, to the best of the Manufacturer's knowledge, the Product does not infringe any Canadian patents.

Patent Information for the Original Product

Please enter information for all Canadian patents, including use patents, for the original product. Please provide all strengths approved by Health Canada for the original product. Please indicate if the Manufacturer does not market a particular strength for the submitted Product.

[+ Add Patent Information](#)

[Back](#)

[Next](#)

[Submit](#)

Figure 73 – Screenshot of the Attestations screen

3.4.47. Review and click to select checkmarks for each attestation, if appropriate.

3.4.48. Select the **<Add Patent Information>** link.

3.4.49. The **Patent Information** section displays. Enter information for all Canadian patents, including use patents, for the original product. Provide all strengths approved by Health Canada for the original product. Indicate if the Manufacturer does not market a particular strength for the submitted Product.

[+ Add Patent Information](#)

Original Product Name (required)

Manufacturer Name (required)

Active Ingredient(s) (required)

Strength (required)

DIN (required)

Does patent exist and still in effect? (required)

☐ Yes
 ☒ No
 ✕

[Delete Patent Information](#)

Back

Next

Figure 74 – Screenshot of the Patent Information section

3.4.50. Enter the Original Product Name, Manufacturer Name, Active Ingredient(s), Strength, and DIN.

3.4.51. Select the appropriate radio button for the question: *Does patent exist and still in effect?*

3.4.52. Click the **<Next>** button to review all information provided for the submission, before submitting.



Note that you can choose to click the **<Submit>** button from this screen to submit, but it is recommended to first review information on the **Review** screen, which summarizes your submission and highlights any required information that must still be provided before submitting. **It is highly recommended to review all information before submitting, because you cannot edit a submission through DIRECT after it is submitted.**

3.4.53. The **Review** screen displays and is bolded in the left menu.

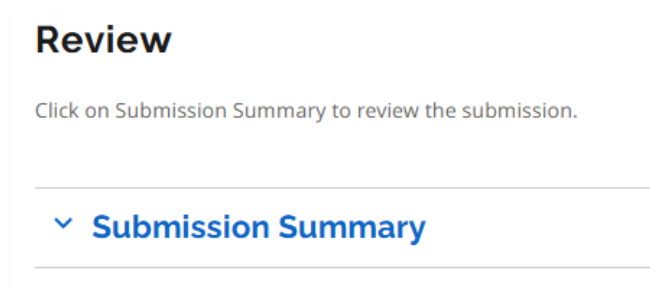


Figure 75 – Screenshot of the Submission Summary Link on the Review screen

3.4.54. Click the **<Submission Summary>** link to expand the screen to show all information that has been entered for the submission, including all attachments. Any required information that has been missed will be highlighted.

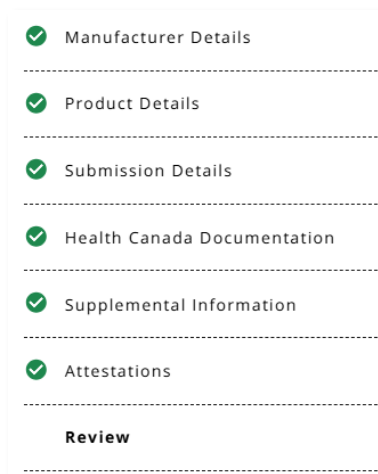


Figure 76 – Screenshot of the Left Menu

3.4.55. If all required information for the submission has been entered, green checkmarks appear for each page in the Left Menu.

3.4.56. If required information for the submission has not been entered, when you click the **<Submit>** button, a **Rationale Required** window (shown below) displays, and a red exclamation mark appears for each page missing information in the Left Menu. You can provide an explanation and continue to submit the submission, or you can edit the submission and enter the missing information.

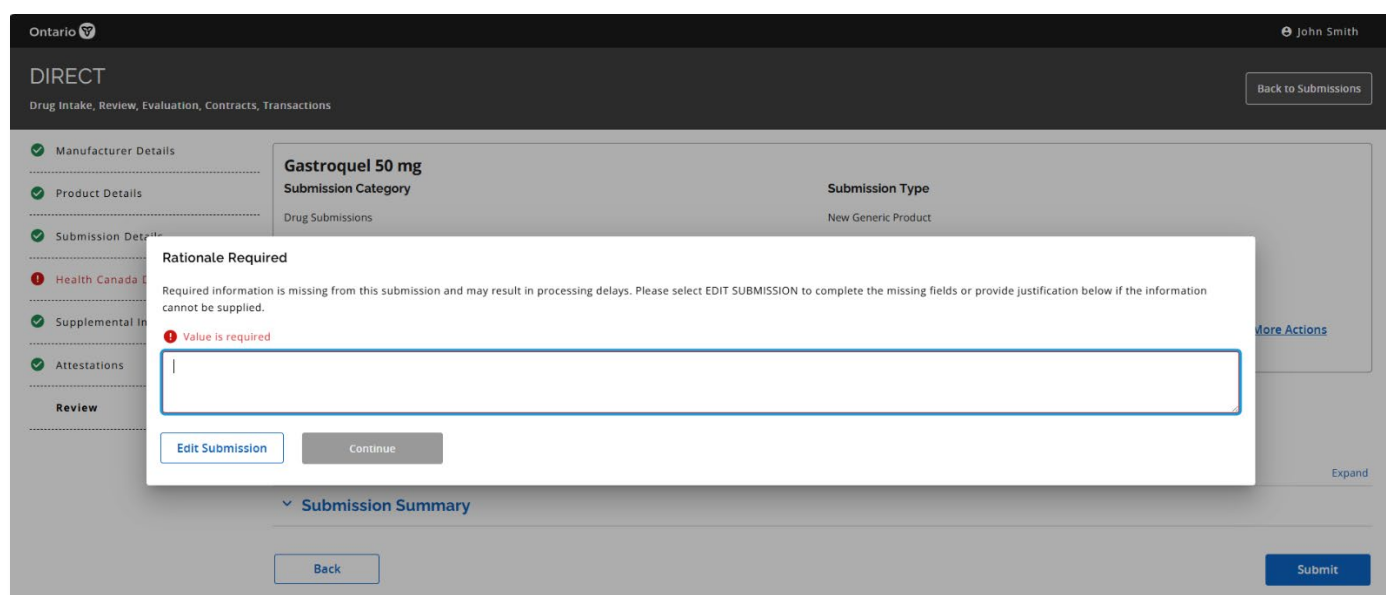
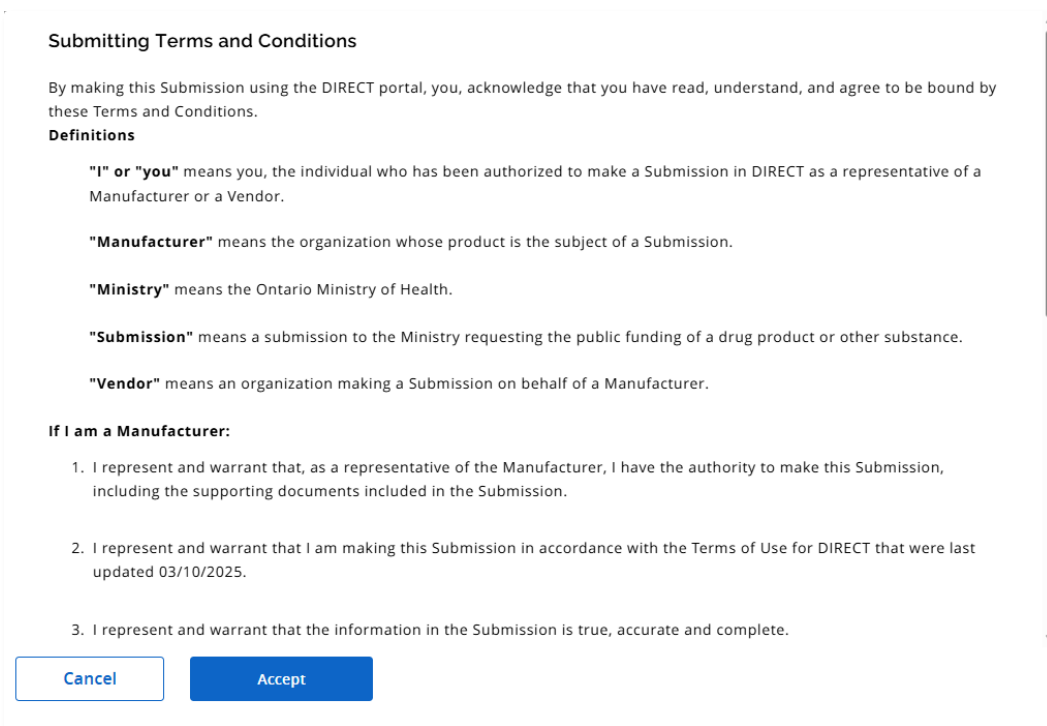


Figure 77 – Screenshot of the Rationale Required Window

3.4.57. Click the **<Submit>** button. DIRECT validates responses and highlights any items requiring review/update.

3.4.58. The **Submitting Terms and Conditions** display, providing definitions and statements for manufacturers and vendors.



Submitting Terms and Conditions

By making this Submission using the DIRECT portal, you, acknowledge that you have read, understand, and agree to be bound by these Terms and Conditions.

Definitions

"I" or "you" means you, the individual who has been authorized to make a Submission in DIRECT as a representative of a Manufacturer or a Vendor.

"Manufacturer" means the organization whose product is the subject of a Submission.

"Ministry" means the Ontario Ministry of Health.

"Submission" means a submission to the Ministry requesting the public funding of a drug product or other substance.

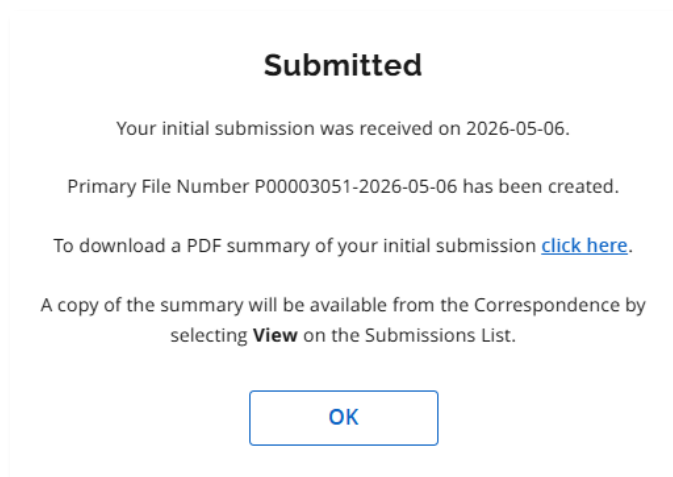
"Vendor" means an organization making a Submission on behalf of a Manufacturer.

If I am a Manufacturer:

1. I represent and warrant that, as a representative of the Manufacturer, I have the authority to make this Submission, including the supporting documents included in the Submission.
2. I represent and warrant that I am making this Submission in accordance with the Terms of Use for DIRECT that were last updated 03/10/2025.
3. I represent and warrant that the information in the Submission is true, accurate and complete.

Figure 78 – Screenshot of the Submitting Terms and Conditions

3.4.59. Scroll to review the complete terms and conditions, and if desired, click the **<Accept>** button.



Submitted

Your initial submission was received on 2026-05-06.

Primary File Number P00003051-2026-05-06 has been created.

To download a PDF summary of your initial submission [click here](#).

A copy of the summary will be available from the Correspondence by selecting **View** on the Submissions List.

Figure 79 – Screenshot of the Submitted Message

3.4.60. A pop-up message indicates the submission has been successfully submitted. The initial submission date is provided, along with the 'Primary File Number' that has been

generated. A PDF summary of the submission can be downloaded by selecting the **<click here>** link, and a copy is available anytime by selecting the **<View>** button in the **Correspondence** section for the submission, on the Submissions List.

3.4.61. Select the **<OK>** button to return to the submission list. The Submission Status is 'Submitted'.

P00003051-2026-05-06
Gastroquel 50 mg

Status Submitted	Manufacturer VitalCure Medications	Primary Contact Smith, John	Status Updated 2026-05-06
Submission Category Drug Submissions	Product Type Multiple Source Drug Product	Submission Type New Generic Product	Generic Classification New Streamlined Product
Active Ingredient(s) GASTROLINE CITRATE	Dosage Form Tablet	View	

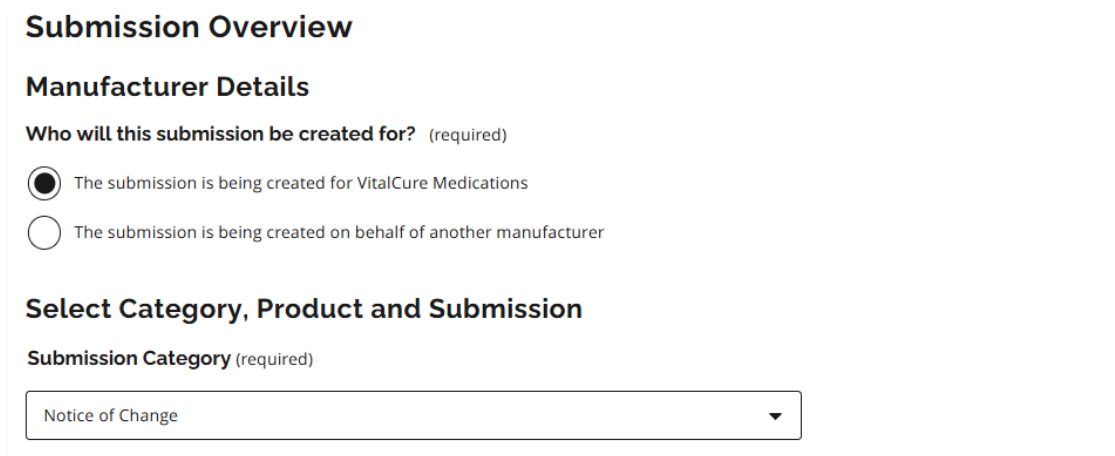
Figure 80 – Screenshot of the submission with a status of submitted in the Submission List

You have successfully submitted the submission to the ministry. You can expect the *status* of the submission to change after the ministry has completed their screening.

3.5. How to Create a New Notice of Change Submission

New Notice of Change submissions can be entered, according to the guidelines.

- 3.5.1. To begin to record a new Notice of a Change submission, click on the **<+ Create Submission>** button and the **Submission Overview** screen displays.



The screenshot shows the 'Submission Overview' screen. It has a title 'Submission Overview' at the top. Below it is a section 'Manufacturer Details' with the question 'Who will this submission be created for?' (required). There are two radio buttons: the first is selected and labeled 'The submission is being created for VitalCure Medications', and the second is labeled 'The submission is being created on behalf of another manufacturer'. Below this is a section 'Select Category, Product and Submission' with the label 'Submission Category' (required). There is a drop-down menu showing 'Notice of Change' with a downward arrow.

Figure 81 – Screenshot of the Submission Overview screen

- 3.5.2. Select the default radio button to indicate the new notice of change submission is being created for your organization. (See [Section 3.7](#) for details about creating a submission on behalf of another manufacturer, i.e., as a 'vendor'.)
- 3.5.3. Click the **Submission Category** drop-down and select the value, '*Notice of Change*'.
- 3.5.4. Click the **Product Type** drop-down and select the product type value for the submission that requires a change.

Product Type (required)

Single Source Drug Product
▼

Select

- Biosimilar Product
- Continuous Glucose Monitoring (CGM)
- Diabetic Testing Agent (DTA)
- Multiple Source Drug Product
- Natural Health Product
- Nutrition Product
- Single Source Drug Product
- Valved Holding Chamber (VHC)

Figure 82 – Screenshot of the Product Type drop-down field

- 3.5.5. Click the **Change Type** drop-down and select the value for the type of change being requested.



Note that the submission requirements will differ depending on the change type and the product type.

Change Type (required)

Product Monograph Change
▼

Select

- Distributor Change
- Drug Identification Number (DIN) Change
- Drug Product Name Change
- Formulation Change
- Organization Name Change
- Ownership Change
- Price Change
- Product Discontinuation
- Product Monograph Change

Figure 83 – Screenshot of the Change Type drop-down field

- 3.5.6. Select the **<Applicable Guidelines>** link, if desired, and the relevant Guidelines are downloaded to your Downloads folder, as a PDF document that can be opened and viewed.

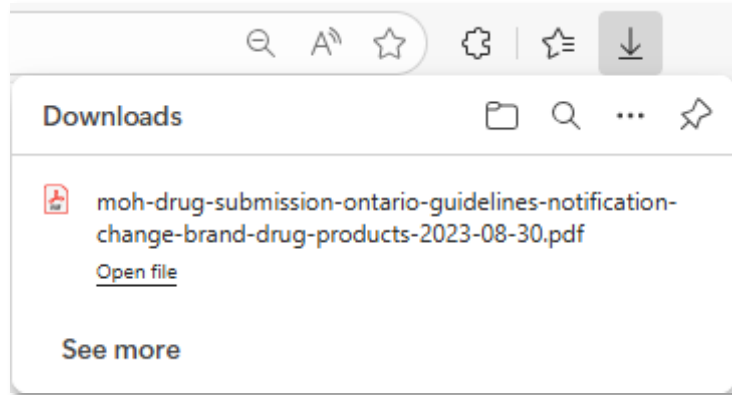


Figure 84 – Screenshot of a Downloaded Guidelines document as a PDF

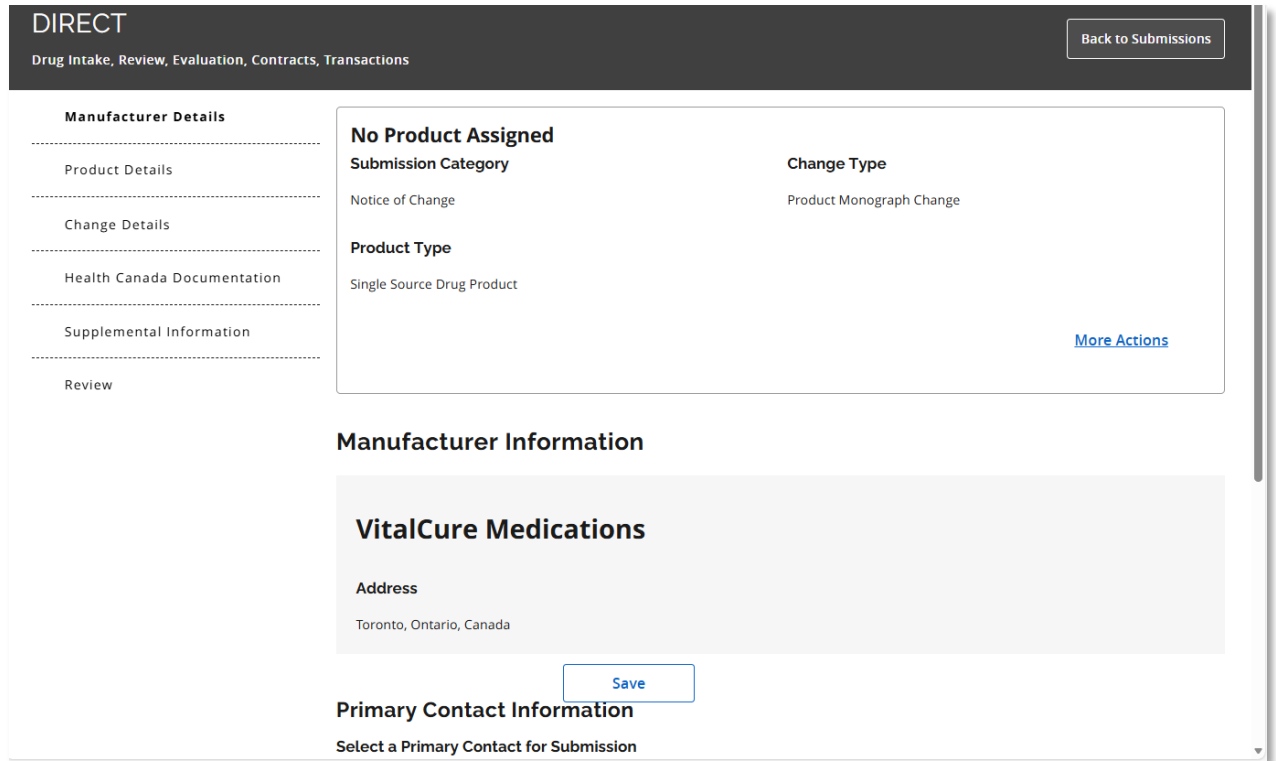
- 3.5.7. Click the **<Cancel>** button to remove all selections on the screen, and return to the Submissions home screen, or click the **<Next>** button to continue to create the Notice of Change submission.



Figure 85 – Screenshot of the Left Menu Tabs on the Manufacturer Details screen

- 3.5.8. The **Manufacturer Details** screen displays and is bolded in the left menu. Users must

provide information in the *required* fields in each of the screens shown in the left menu, before completing a submission.



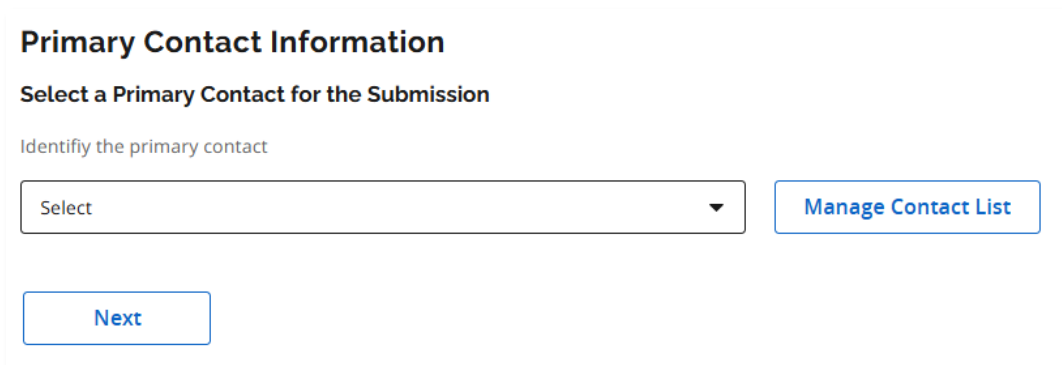
The screenshot shows the 'DIRECT' web application interface. At the top, a dark header bar contains the word 'DIRECT' and a 'Back to Submissions' button. Below the header, a left-hand navigation menu lists several sections: 'Manufacturer Details' (which is highlighted), 'Product Details', 'Change Details', 'Health Canada Documentation', 'Supplemental Information', and 'Review'. The main content area is titled 'Manufacturer Details' and is divided into two main sections. The top section, 'No Product Assigned', contains a 'Submission Category' dropdown menu with 'Notice of Change' selected, a 'Change Type' dropdown menu with 'Product Monograph Change' selected, and a 'Product Type' dropdown menu with 'Single Source Drug Product' selected. A 'More Actions' link is located at the bottom right of this section. The bottom section, 'Manufacturer Information', features a 'VitalCure Medications' header and an 'Address' field with the text 'Toronto, Ontario, Canada'. A 'Save' button is positioned below the address field. At the very bottom of the screen, the 'Primary Contact Information' section is partially visible, showing a prompt to 'Select a Primary Contact for Submission'.

Figure 86 – Screenshot of the Manufacturer Details screen



Note that if required information cannot be provided due to exceptional circumstances, please see [Section 3.5.38](#) for more information about entering a rationale.

- 3.5.9. Scroll down to the **Primary Contact Information** section and click on the **Primary Contact** drop-down and select the '*Primary Contact*' value.



Primary Contact Information

Select a Primary Contact for the Submission

Identify the primary contact

Select ▼

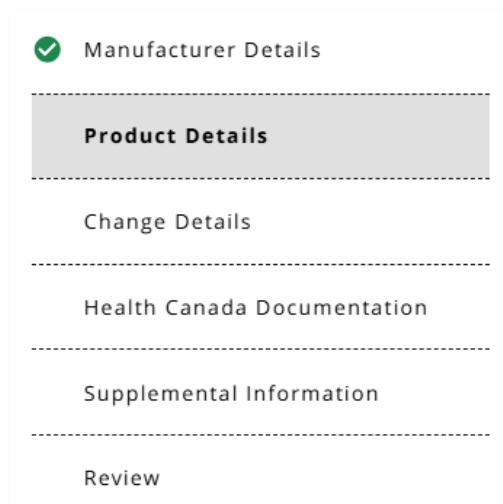
Manage Contact List

Next

Figure 87 – Screenshot of the Primary Contact Information section

3.5.10. Note that the Primary Contact for the organization displays with “*Primary*” in brackets, in the drop-down. Users can select the **<Manage Contact List>** button to view/edit/add contacts. ([See Section 1.2](#) How to Manage an Organization’s Contact List, for more details.)

3.5.11. The selected contact’s information displays (company, job title, email). Click the **<Next>** button.



✓ Manufacturer Details

Product Details

Change Details

Health Canada Documentation

Supplemental Information

Review

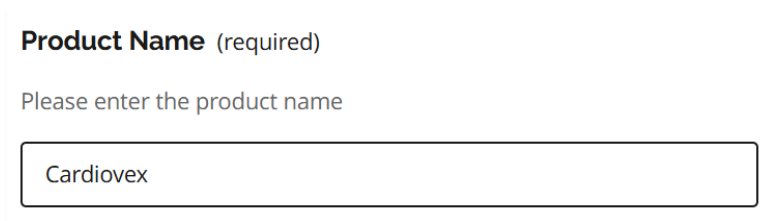
Figure 88 – Screenshot of the Left Menu Tabs on the Product Details screen

3.5.12. The **Product Details** screen displays and is bolded in the left menu.



Note that after completing the required details on the **Manufacturer Details** screen, there is now a green checkmark beside *Manufacturer Details*, in the Left Menu. DIRECT guides users as screens are completed, using green checkmarks as a visual indicator that required details have been entered.

3.5.13. Click in the **Product Name** field and enter the product name.



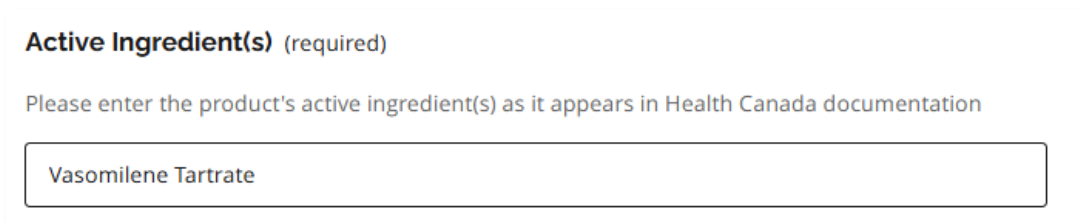
Product Name (required)

Please enter the product name

Cardiovox

Figure 89 – Screenshot of the Product Name field on the Product Details screen

3.5.14. Click in the **Active Ingredient(s)** field and enter the active ingredient(s) as it appears in Health Canada documentation.



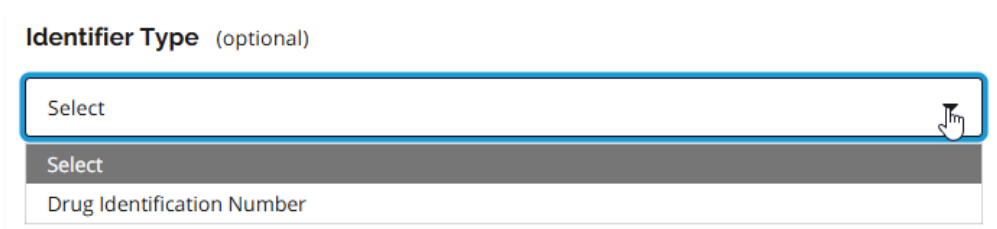
Active Ingredient(s) (required)

Please enter the product's active ingredient(s) as it appears in Health Canada documentation

Vasomilene Tartrate

Figure 90 – Screenshot of the Active Ingredient(s) field on the Product Details screen

3.5.15. If desired, click in the **Identifier Type** drop-down field and select the value '*Drug Identification Number*'. (Note, this field is 'optional'.)



Identifier Type (optional)

Select

Select

Drug Identification Number

Figure 91 – Screenshot of the Identifier Type drop-down field on the Product Details screen

3.5.16. The **Identifier** field displays, if the Identifier Type was selected. Enter the unique identifier assigned by Health Canada for the identifier type selected.



Identifier (required)

Please enter the unique identifier assigned by Health Canada for the identifier type selected above

12345679

Figure 92 – Screenshot of the Identifier field on the Product Details screen

3.5.17. Click the **Dosage Form** drop-down and select the applicable value.

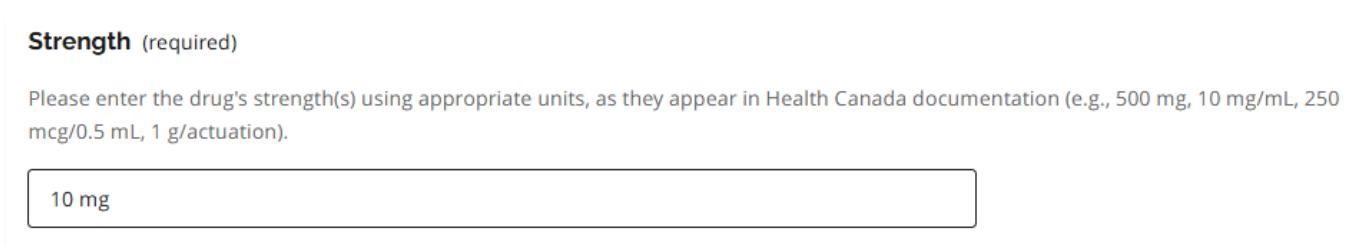


Dosage Form (required)

Tablet ▼

Figure 93 – Screenshot of the Dosage Form drop-down field on the Product Details screen

3.5.18. Click in the **Strength** field and enter the drug's strength(s) using appropriate units, as they appear in Health Canada documentation (e.g., 500 mg, 10 mg/mL, 250 mcg/0.5 mL, 1 g/actuation).



Strength (required)

Please enter the drug's strength(s) using appropriate units, as they appear in Health Canada documentation (e.g., 500 mg, 10 mg/mL, 250 mcg/0.5 mL, 1 g/actuation).

10 mg

Figure 94 – Screenshot of the Strength field on the Product Details screen

3.5.19. Click in the **Route of Administration** drop-down field and select the applicable value.

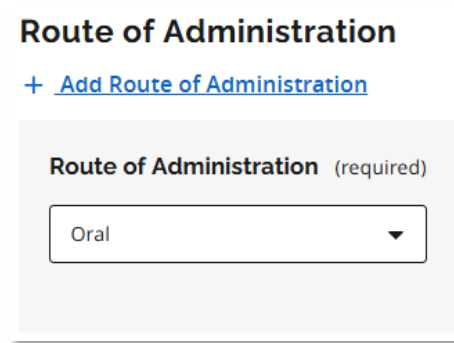


Figure 95 – Screenshot of the Route of Administration drop-down field on the Product Details screen

3.5.20. Select the required radio button in the **Preservatives** field to indicate whether the product is preservative free or with preservative for injectable and ophthalmic products, otherwise select 'Not Applicable'.

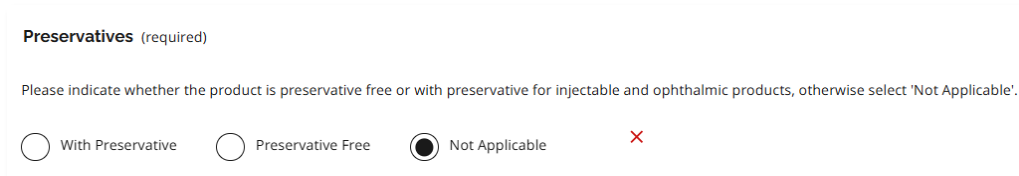


Figure 96 – Screenshot of the Preservative field on the Product Details screen

3.5.21. Select the required radio buttons in the **Product Classification** section to indicate if the product is a biologic, and if the indication(s) for the submission is oncology-related.

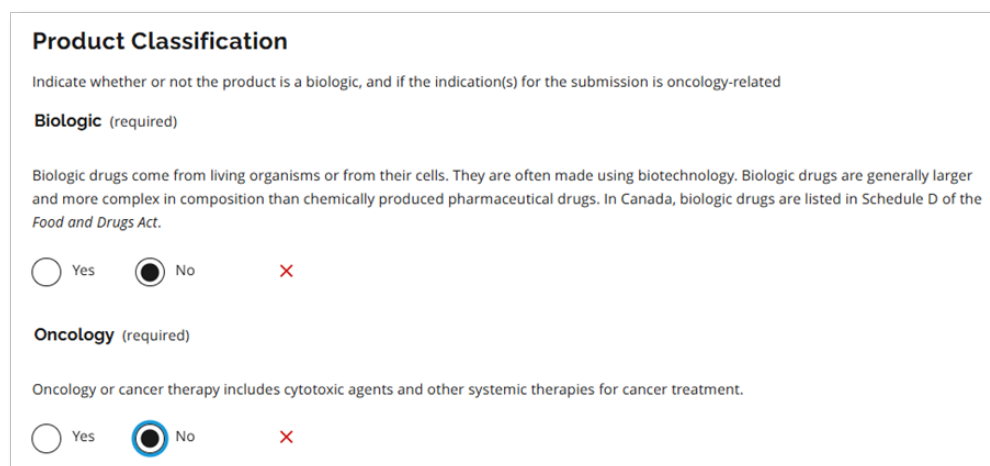


Figure 97 – Screenshot of the Product Classification section on the Product Details screen

3.5.22. Select the **<Next>** button to continue to create the Notice of Change submission.

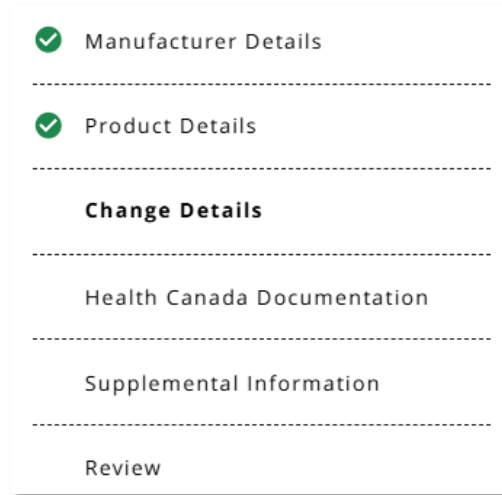


Figure 98 – Screenshot of the Left Menu Tabs on the Change Details screen

3.5.23. The **<Change Details>** screen displays and is bolded in the left menu.

Cardiovex 10 mg

Submission Category

Notice of Change

Change Type

Product Monograph Change

Product Type

Single Source Drug Product

[More Actions](#)

Change Details

Rationale for the change(s) (required)

Drag and drop the file to upload or [Browse Files](#)

Rationale for Change.docx

2026-05-06 15:13

Delete

Effective date for the change(s) (required)

2026-08-01

Back

Next

Submit

Figure 99 – Screenshot of the Change Details section

3.5.24. In the **Rationale for the change(s)** field, supporting document(s) can be added by

dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.

3.5.25. Enter the appropriate date in the **Effective date for the change(s)** field and then click the **<Next>** button to continue to create the Notice of Change submission.

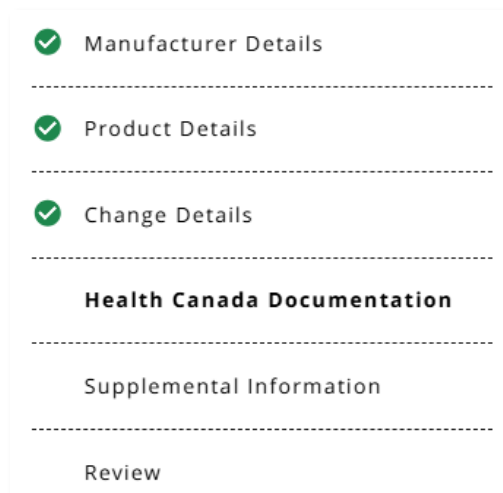


Figure 100 – Screenshot of the Left Menu Tabs on the Health Canada Documentation screen

3.5.26. The **Health Canada Documentation** screen displays and is bolded in the left menu.

3.5.27. Select the checkmark to confirm that Health Canada has approved the change(s).

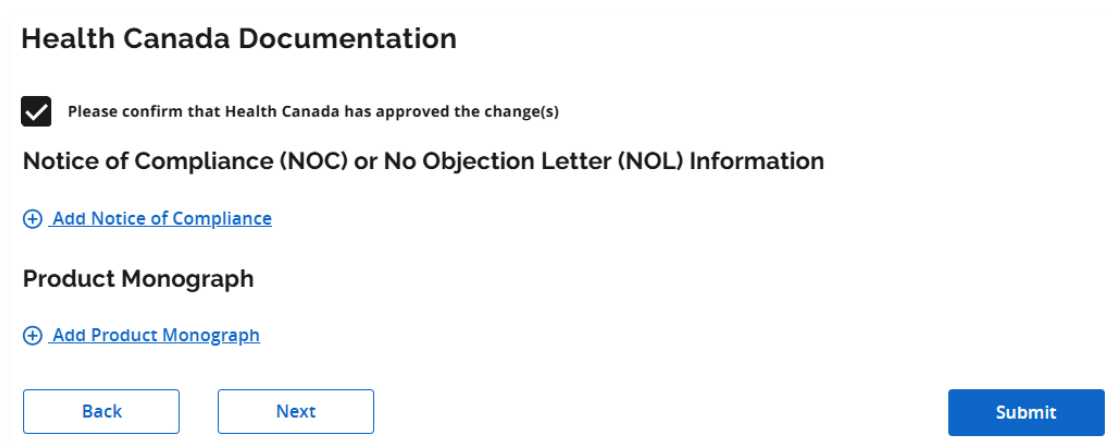
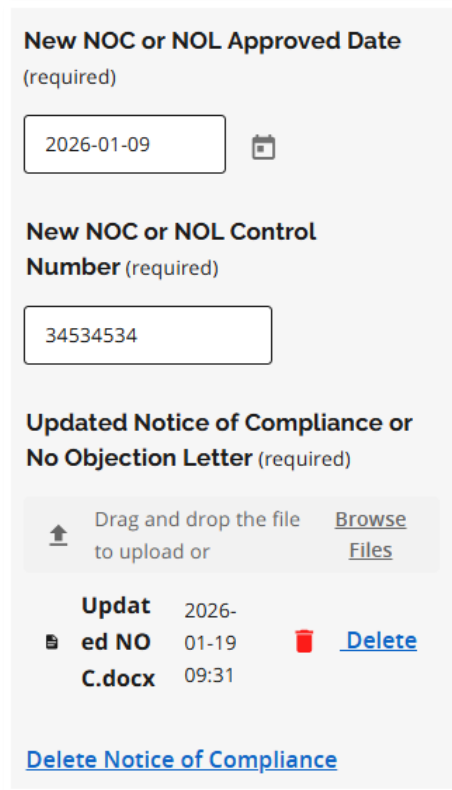


Figure 101 – Screenshot of the Health Canada Documentation screen

3.5.28. Select the **<Add Notice of Compliance>** link. Enter the appropriate date in the **New NOC**

or **NOL Approved Date** field and enter the value in the **New NOC or NOL Control Number** field.



New NOC or NOL Approved Date
(required)

2026-01-09 

New NOC or NOL Control Number (required)

34534534

Updated Notice of Compliance or No Objection Letter (required)

 Drag and drop the file to upload or [Browse Files](#)

Updated NOC or NOL	Date	Time	Actions
Updated NOC or NOL C.docx	2026-01-19	09:31	 Delete

[Delete Notice of Compliance](#)

Figure 102 – Screenshot of the Notice of Compliance section

3.5.29. Upload the *Notice of Compliance* file or the *No Object Letter* file by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.

3.5.30. Select the **<Add Product Monograph>** link. Enter the appropriate date in the **Date of the new Product Monograph** field and enter the value in the **New Product Monograph Control Number** field.

Date of the new Product Monograph (required)

2026-01-09 

New Product Monograph Control Number (required)

34534534

Non-annotated copy of the new Product Monograph (required)


 Drag and drop the file to upload or
 [Browse Files](#)


PM-1.d ocx

2026-01-19 09:37
 
[Delete](#)

Annotated/tracked copy of the new Product Monograph (required)


 Drag and drop the file to upload or
 [Browse Files](#)


PM-2.d ocx

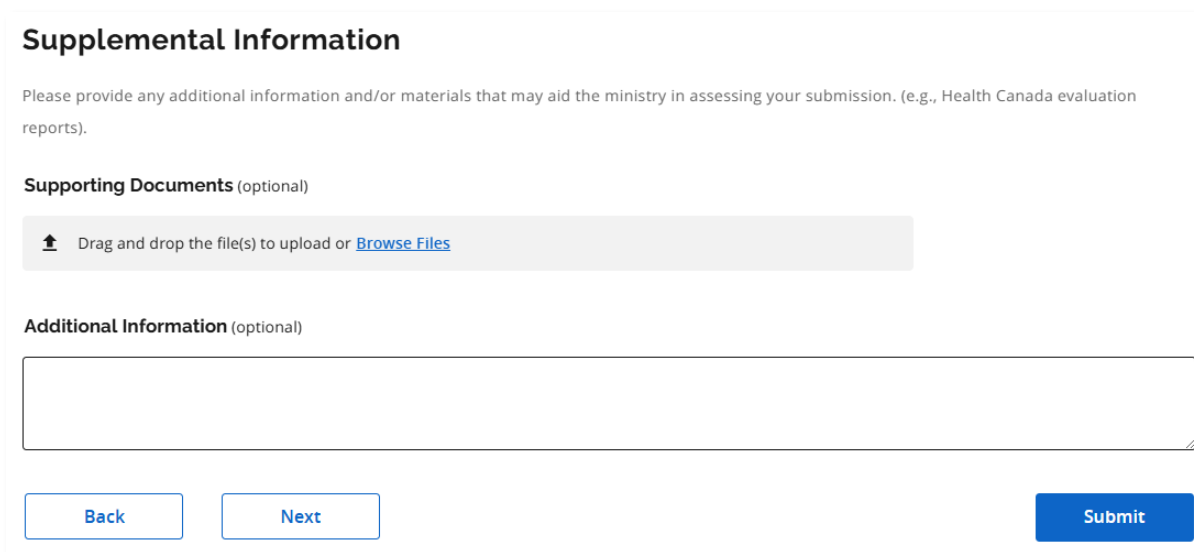
2026-01-19 09:37
 
[Delete](#)

[Delete Product Monograph](#)

Figure 103 – Screenshot of the Product Monograph section

- 3.5.31. Upload the *Non-annotated copy of the new Product Monograph* file and the *Annotated/tracked copy of the new Product Monograph* file by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.
- 3.5.32. Click the **<Next>** button to continue to create the Notice of Change submission.
- 3.5.33. The **Supplemental Information** screen displays and is bolded in the left menu. This

optional screen is available to provide any additional information and/or materials that may aid the ministry in assessing your submission. (e.g., Health Canada evaluation reports).



The screenshot shows a web form titled "Supplemental Information". Below the title is a paragraph of instructions: "Please provide any additional information and/or materials that may aid the ministry in assessing your submission. (e.g., Health Canada evaluation reports)." The form is divided into two sections. The first section, "Supporting Documents (optional)", contains a light gray box with a file upload icon and the text "Drag and drop the file(s) to upload or [Browse Files](#)". The second section, "Additional Information (optional)", contains a large, empty text input field. At the bottom of the form are three buttons: "Back", "Next", and "Submit". The "Back" and "Next" buttons are outlined in blue, while the "Submit" button is solid blue.

Figure 104 – Screenshot of the Supplemental Information screen

3.5.34. Upload any supporting documents by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if desired.

3.5.35. Select the **Additional Information** field and enter supplemental information, if desired.



Note that you can choose to click the **<Submit>** button from this screen to submit, but it is recommended to first review information on the **Review** screen, which summarizes your submission and highlights any required information that must still be provided before submitting. **It is highly recommended to review all information before submitting, because you cannot edit a submission through DIRECT after it is submitted.**

3.5.36. Click the **<Next>** button to continue to create the submission.

3.5.37. The **Review** screen displays and is bolded in the left menu.

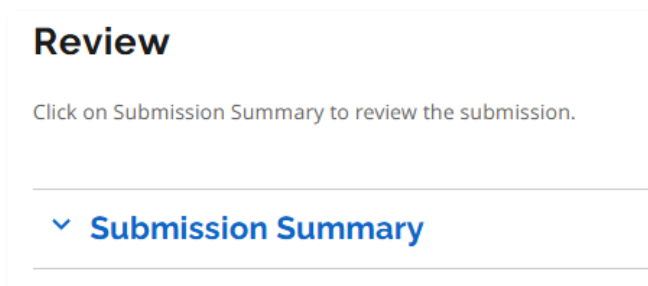


Figure 105 – Screenshot of the Submission Summary Link on the Review screen

3.5.38. Click the **<Submission Summary>** link to expand the screen to show all information that has been entered for the submission, including all attachments. Any required information that has been missed will be highlighted.

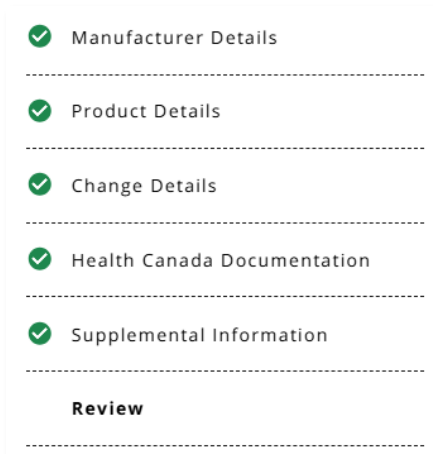


Figure 106 – Screenshot of the Left Menu

3.5.39. If all required information for the submission has been entered, green checkmarks appear for each page in the Left Menu.

3.5.40. If required information for the submission has not been entered, when you click the **<Submit>** button, a Rationale Required window displays, and a red exclamation mark appears for each page missing information in the Left Menu. You can provide an explanation and continue to submit the submission, or you can edit the submission and enter the missing information.



Note that some fields are noted as *Optional*, while others are *Required*. Certain *required* fields are mandatory to submit a submission, for example the Primary Contact for your organization must be selected. Other *required* fields are also necessary; however, it is recognized that at times you may be unable to provide details for a required field (e.g., it cannot be provided due to exceptional circumstances). If information that is required is not provided, the submission may be deemed incomplete.

3.5.41. Click the **<Submit>** button. DIRECT validates responses and highlights any items requiring review/update.

3.5.42. The **Submitting Terms and Conditions** display, providing definitions and statements for manufacturers and vendors.

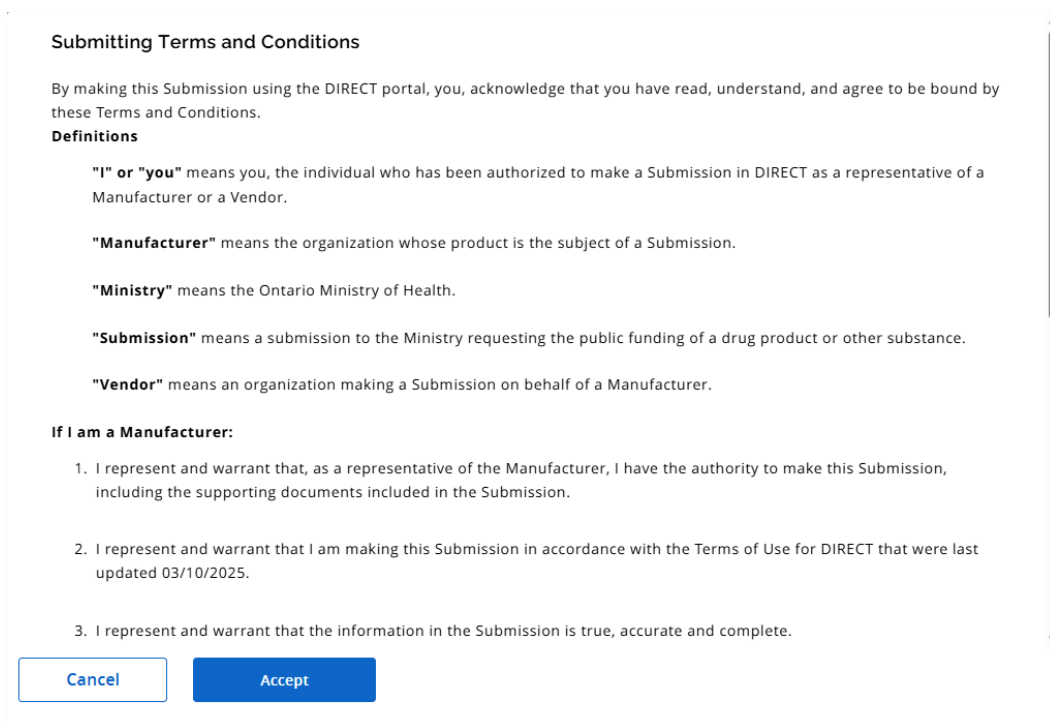


Figure 107 – Screenshot of the Submitting Terms and Conditions window

3.5.43. Scroll to review the complete terms and conditions, and if desired, click the **<Accept>** button.

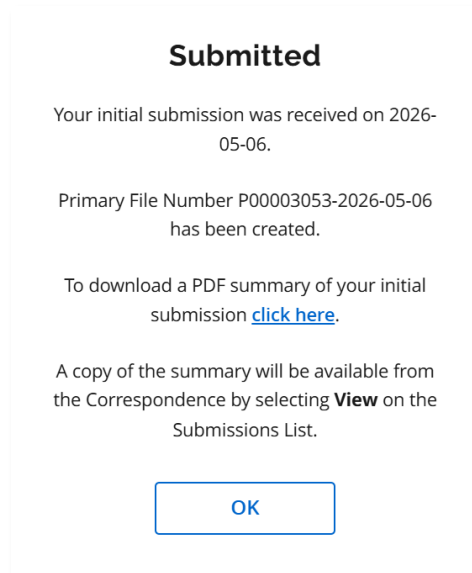


Figure 108 – Screenshot of the Submitted Message

3.5.44. A pop-up message indicates the submission has been successfully submitted. The initial submission date is provided, along with the 'Primary File Number' that has been generated for the Notice of Change.

3.5.45. A PDF summary of the submission can be downloaded by selecting the <click here> link, and a copy is available anytime by selecting the <View> button in the **Correspondence** section for the submission, on the Submissions List.

3.5.46. Select the **OK** button to return to the submission list. The submission **Status** is 'Submitted' and the Submission Category is 'Notice of Change'.

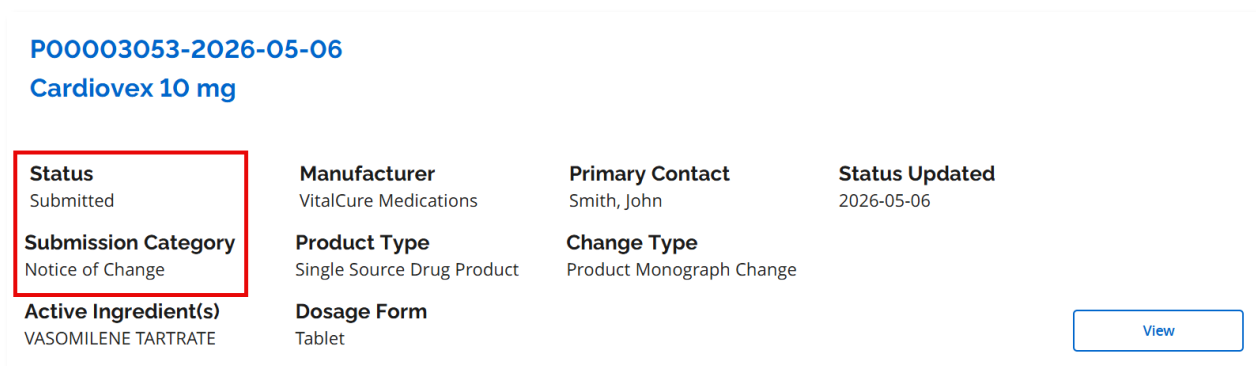


Figure 109 – Screenshot of the Notice of Change Submission in the Submission List

You have successfully submitted the Notice of Change submission to the ministry. You can expect the *status* of the submission to change after the ministry has completed their screening.

3.5.47. Select the **<View>** button to view a record of the submission including the **Submission Category**, **Change Type** and **Product Type**.

P00003053-2026-05-06

Cardiovex 10 mg

Status

Submitted

Primary Contact

Smith, John

Submission Category

Notice of Change

Change Type

Product Monograph Change

Product Type

Single Source Drug Product

Correspondence

Correspondence History

Correspondence Type Show All ▼ **Sort By:** Date New to Old ▼

Initial Submission		
From	To	Submitted Date and Time
Submitter	Ministry	May 6, 2026, 3:50 PM

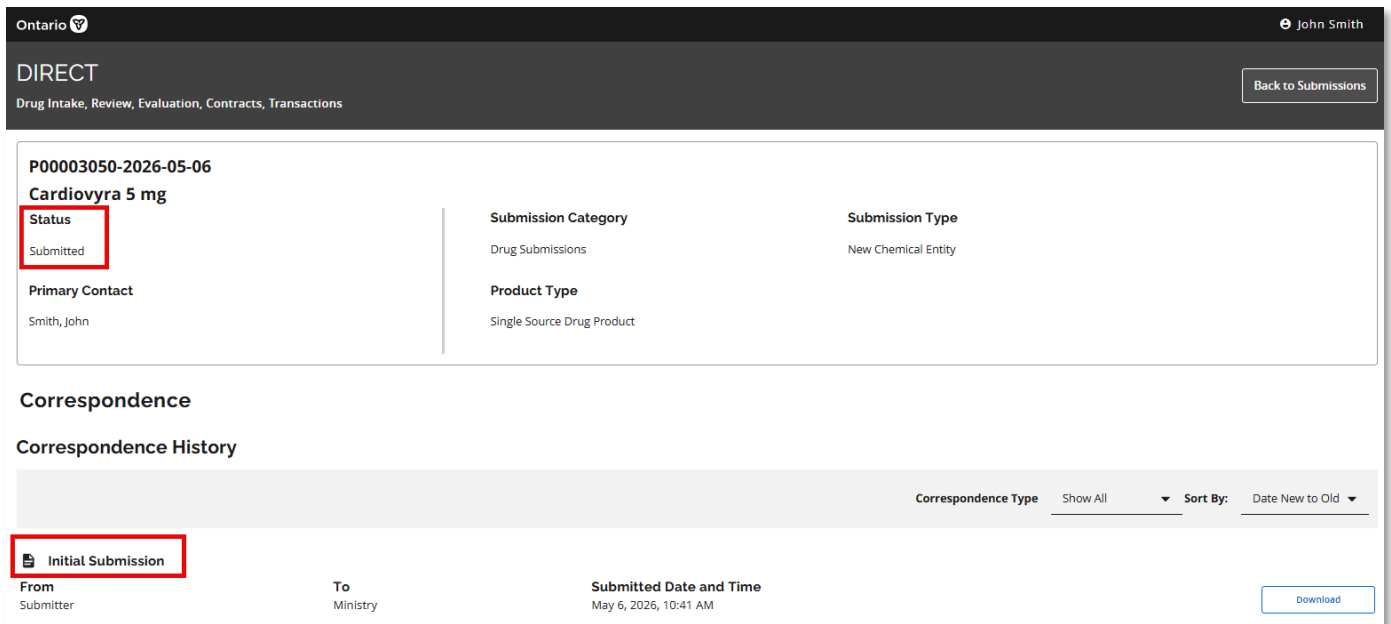
Download

Figure 110 – Screenshot of the Notice of Change Submission Record

3.5.48. In the **Correspondence History** section, select the **<Download>** button to download a PDF copy of the Notice of Change submission.

3.6. How to Submit Additional Information

After entering a submission through DIRECT, the Status displays as '*Submitted*,' and the *Initial Submission PDF* is maintained in the **Correspondence History** section.



Ontario  John Smith

DIRECT
Drug Intake, Review, Evaluation, Contracts, Transactions [Back to Submissions](#)

P00003050-2026-05-06
Cardiovyra 5 mg

Status Submitted	Submission Category Drug Submissions	Submission Type New Chemical Entity
Primary Contact Smith, John	Product Type Single Source Drug Product	

Correspondence

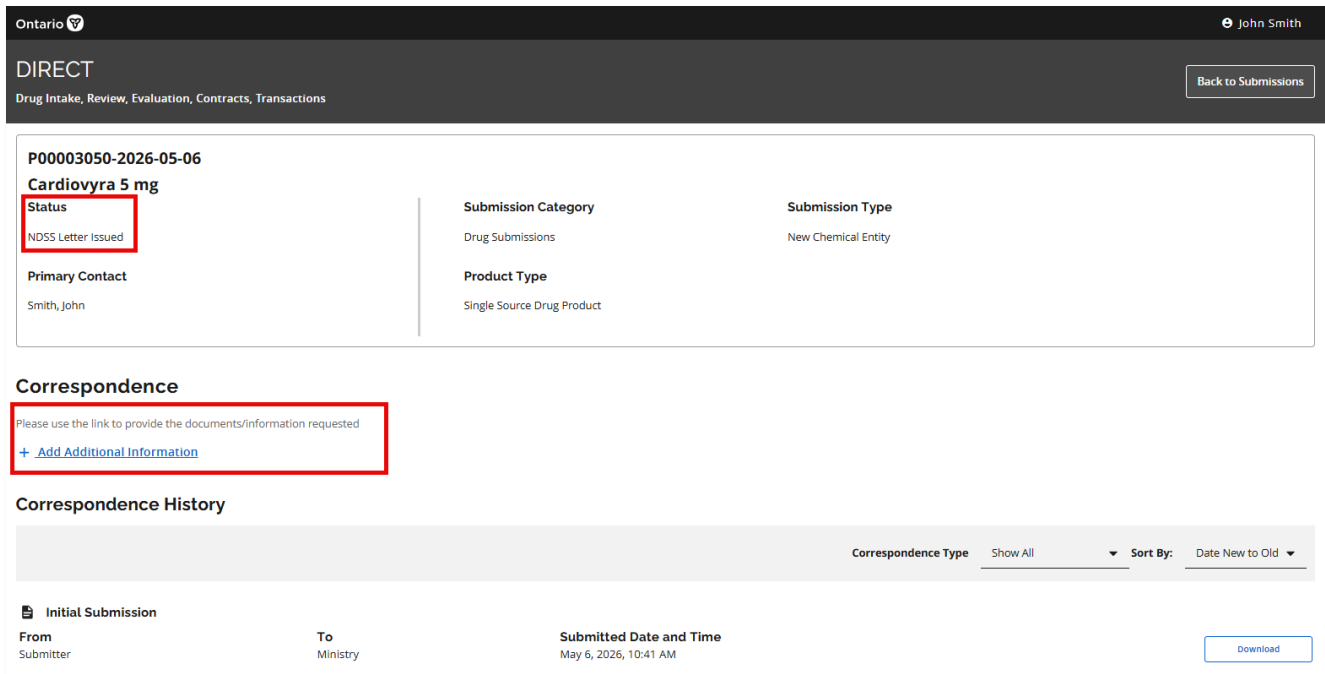
Correspondence History

Correspondence Type	Show All	Sort By:	Date New to Old
 Initial Submission			
From Submitter	To Ministry	Submitted Date and Time May 6, 2026, 10:41 AM	Download

Figure 111 – Screenshot of the Submission Overview screen

Note that the ministry sometimes requires manufacturers to submit additional information in support of a submission. The example below is one potential reason additional information may be required.

For example, during screening, the ministry determines that an attachment is unreadable, and they have sent an NDSS Letter requesting the document be re-submitted. The Status of the submission has changed to '*NDSS Letter Issued*,' and a **<+ Add Additional Information>** link is now available in the **Correspondence** section.



Ontario  John Smith

DIRECT
Drug Intake, Review, Evaluation, Contracts, Transactions [Back to Submissions](#)

P00003050-2026-05-06
Cardiovyra 5 mg

Status NDSS Letter Issued	Submission Category Drug Submissions	Submission Type New Chemical Entity
Primary Contact Smith, John	Product Type Single Source Drug Product	

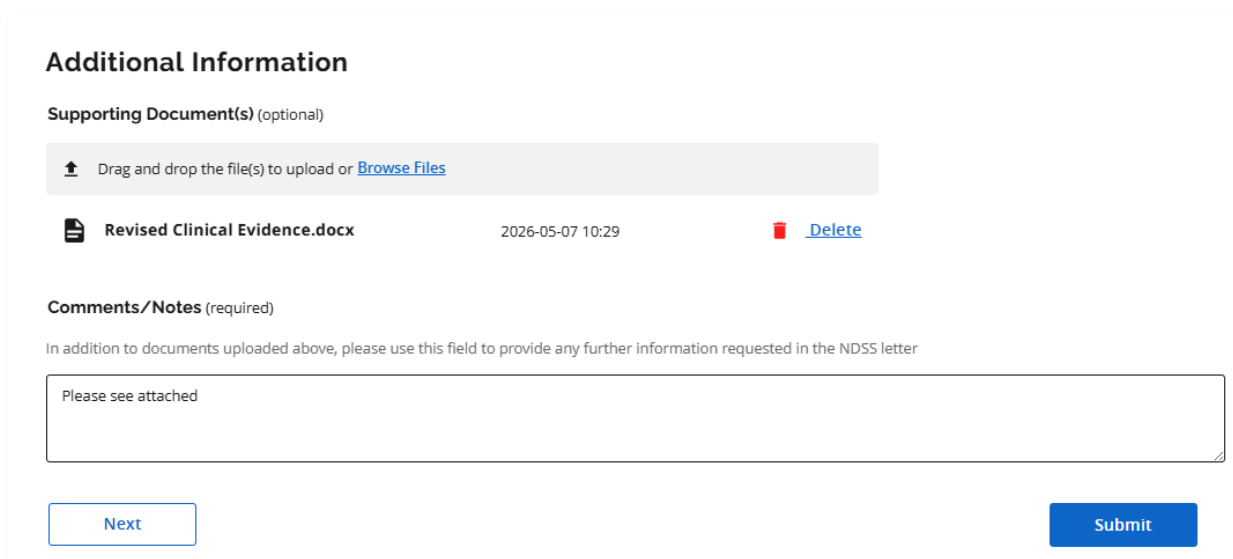
Correspondence
Please use the link to provide the documents/information requested
[+ Add Additional Information](#)

Correspondence History

Correspondence Type	Show All	Sort By:	Date New to Old
Initial Submission			
From Submitter	To Ministry	Submitted Date and Time May 6, 2026, 10:41 AM	Download

Figure 112 – Screenshot of the Submission Overview screen

3.6.1. To provide the required information, click the **<+ Additional Information>** link.



Additional Information

Supporting Document(s) (optional)

Drag and drop the file(s) to upload or [Browse Files](#)

Revised Clinical Evidence.docx 2026-05-07 10:29 [Delete](#)

Comments/Notes (required)
In addition to documents uploaded above, please use this field to provide any further information requested in the NDSS letter

Please see attached

[Next](#) [Submit](#)

Figure 113 – Screenshot of the Additional Information screen

3.6.2. The **Additional Information** screen displays. Supporting document(s) can be added by dragging and dropping it, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.



Important: Refer to [Section 2.4](#) for information related to file uploads.

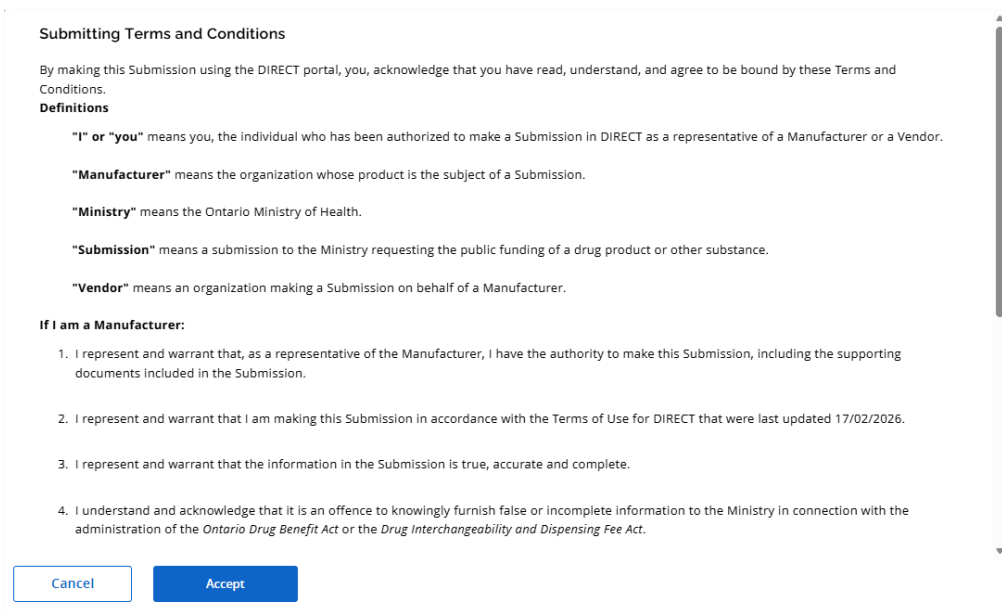
3.6.3. Select the **Comments/Notes** field and enter any information requested in the NDSS letter.



Note that the **Supporting Document(s)** field is *optional*, and the **Comments/Notes** field is *required*.

3.6.4. Click the **<Submit>** button.

3.6.5. The Submitting Terms and Conditions display, providing definitions and statements for manufacturers and vendors.



The screenshot shows a dialog box titled "Submitting Terms and Conditions". It contains the following text:

By making this Submission using the DIRECT portal, you, acknowledge that you have read, understand, and agree to be bound by these Terms and Conditions.

Definitions

"I" or "you" means you, the individual who has been authorized to make a Submission in DIRECT as a representative of a Manufacturer or a Vendor.

"Manufacturer" means the organization whose product is the subject of a Submission.

"Ministry" means the Ontario Ministry of Health.

"Submission" means a submission to the Ministry requesting the public funding of a drug product or other substance.

"Vendor" means an organization making a Submission on behalf of a Manufacturer.

If I am a Manufacturer:

1. I represent and warrant that, as a representative of the Manufacturer, I have the authority to make this Submission, including the supporting documents included in the Submission.
2. I represent and warrant that I am making this Submission in accordance with the Terms of Use for DIRECT that were last updated 17/02/2026.
3. I represent and warrant that the information in the Submission is true, accurate and complete.
4. I understand and acknowledge that it is an offence to knowingly furnish false or incomplete information to the Ministry in connection with the administration of the *Ontario Drug Benefit Act* or the *Drug Interchangeability and Dispensing Fee Act*.

At the bottom of the dialog box are two buttons: "Cancel" and "Accept".

Figure 114 – Screenshot of the Submitting Terms and Conditions

3.6.6. Scroll to review the complete terms and conditions, and if desired, click the **<Accept>** button.

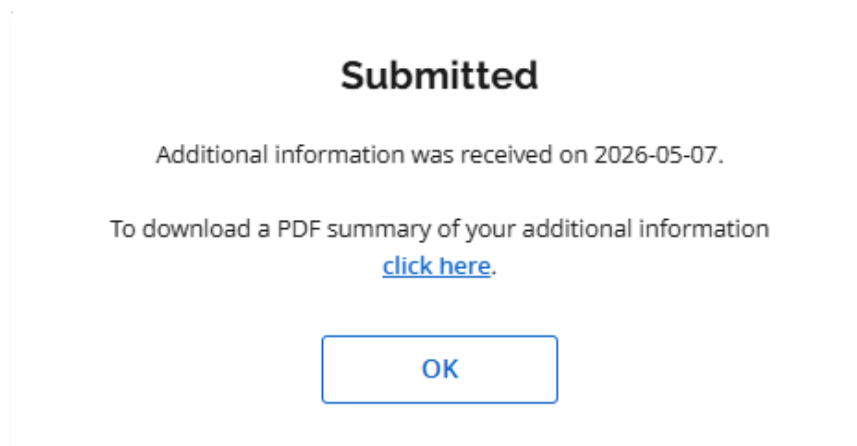


Figure 115 – Screenshot of the Successful Submission Message

- 3.6.7. The Submitted pop-up message displays with a date stamp to indicate that the Additional Information was received. A PDF summary of the submission can be downloaded by selecting the **<click here>** link, and a copy is available anytime by selecting the **<View>** button in the **Correspondence** section for the submission, on the Submissions List.
- 3.6.8. Select the **<OK>** button to return to the submission record. The Status is now 'Additional Information Submitted'.

P00003050-2026-05-06
Cardiovyra 5 mg

Status
Additional Information Submitted

Primary Contact
Smith, John

Submission Category
Drug Submissions

Product Type
Single Source Drug Product

Submission Type
New Chemical Entity

Correspondence

Correspondence History

Correspondence Type

Show All

Sort By: Date New to Old

 Additional Information			
From Submitter	To Ministry	Submitted Date and Time May 7, 2026, 10:36 AM	Download
 Initial Submission			
From Submitter	To Ministry	Submitted Date and Time May 6, 2026, 10:41 AM	Download

Figure 116 – Screenshot of the Submission Record with Additional Information Correspondence

3.6.9. The *Additional Information* submission appears in the **Correspondence History** section, with a date and time stamp. Click the **<Download>** button to view/download a PDF copy of the additional information that was submitted.

You have successfully submitted the Additional Information submission to the ministry. You can expect the *status* of the submission to change after the ministry has completed their screening.

3.7. How to Create a Submission on Behalf of the Notice of Compliance (NOC) or Drug Identification Number (DIN) Holder

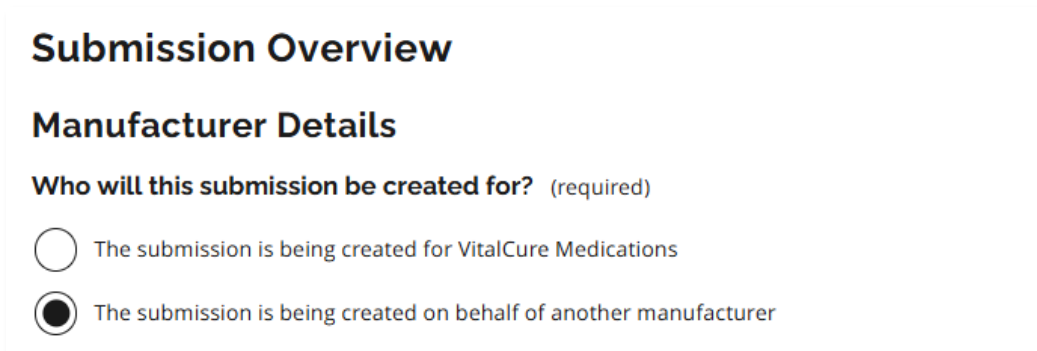
The following steps outline the processes for:

- Vendors submitting on behalf of manufacturers



Important: All organizations and new users that require access to DIRECT must be onboarded individually. Manufacturers cannot register or grant DIRECT access to vendors, and vendors cannot do so on behalf of manufacturers. Each organization must contact DIRECT@ontario.ca to be authenticated and granted access to DIRECT. Users can only manage contact details within their own organization. Vendors should contact DIRECT@ontario.ca if the manufacturer they are submitting on behalf of is not visible in the system.

- 3.7.1. As a vendor acting on behalf of the NOC or DIN holder (i.e., manufacturer), log in to DIRECT and click on the **<+Create Submission>** button. The **Submission Overview** screen displays.



Submission Overview

Manufacturer Details

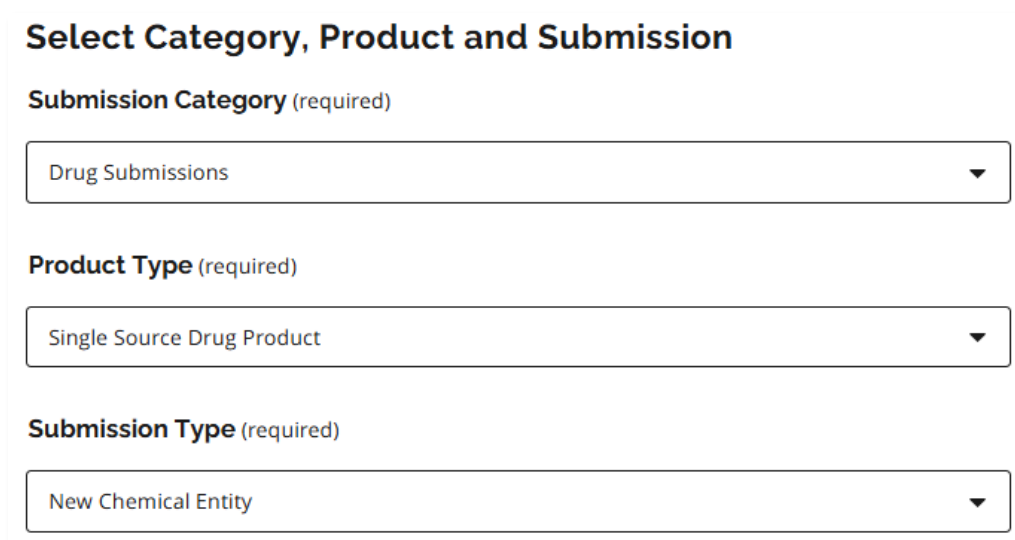
Who will this submission be created for? (required)

☐ The submission is being created for VitalCure Medications

☒ The submission is being created on behalf of another manufacturer

Figure 117 – Screenshot of the Submission Overview screen

- 3.7.2. Select the default radio button to indicate the submission is being created on behalf of the NOC or DIN holder.
- 3.7.3. Select the appropriate values for the **Submission Category**, **Product Type**, and **Submission Type** drop-downs.



Select Category, Product and Submission

Submission Category (required)

Drug Submissions ▼

Product Type (required)

Single Source Drug Product ▼

Submission Type (required)

New Chemical Entity ▼

Figure 118 – Screenshot of the Category, Product and Submission section

- 3.7.4. Select the **<Applicable Guidelines>** link, if desired, and the relevant Guidelines open in PDF format in a separate tab, or they are downloaded to your Downloads folder, as a PDF document that can be opened and viewed.

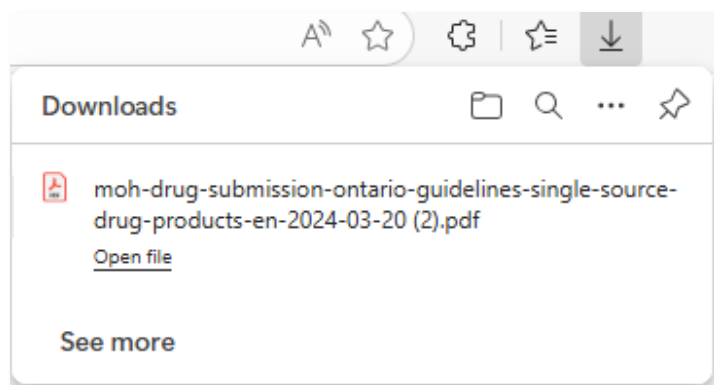


Figure 119 – Screenshot of a Downloaded Guidelines document as a PDF

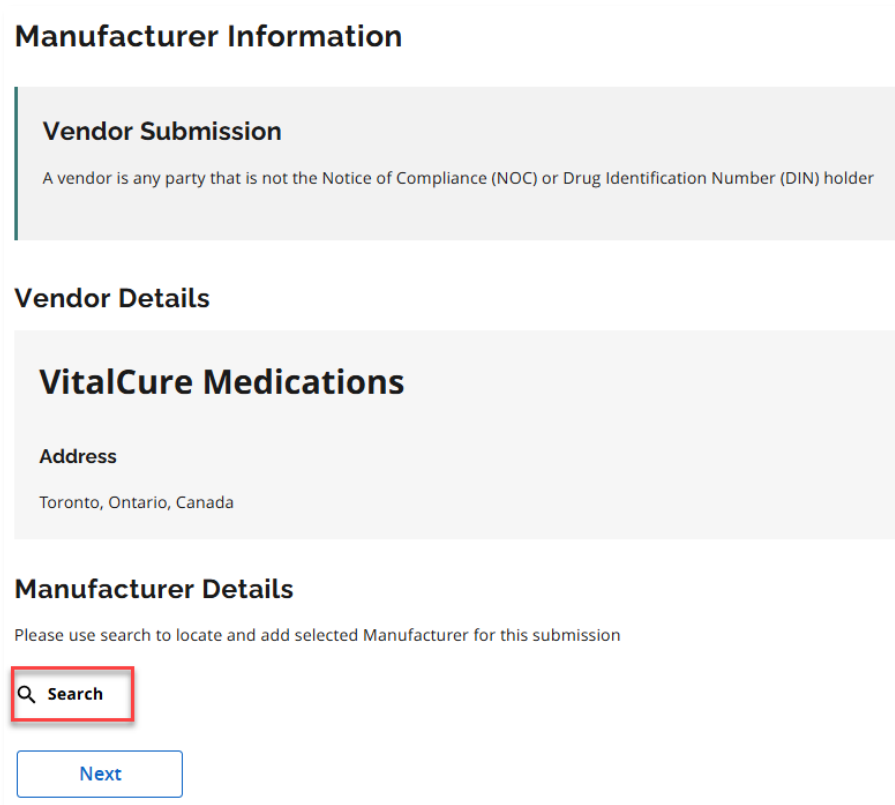
- 3.7.5. Click the **<Cancel>** button to remove all selections on the screen, and return to the Submissions home screen, or click the **<Next>** button to continue to create the submission.



Figure 120 – Screenshot of the Left Menu Tabs on the Manufacturer Details screen

3.7.6. The **Manufacturer Details** screen displays and is bolded in the left menu. The **Vendor Submission** section states that “A vendor is any party that is not the Notice of Compliance (NOC) or Drug Identification Number (DIN) holder”. The **Vendor Details** section displays the name and address for the logged in vendor.

3.7.7. Scroll down to the **Manufacturer Details** section and click on the **<Search>** link.



Manufacturer Information

Vendor Submission

A vendor is any party that is not the Notice of Compliance (NOC) or Drug Identification Number (DIN) holder

Vendor Details

VitalCure Medications

Address

Toronto, Ontario, Canada

Manufacturer Details

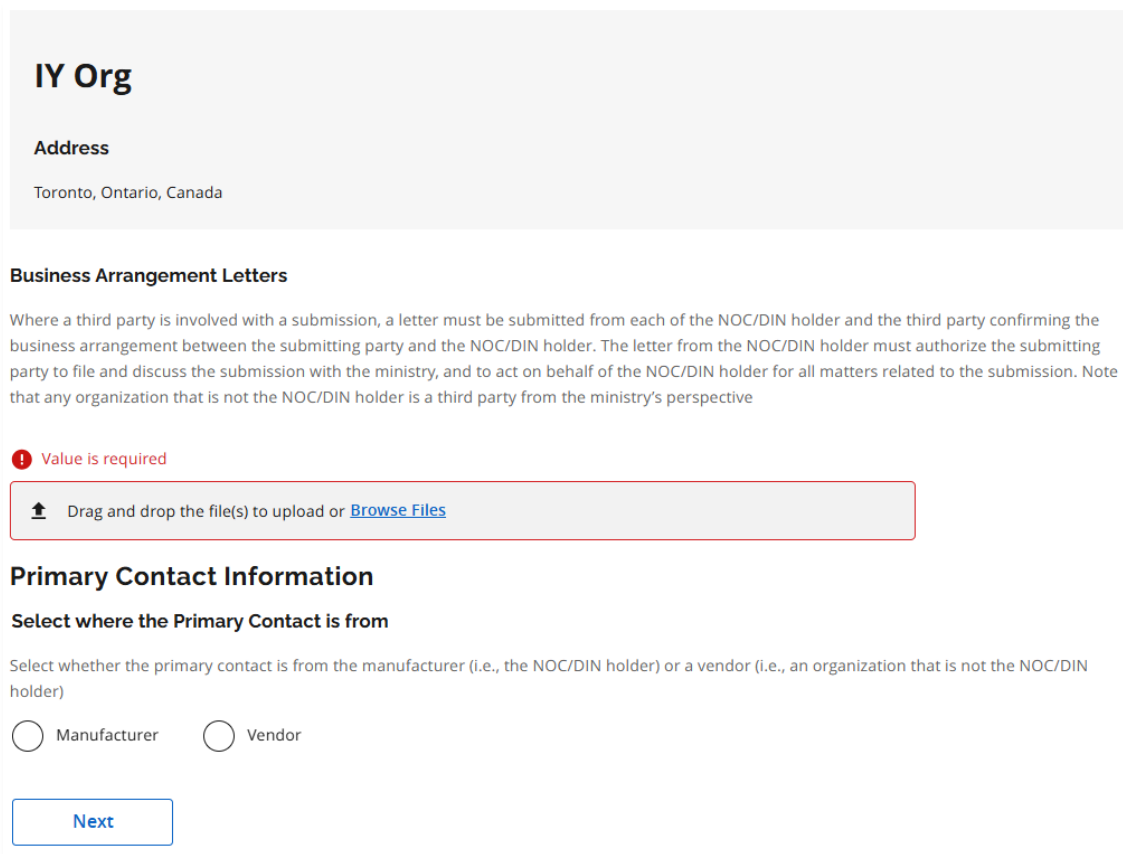
Please use search to locate and add selected Manufacturer for this submission

Figure 121 – Screenshot of the Manufacturer Details section

- 3.7.8. Type the name of the manufacturer for whom the submission is being created and select the manufacturer from the drop-down list.



Important: Only select organizations will display in the search result of manufacturers in DIRECT. Vendors should contact DIRECT@ontario.ca if the manufacturer they are submitting on behalf of is not visible in the system.



IY Org

Address

Toronto, Ontario, Canada

Business Arrangement Letters

Where a third party is involved with a submission, a letter must be submitted from each of the NOC/DIN holder and the third party confirming the business arrangement between the submitting party and the NOC/DIN holder. The letter from the NOC/DIN holder must authorize the submitting party to file and discuss the submission with the ministry, and to act on behalf of the NOC/DIN holder for all matters related to the submission. Note that any organization that is not the NOC/DIN holder is a third party from the ministry's perspective

 Value is required

 Drag and drop the file(s) to upload or [Browse Files](#)

Primary Contact Information

Select where the Primary Contact is from

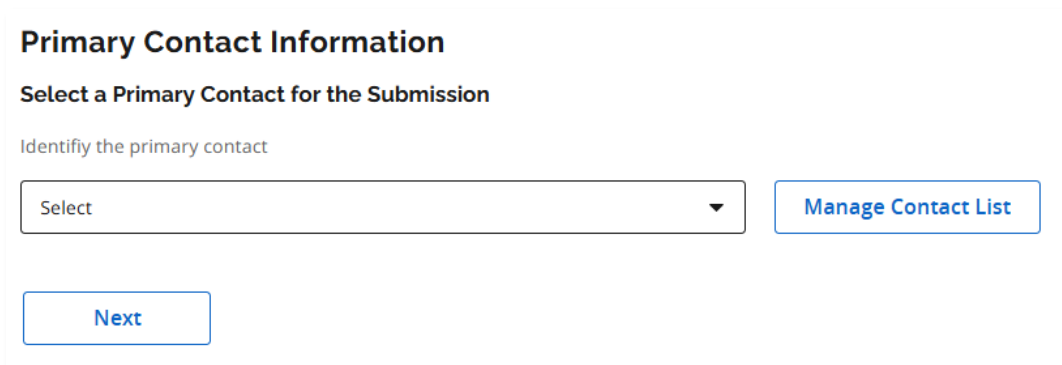
Select whether the primary contact is from the manufacturer (i.e., the NOC/DIN holder) or a vendor (i.e., an organization that is not the NOC/DIN holder)

☐ Manufacturer ☐ Vendor

[Next](#)

Figure 122 – Screenshot of the Business Arrangement Letter field

- 3.7.9. Upload the Business Arrangement Letter(s) in the required fields by dragging and dropping them, or by clicking the Browse Files option. Multiple files can be uploaded, if necessary.
- 3.7.10. In the **Primary Contact Information** section, select the required radio buttons to indicate whether the primary contact is from the manufacturer (i.e., the NOC/DIN holder) or a vendor (i.e., an organization that is not the NOC/DIN holder).
- 3.7.11. Click on the **Primary Contact** drop-down and select the 'Primary Contact' value.



The screenshot shows a web form titled "Primary Contact Information". Below the title is the instruction "Select a Primary Contact for the Submission". A sub-label "Identify the primary contact" is positioned above a dropdown menu. The dropdown menu currently displays the word "Select" and a downward arrow. To the right of the dropdown is a button labeled "Manage Contact List". Below the dropdown is a button labeled "Next".

Figure 123 – Screenshot of the Primary Contact Information section

3.7.12. The *Primary Contact* for the organization displays with “*Primary*” in brackets, in the drop-down.



Note that the **<Manage Contact List>** button to view/edit/add contacts is available if the vendor option is selected. It is not available if the primary contact is from the manufacturer’s organization since you cannot manage another organization’s contacts. ([See Section 1.2](#) How to Manage an Organization’s Contact List, for more details.)

3.7.13. The selected contact’s information displays (company, job title, email).

3.7.14. Click the **<Next>** button to continue to create the submission per the guidelines.

3.8. How to Create Other Submission Types

DIRECT is designed to be user-friendly, using guided data entry to present questions and options aligned with ministry guidelines. This guides users to submit the required information or files, reducing incomplete submissions and delays. Although specific requirements vary, the guided process works consistently across all submission categories including submissions for the product types below:

Drug Submissions:

- Biosimilar Products

Non-Drug Submissions:

- Continuous Glucose Monitoring (CGM)
- Diabetic Testing Agent (DTA)
- Nutrition Product
- Valved Holding Chamber (VHC)

To complete the above submissions, please follow the general workflows outlined in this chapter.

Chapter 4 – Manage Submissions

This chapter provides you with guidelines on how to search for submissions by their Primary File Number or Product Name, use Filter Fields to filter by submission status, and how to change the order of the display of submissions.

The following screenshot displays the Search, Sort, and Filter Options available from the **Submissions** screen.

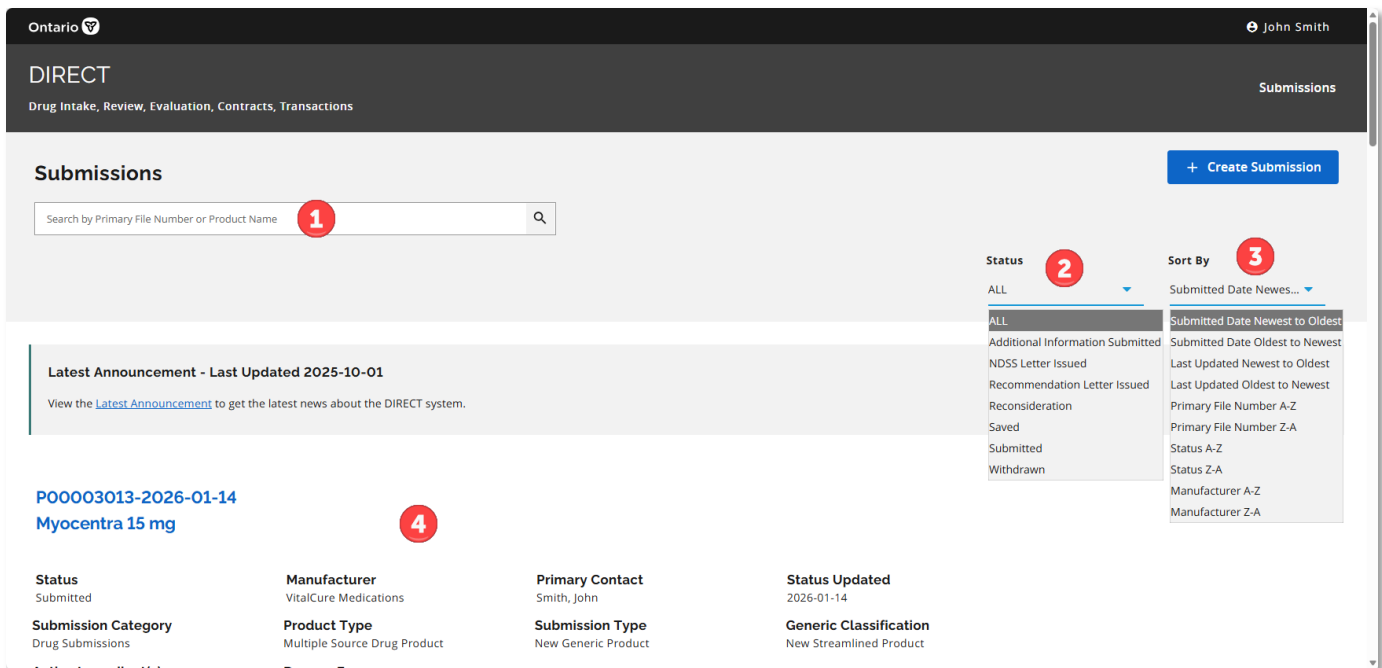


Figure 124 - Image of the Search, Sort, and Filter Options on the Submissions Screen

Submissions Screen Descriptions:

Item	Description
1. Search field	Search for organization's submissions submitted via DIRECT, by Primary File Number or Product Name.
2. Status filter	Filter organization's submissions submitted via DIRECT by Status.
3. Sort By filter	Sort organization's submissions submitted via DIRECT by

displaying in a different order.

4. **Submission List**

Includes all submissions saved and/or submitted by an organization, using DIRECT.

4.1. How to Search for Submissions

Submissions that have been entered through DIRECT are maintained and users can search for them on the **Submissions** screen, using the search field.



Note that historical submissions (pre-DIRECT) and submissions provided by email are not available in DIRECT. Users will only be able to search for submissions entered using DIRECT.

- 4.1.1. To search for a submission, navigate to the **Submissions** screen, then select the search field.

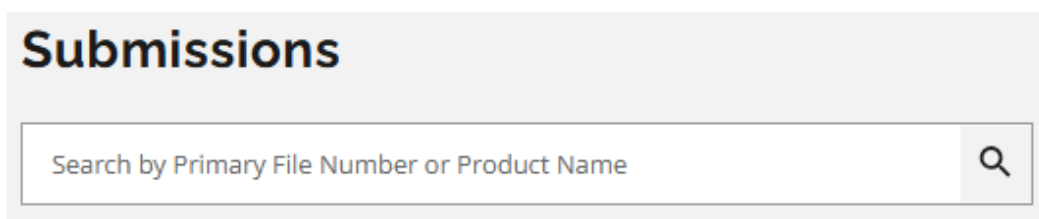


Figure 125 – Screenshot of the Submissions Search Field

- 4.1.2. Enter either the **Primary File Number** or **Product Name** in the search field.
- 4.1.3. As you type, DIRECT returns submissions that match the search criteria, in the **Submissions List**. To remove the search criteria entered in the search field, click the **<X Clear>** link.

Submissions

Q
✕ Clear

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P00003008-2026-01-13

Ostonix 70 mg

Status Submitted	Manufacturer VitalCure Medications	Primary Contact Smith, John	Status Updated 2026-01-15
Submission Category Drug Submissions	Product Type Single Source Drug Product	Submission Type New Chemical Entity	

Figure 126 – Screenshot of the Submissions Search Field with Clear Link



Note that all DIRECT users in your organization can search for all submissions your organization has entered using DIRECT, including submissions in a ‘Draft’ status.

4.2. How to Filter Submissions by Status

All DIRECT users in your organization can apply a filter of the ‘*Status*’ of submissions to the **Submissions List** to narrow down the results for submissions your organization has entered using DIRECT.

Submissions can be filtered by these statuses:

Item	Description
1. ALL	The default filter, ALL, displays all submissions regardless of the state.
2. Additional Information Submitted	The Additional Information submission has been received by the ministry.
3. NDSS Letter Issued	The submission has been screened and the ministry has issued a notice of drug submission status to the primary contact via email.
4. Recommendation Letter Issued	The submission has been reviewed and the ministry has issued a summary of the recommendation to the primary contact via email.
5. Reconsideration	The submission is undergoing the reconsideration review process.
6. Saved	The submission has been started and is draft. It has not been submitted.
7. Submitted	The submission has been received by the ministry.
8. Withdrawn	The submission has been withdrawn.

By default, *all* submissions an organization has submitted using DIRECT display in the Submissions List. If you cannot find the submission you are looking for, you may need to select another Status or set the filter to display ALL statuses.

- 4.2.1. To apply a 'Status' filter to the Submission List, navigate to the **<Submissions>** screen, then select the 'Status' drop-down field.

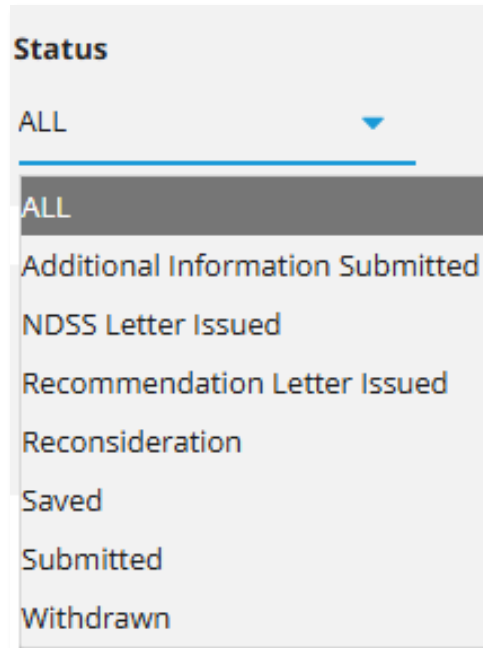
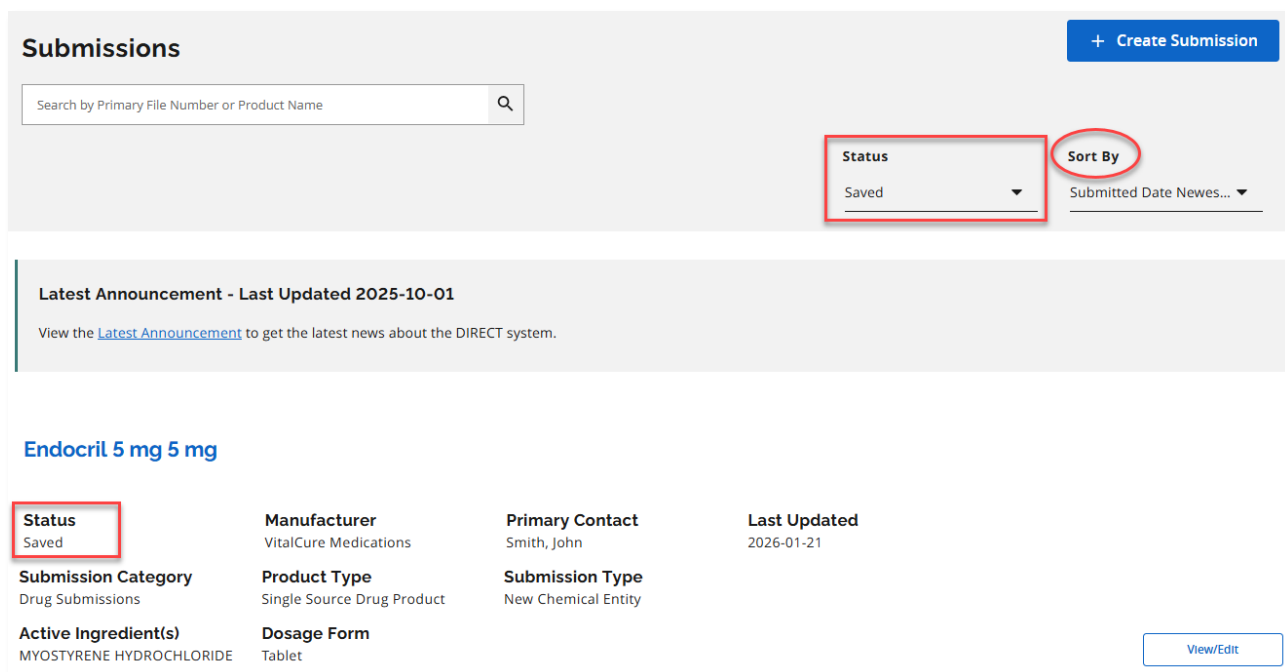


Figure 127 – Screenshot of the Status Filter Drop-down Field

- 4.2.2. Click on a value and DIRECT returns a list of submissions entered by your organization with the set value.



The screenshot shows the 'Submissions' page with a search bar and filters. The 'Status' filter is set to 'Saved' and the 'Sort By' dropdown is set to 'Submitted Date Newest to Oldest'. Below the filters, there is a section for 'Endocril 5 mg 5 mg' with a table of submission details.

Status	Manufacturer	Primary Contact	Last Updated
Saved	VitalCure Medications	Smith, John	2026-01-21

Submission Category	Product Type	Submission Type
Drug Submissions	Single Source Drug Product	New Chemical Entity

Active Ingredient(s)	Dosage Form
MYOSTYRENE HYDROCHLORIDE	Tablet

View/Edit

Figure 128 – Screenshot of the Status Filter Returned Results



Note that in addition to applying a filter by 'Status', all DIRECT users in your organization can sort the Submissions List to display the returned results in different ways. [See Section 4.3](#) for details about how to sort submissions.

4.3. How to Sort Submissions in the Submissions List

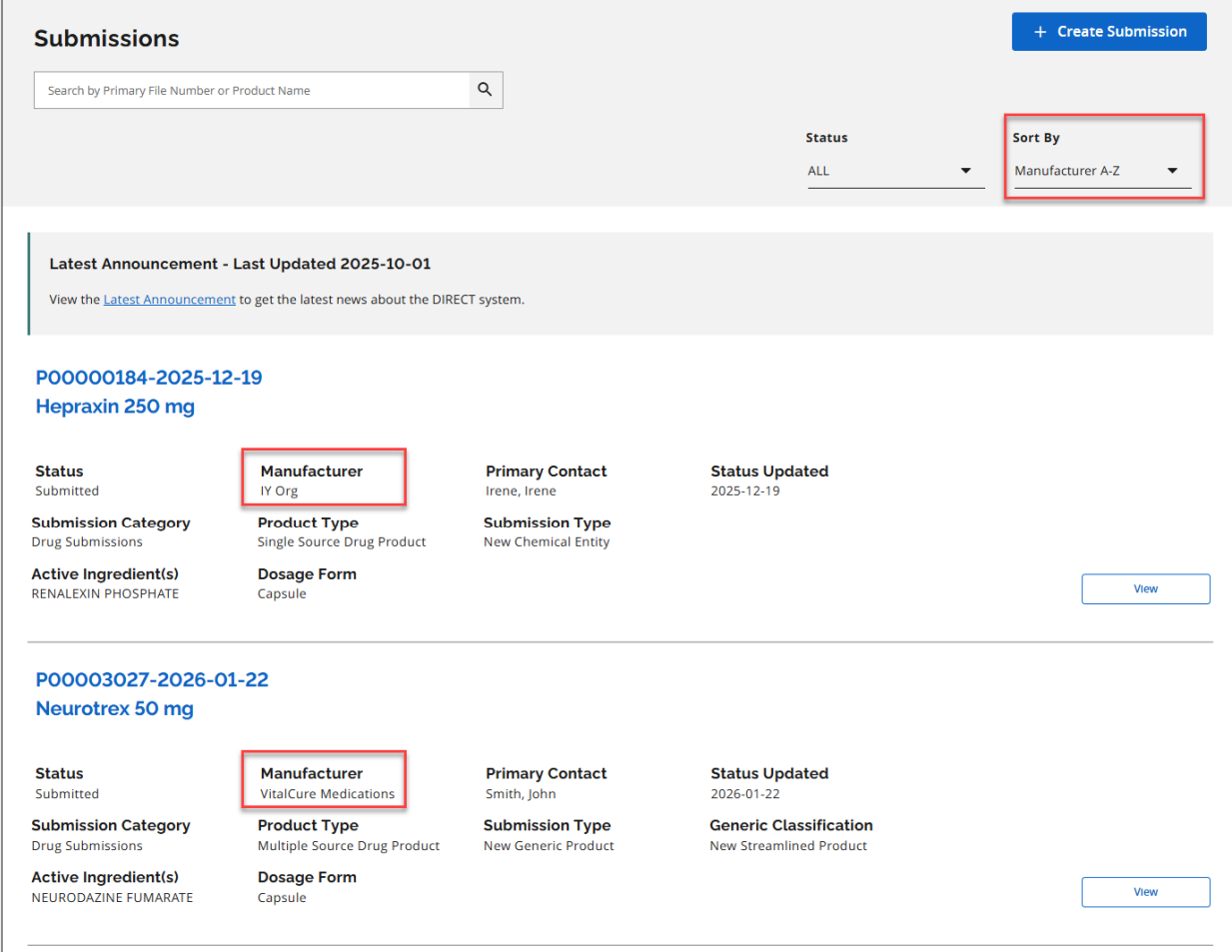
You can sort submissions in the Submissions List in different ways, to display the results for submissions your organization has entered using DIRECT. The default *Sort By* option, *Submitted Date Newest to Oldest*, displays the most recently submitted submissions at the top of the list, with older submissions at the bottom of the list.

Submissions can be sorted in the following ways:

- Submitted Date Newest to Oldest
- Submitted Date Oldest to Newest
- Last Updated Newest to Oldest
- Last Updated Oldest to Newest

- Primary File Number A-Z
- Primary File Number Z-A
- Status A-Z
- Status Z-A
- Manufacturer A-Z (this option is useful for vendors working for multiple manufacturers)
- Manufacturer Z-A (this option is useful for vendors working for multiple manufacturers)

4.3.1. Click on a 'Sort By' drop-down value and DIRECT displays the Submissions List according to the set value.



Submissions + Create Submission

Search by Primary File Number or Product Name

Status: ALL Sort By: Manufacturer A-Z

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P00000184-2025-12-19
Hepraxin 250 mg

Status Submitted	Manufacturer IV Org	Primary Contact Irene, Irene	Status Updated 2025-12-19
Submission Category Drug Submissions	Product Type Single Source Drug Product	Submission Type New Chemical Entity	
Active Ingredient(s) RENALEXIN PHOSPHATE	Dosage Form Capsule		View

P00003027-2026-01-22
Neurotrex 50 mg

Status Submitted	Manufacturer VitalCure Medications	Primary Contact Smith, John	Status Updated 2026-01-22
Submission Category Drug Submissions	Product Type Multiple Source Drug Product	Submission Type New Generic Product	Generic Classification New Streamlined Product
Active Ingredient(s) NEURODAZINE FUMARATE	Dosage Form Capsule		View

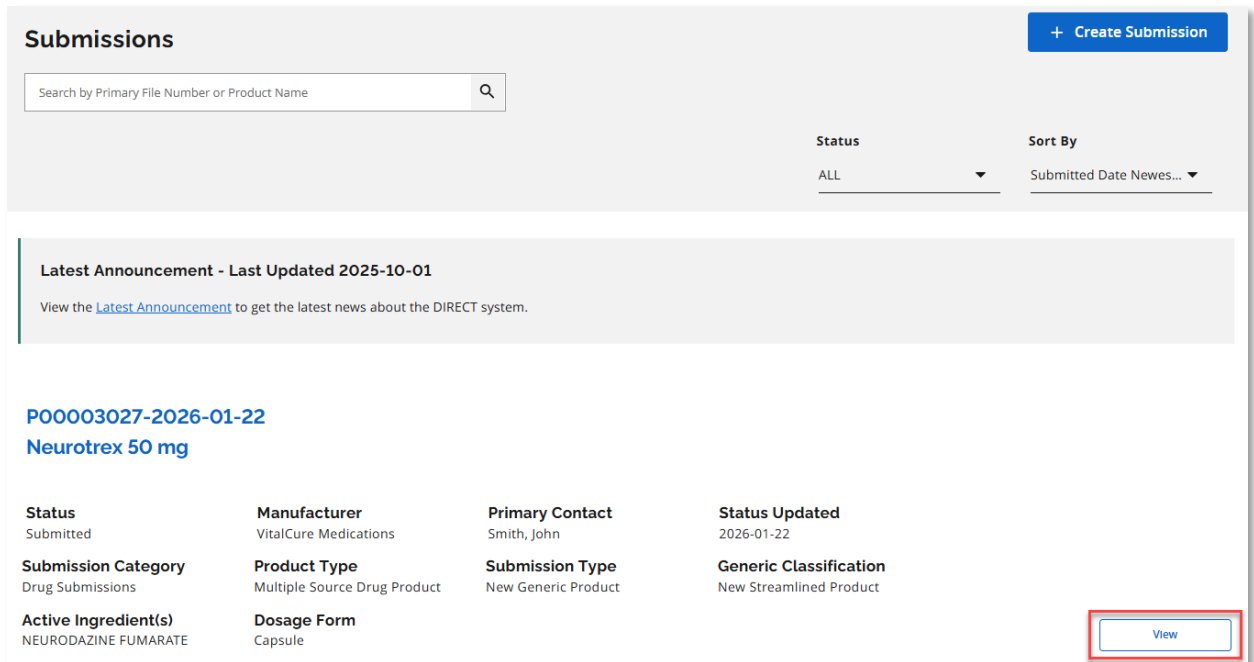
Figure 129 – Screenshot of the Sort by Filter Returned Results

In the above screenshot, the *Sort By* filter value of *Manufacturer A-Z* changes the order of the list of submissions such that the submission at the top comes first, alphabetically, by the manufacturer's name.

4.4. How to View PDF Summary of Submission Data Provided to the Ministry Via DIRECT

Manufacturers can view a summary of all submissions entered using DIRECT, in PDF format.

- 4.4.1. To view a PDF summary of a submission, select the **<View>** button for the submission in the Submissions List.



Submissions [+ Create Submission](#)

Search by Primary File Number or Product Name

Status: ALL Sort By: Submitted Date Newest...

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P00003027-2026-01-22
Neurotrex 50 mg

Status Submitted	Manufacturer VitalCure Medications	Primary Contact Smith, John	Status Updated 2026-01-22
Submission Category Drug Submissions	Product Type Multiple Source Drug Product	Submission Type New Generic Product	Generic Classification New Streamlined Product
Active Ingredient(s) NEURODAZINE FUMARATE	Dosage Form Capsule	View	

Figure 130 – Screenshot of the Submissions List

- 4.4.2. To view a PDF summary of a submission, select the **<View>** button for the submission in the **Submissions List**.

- 4.4.3. The **Submission Details** screen displays. Select the **<Download>** button in the **Correspondence History** section.

P00003027-2026-01-22 Neurotrex 50 mg		
Status Submitted	Submission Category Drug Submissions	Submission Type New Generic Product
Primary Contact Smith, John	Product Type Multiple Source Drug Product	Generic Classification New Streamlined Product

Figure 131 – Screenshot of the Submission Details screen

4.4.4. The **Submission Details** screen displays. Select the **<Download>** button in the **Correspondence History** section.

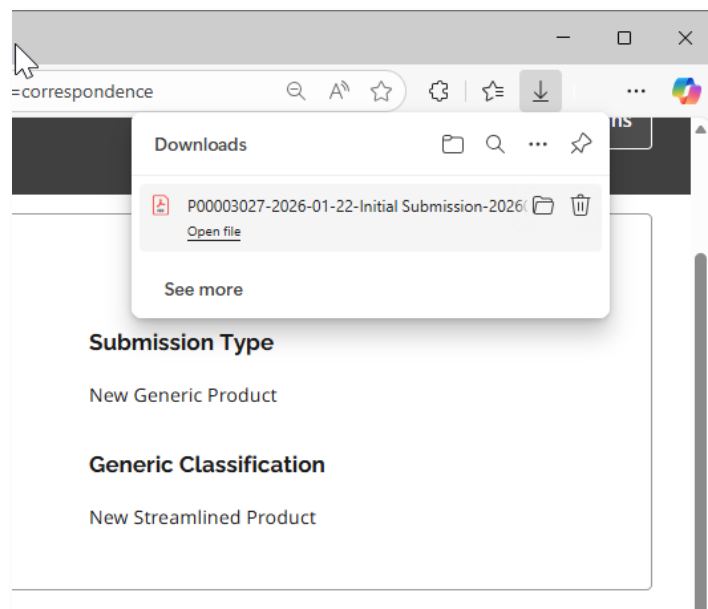


Figure 132 – Screenshot of the File Download

4.4.5. Select the **Open file** link in the **Downloads** folder.

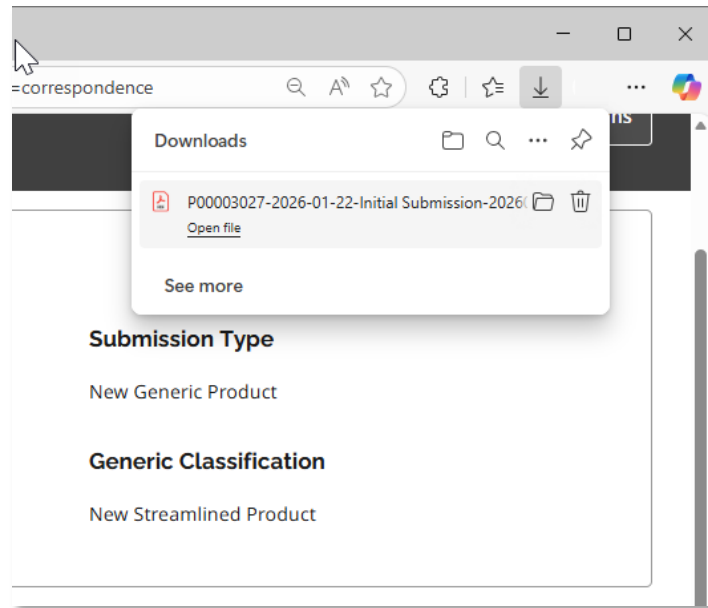


Figure 133 – Screenshot of the File Download

- 4.4.6. The document opens in a separate window or tab (depending on your browser's settings) and provides summary of all information provided to the ministry for the submission, in a read-only PDF document.

Last Updated: 2026-01-22 14:07:34

P00003027-2026-01-22

Neurotrex 50 mg

Submission Category	Submission Type
Drug Submissions	New Generic Product

Product Type

Multiple Source Drug Product

Manufacturer Information

VitalCure Medications

Address
500 Main Street, Toronto, Ontario, Canada

Primary Contact Information

Select a Primary Contact for the Submission

Smith, John
VitalCure Medications

Job Title
Director

Email
john@vitalcure.ca

Product Details

Product Name
Neurotrex

Active Ingredient(s)
NEURODAZINE FUMARATE

Identifier Type

Page 1 of 5

Figure 134 – Screenshot of the PDF Submission Summary Document

Appendix A – How to Get Help

Enrolment and Business-Related Questions about the Portal:

- Contact the DIRECT team at: DIRECT@ontario.ca

Technical Issues or Questions:

- Call 'Inquiry Services' 1-800-262-6524, after the language prompts, press 2, then 3, or email SSContactCentre.MOH@ontario.ca
- Monday – Friday 8 a.m. – 5 p.m.