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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Ontario

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    - Withdrawn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.

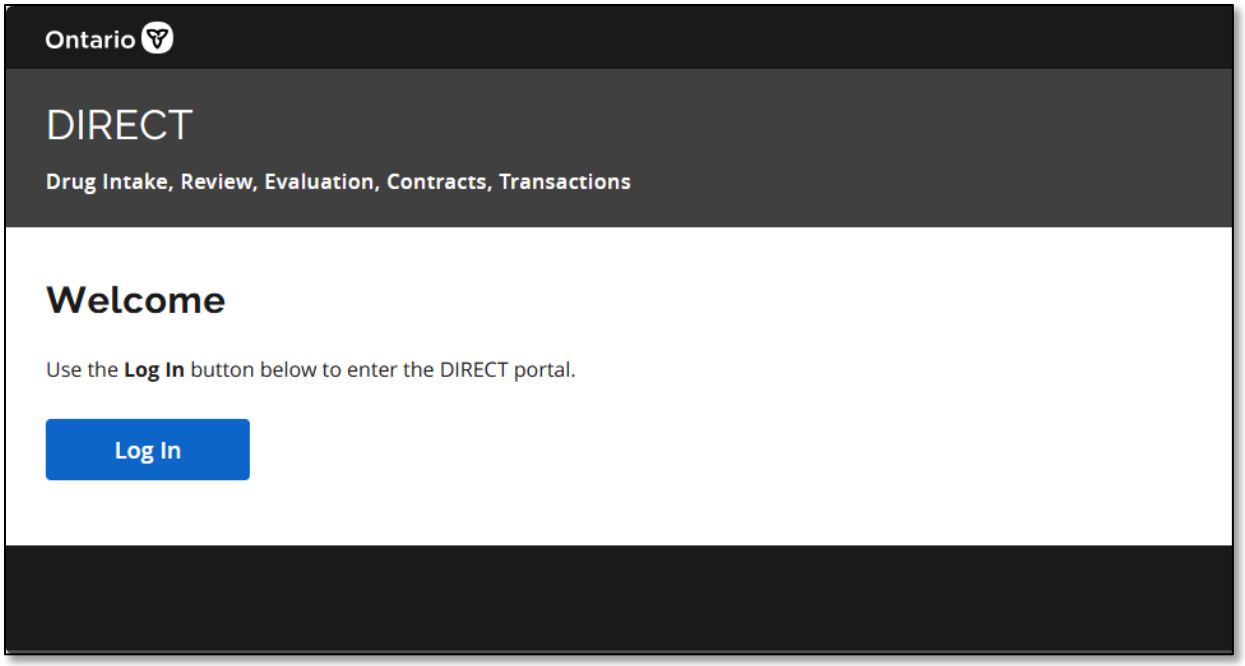


Figure 1 - Image of the DIRECT Log In Button on the Ministry's DIRECT Website

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

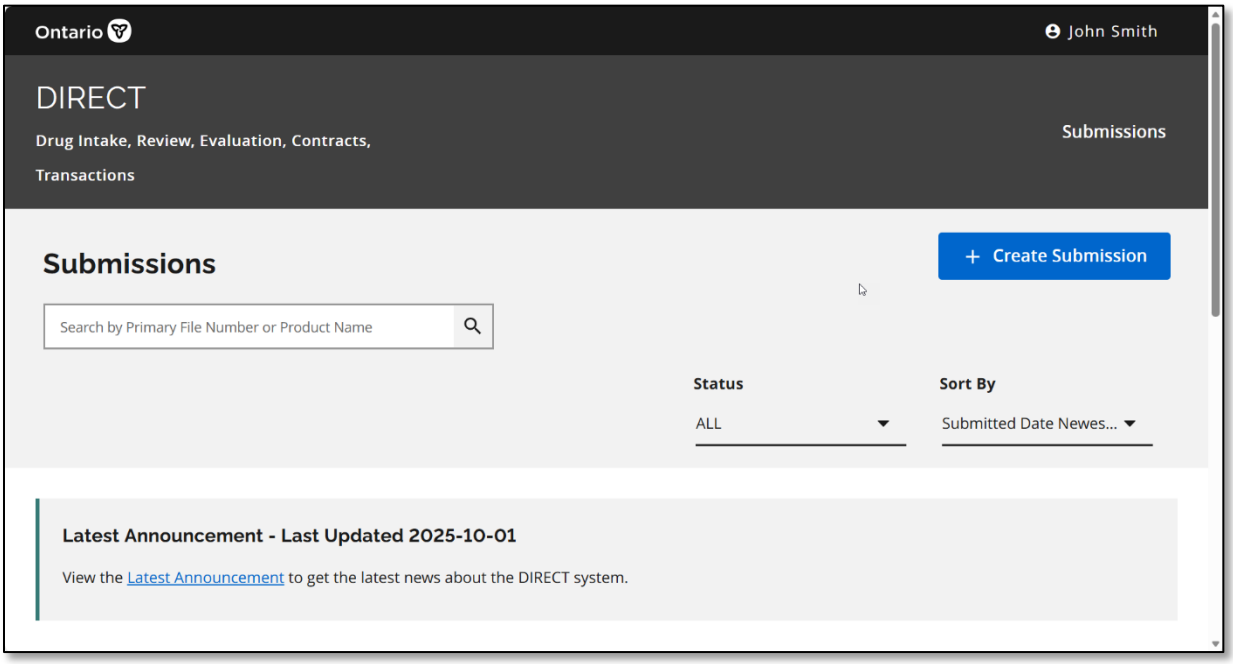


Figure 2 - Image of the Submissions Screen

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.

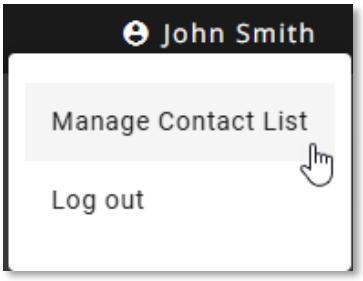


Figure 3 – Screenshot of the Manage Contact List Link

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

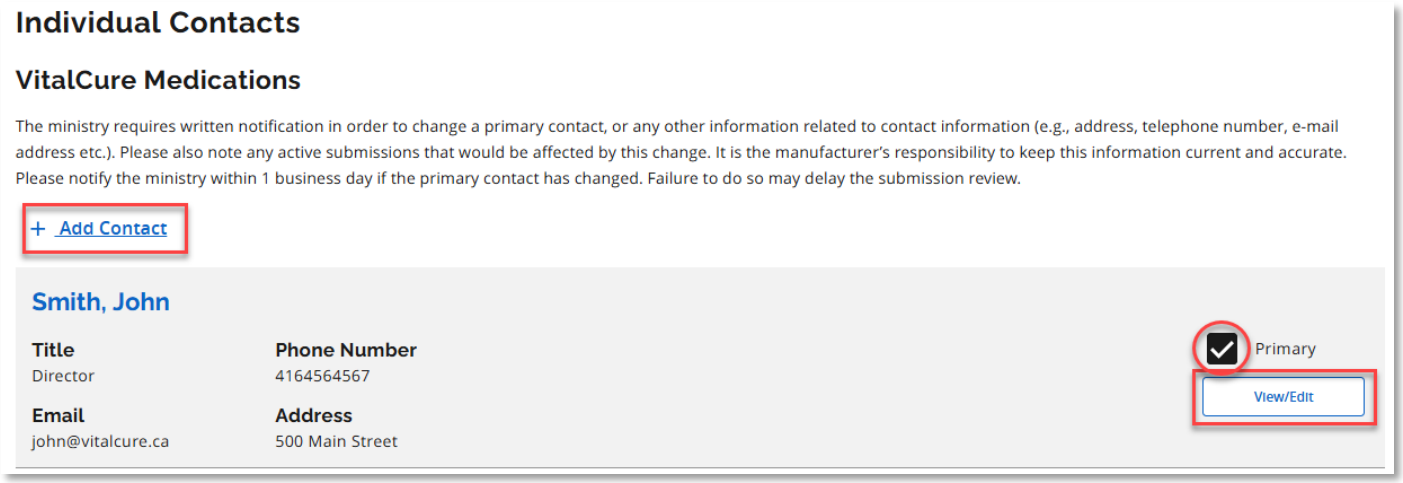


Figure 4 – Screenshot of the Individual Contacts List

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.

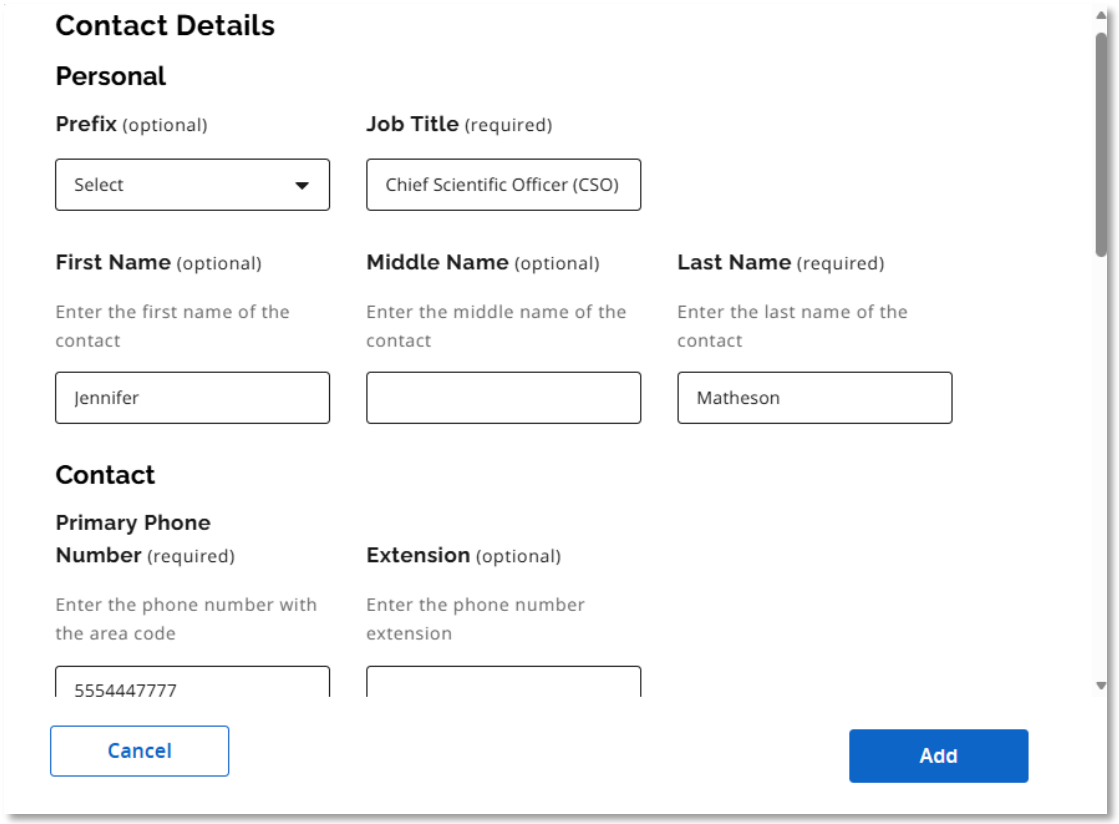


Figure 5 – Screenshot of the Contact Details Pop-up Window

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

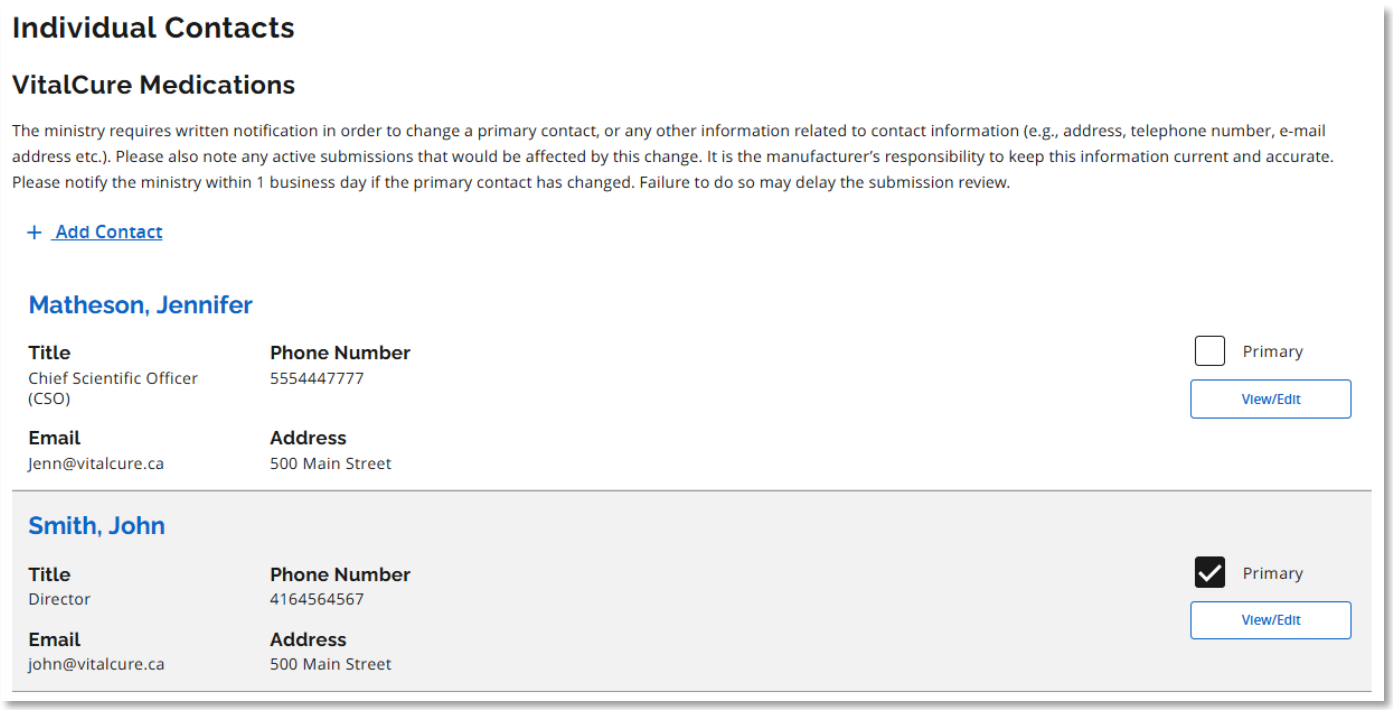


Figure 6 – Screenshot of the Individual Contacts screen

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.

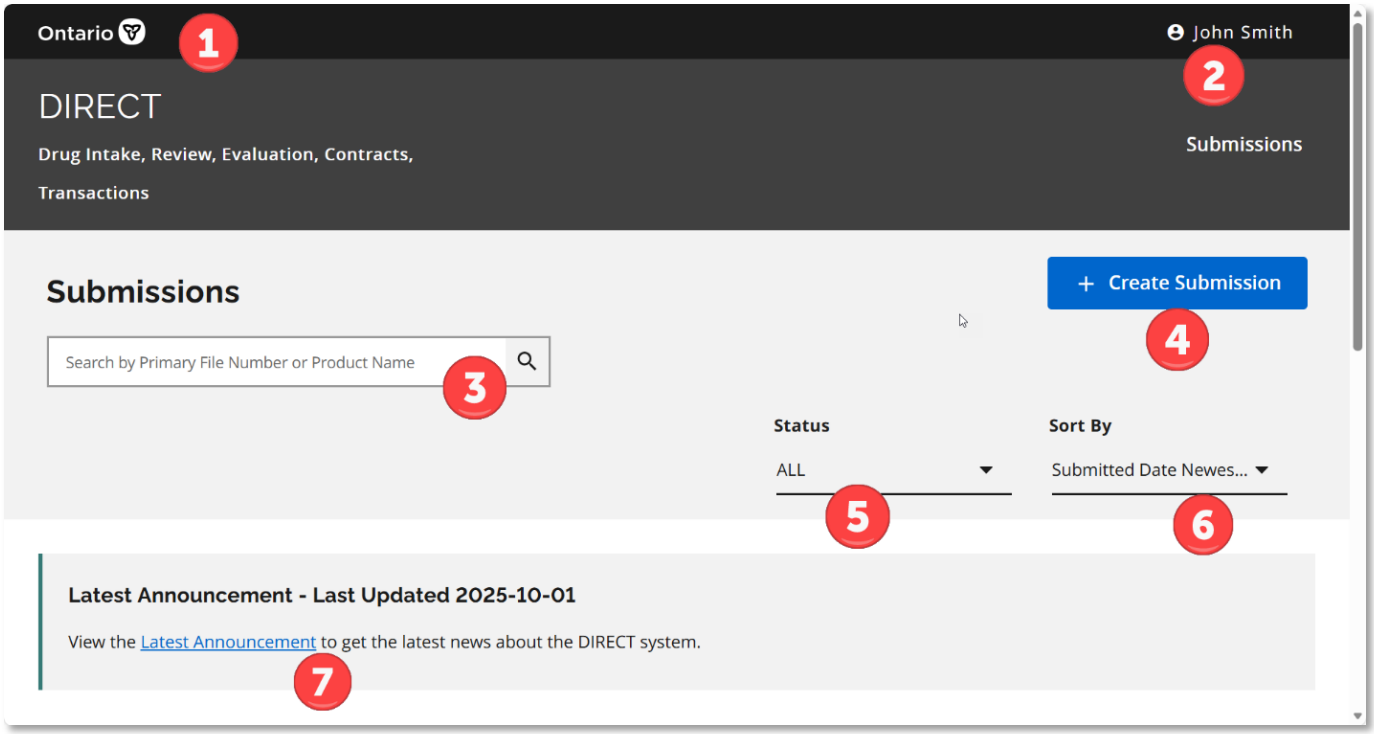


Figure 7 - Image of the Submissions Screen

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:

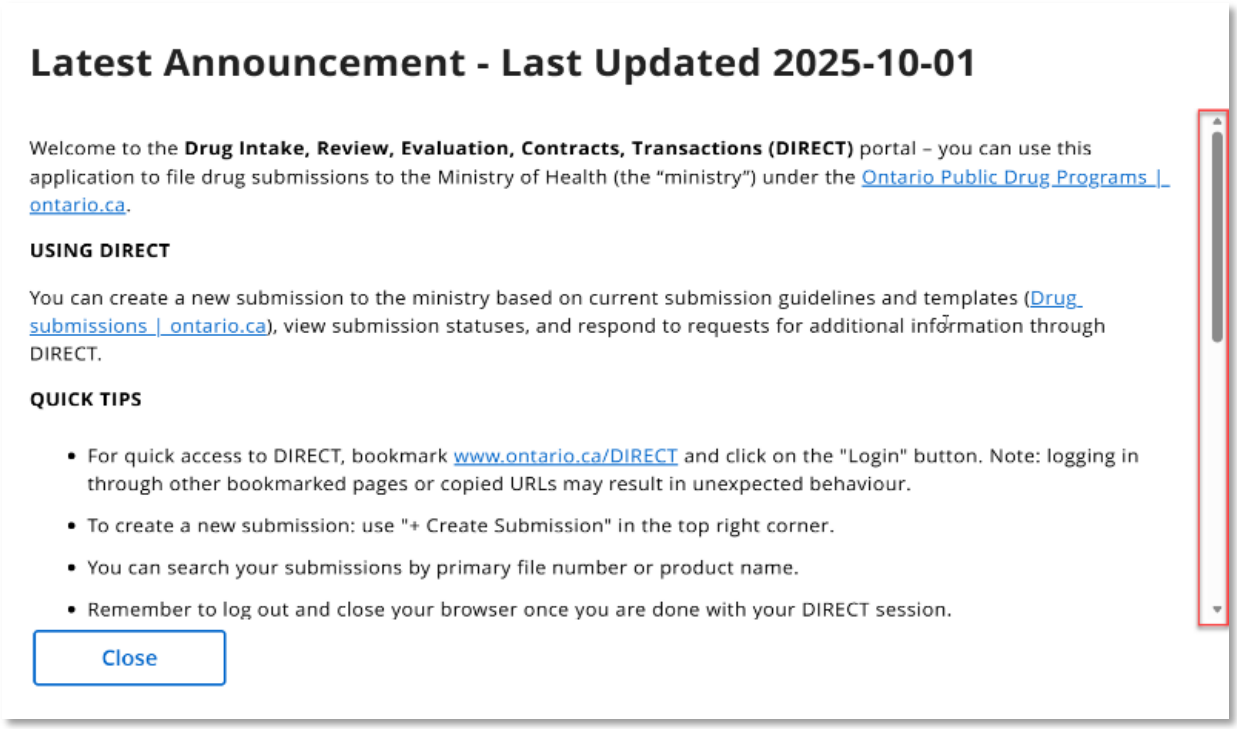


Figure 8 – Image of the Latest Announcement Section

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.

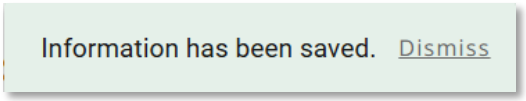


Figure 9 - Image of the Information Saved Message

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

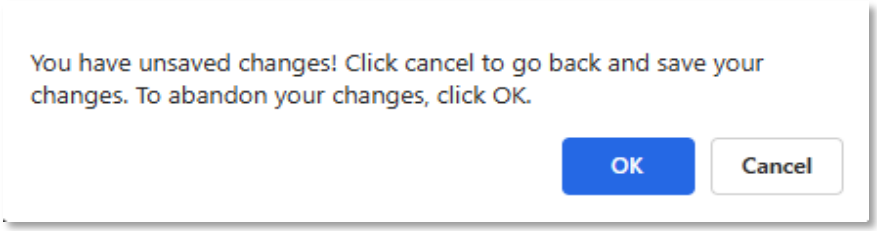


Figure 10 - Image of the Unsaved Changes Message

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.

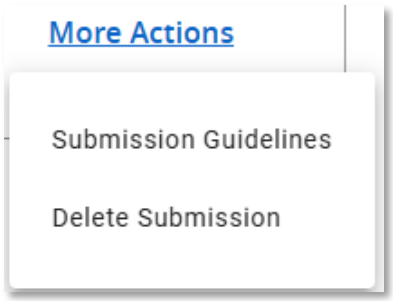


Figure 11 - Image of the More Actions Link

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:

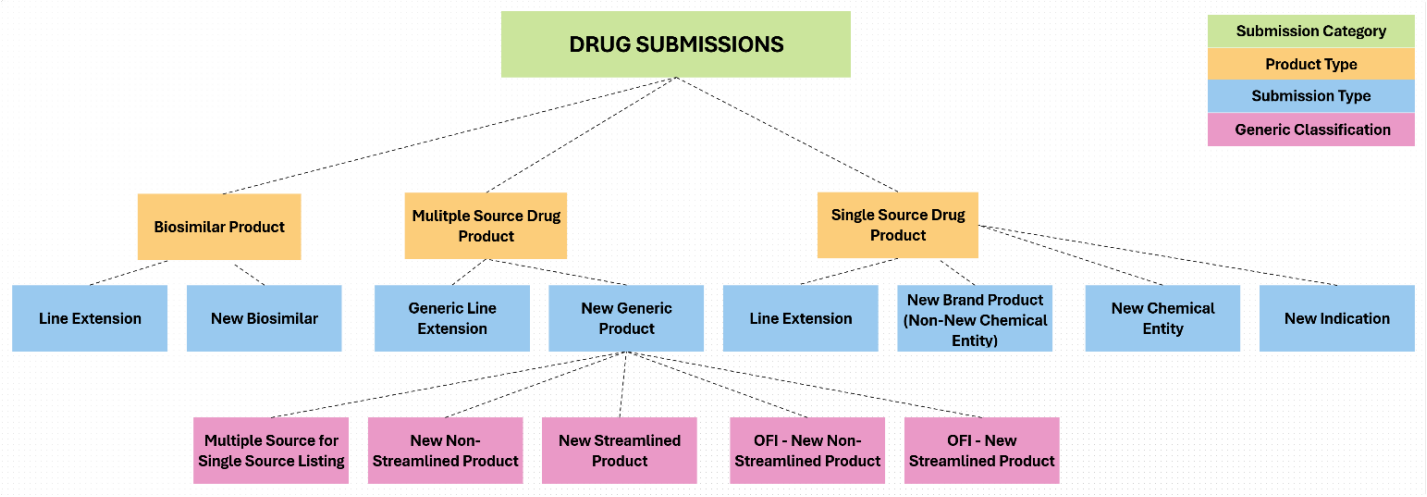


Figure 12 – Diagram of Options for Drug Submissions

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

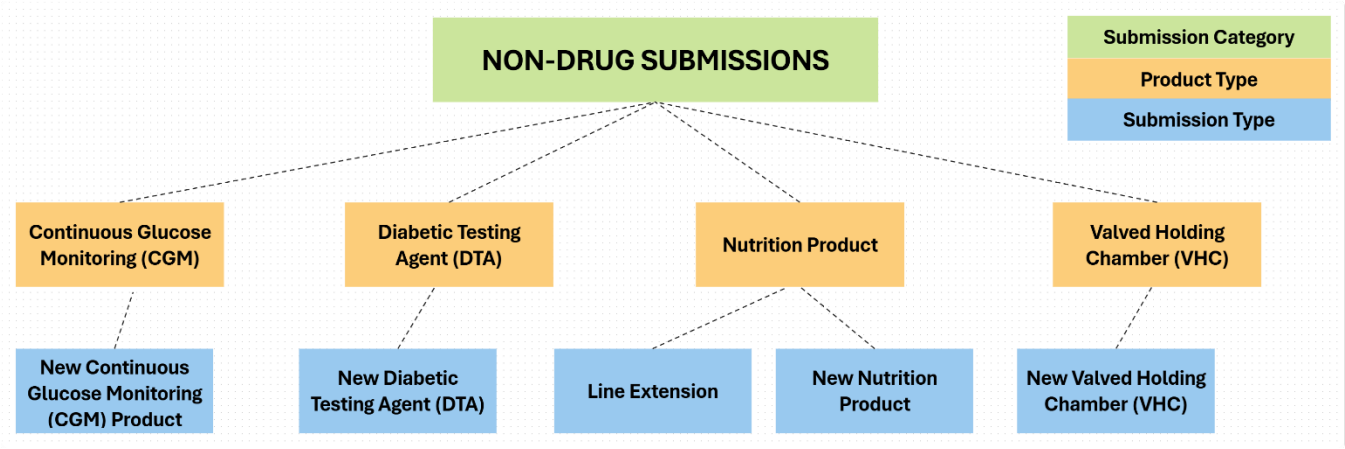


Figure 13 – Diagram of Options for Non-Drug Submissions

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

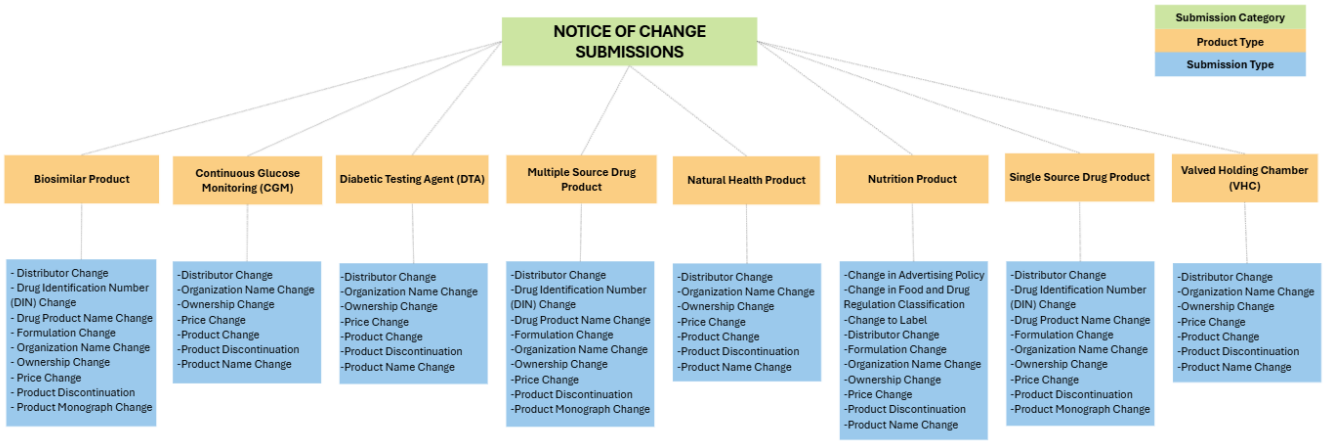


Figure 14 – Diagram of Options for Notice of Change Submissions

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.

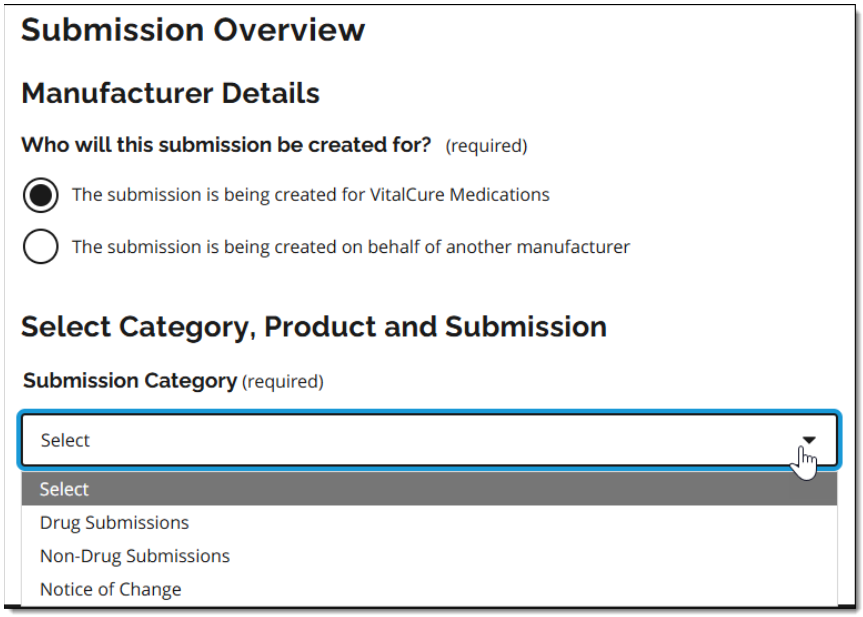


Figure 15 – Screenshot of the Submission Overview screen

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'*.

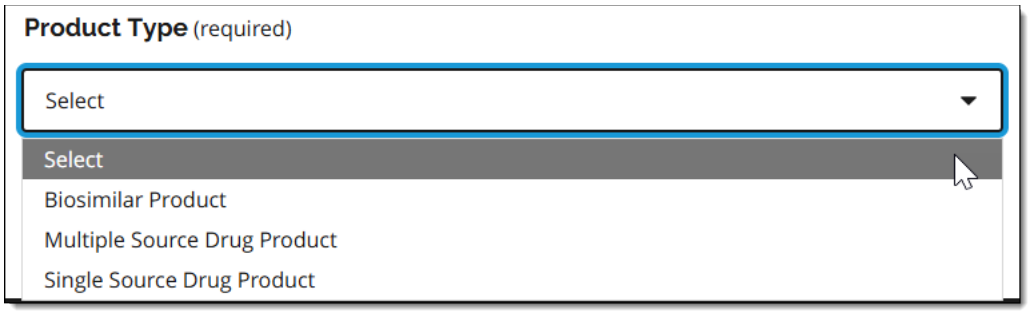


Figure 16 – Screenshot of the Product Type drop-down field

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.)

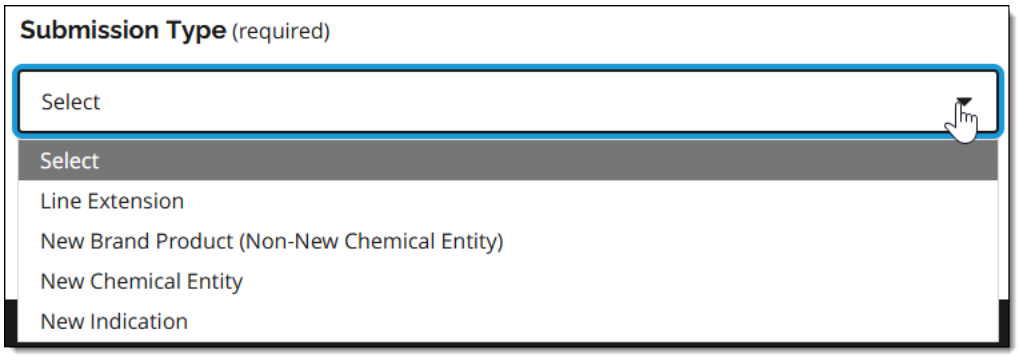


Figure 17 – Screenshot of the Submission Type drop-down field

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.

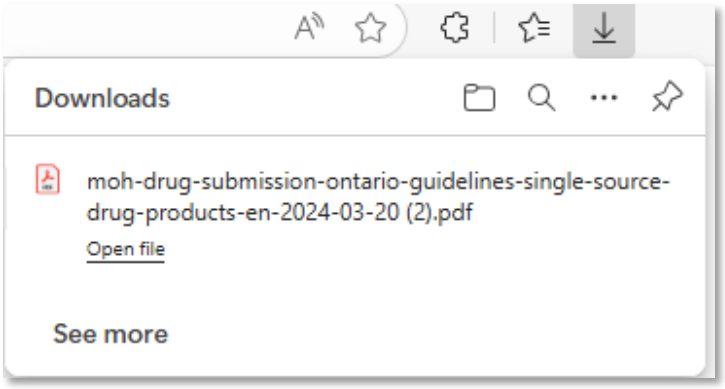


Figure 18 – Screenshot of a Downloaded Guidelines document as a PDF

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.

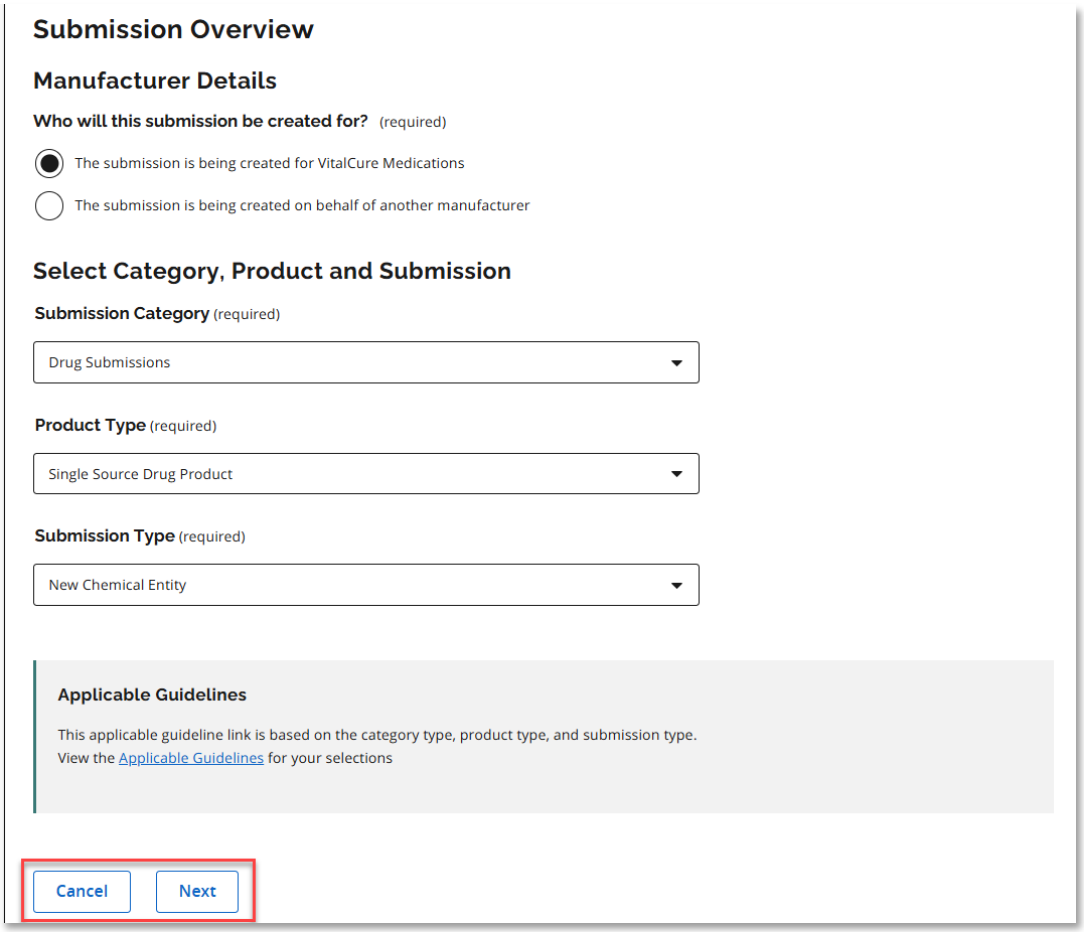


Figure 19 – Screenshot of the Submission Overview screen

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.

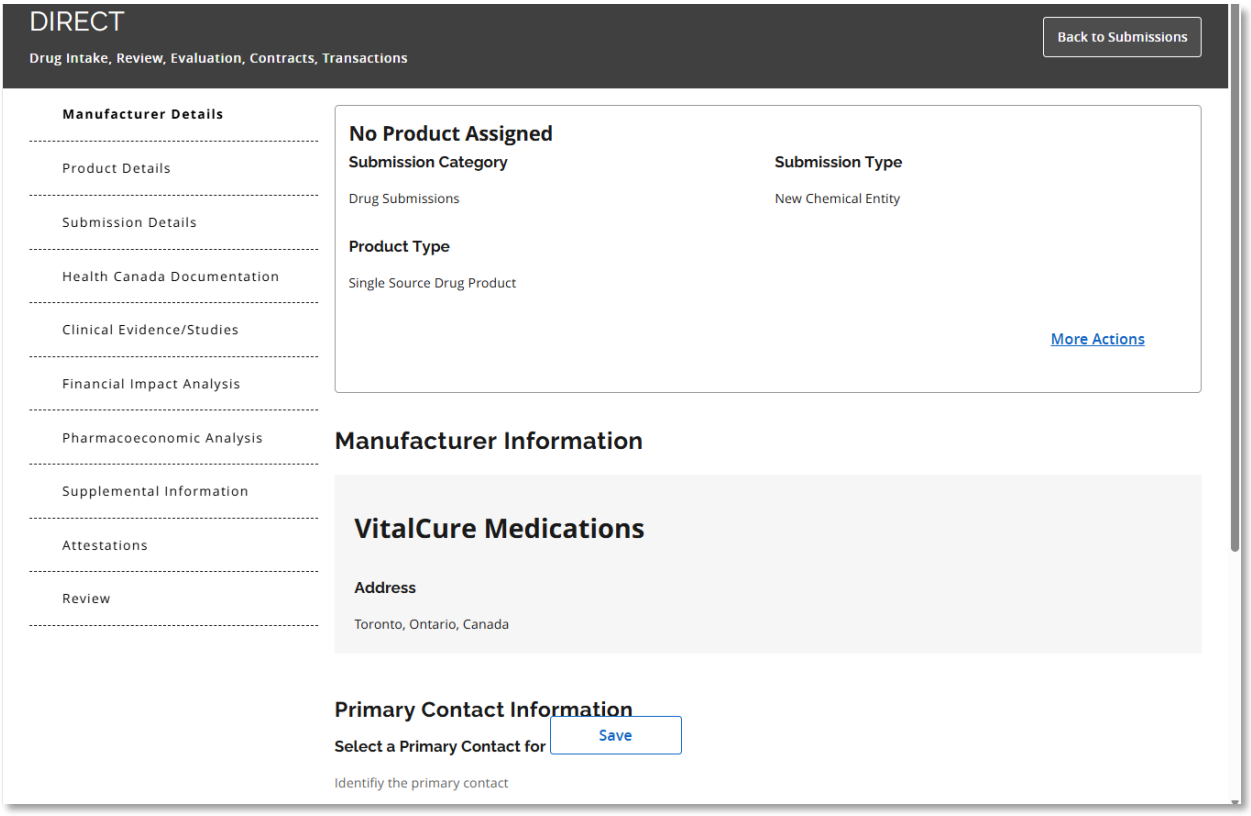


Figure 20 – Screenshot of the Manufacturer Details screen

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.

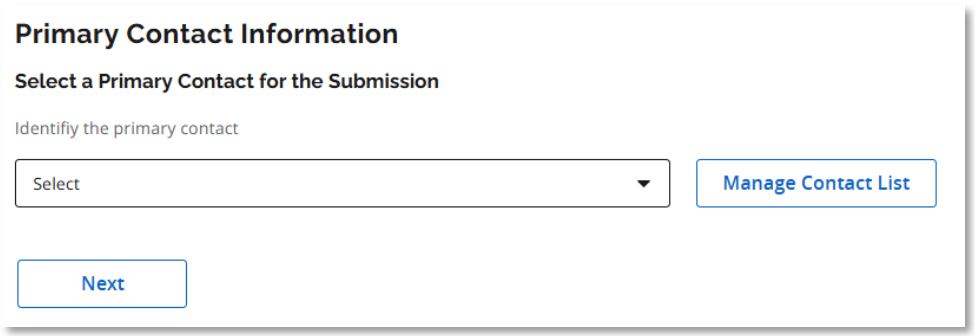


Figure 21 – Screenshot of the Primary Contact Information section

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.

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.

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.

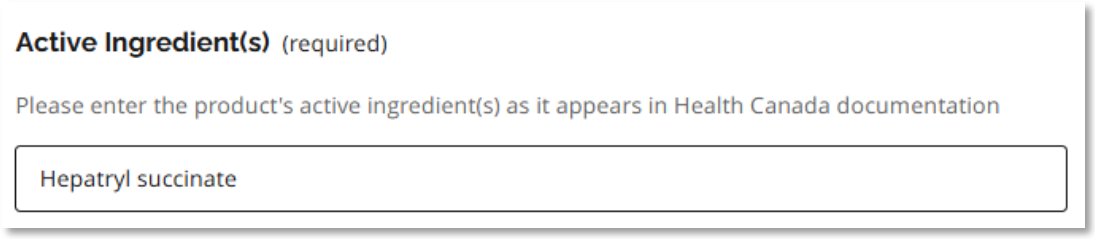


Figure 24 – Screenshot of the Active Ingredient(s) field on the Product Details screen

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.)

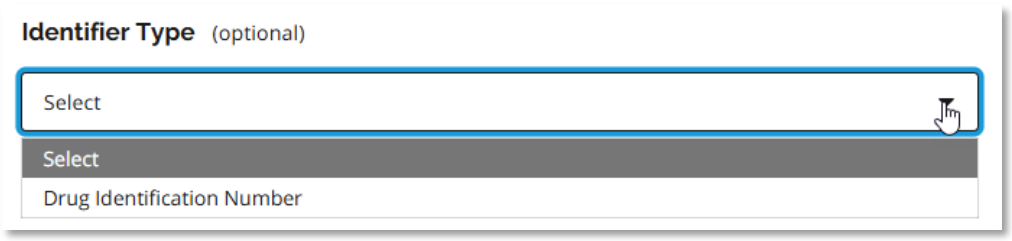


Figure 25 – Screenshot of the Identifier Type drop-down field on the Product Details screen

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.

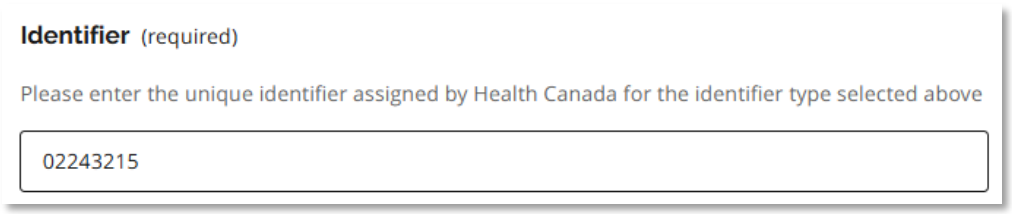


Figure 26 – Screenshot of the Identifier field on the Product Details screen

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).

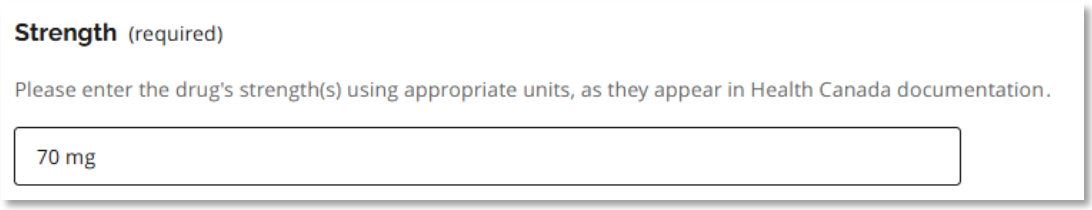


Figure 28 – Screenshot of the Strength field on the Product Details screen

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.

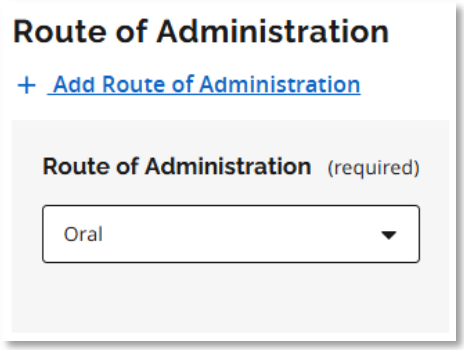


Figure 29 – Screenshot of the Route of Administration drop-down field on the Product Details screen

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'.

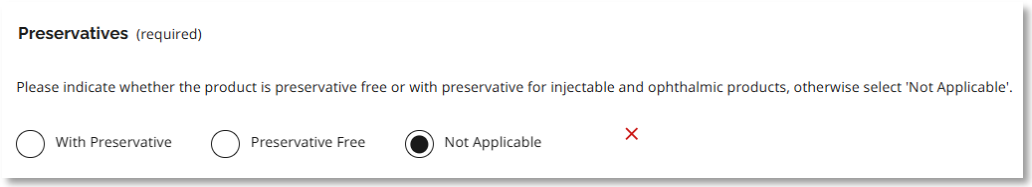


Figure 30 – Screenshot of the Preservative field on the Product Details screen

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.

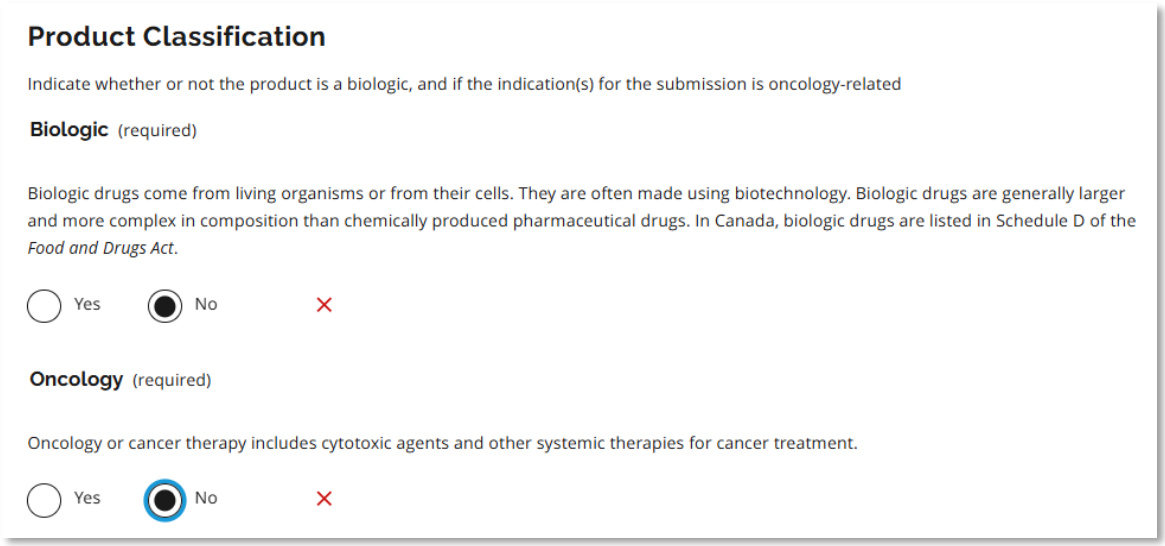


Figure 31 – Screenshot of the Product Classification section on the Product Details screen

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.

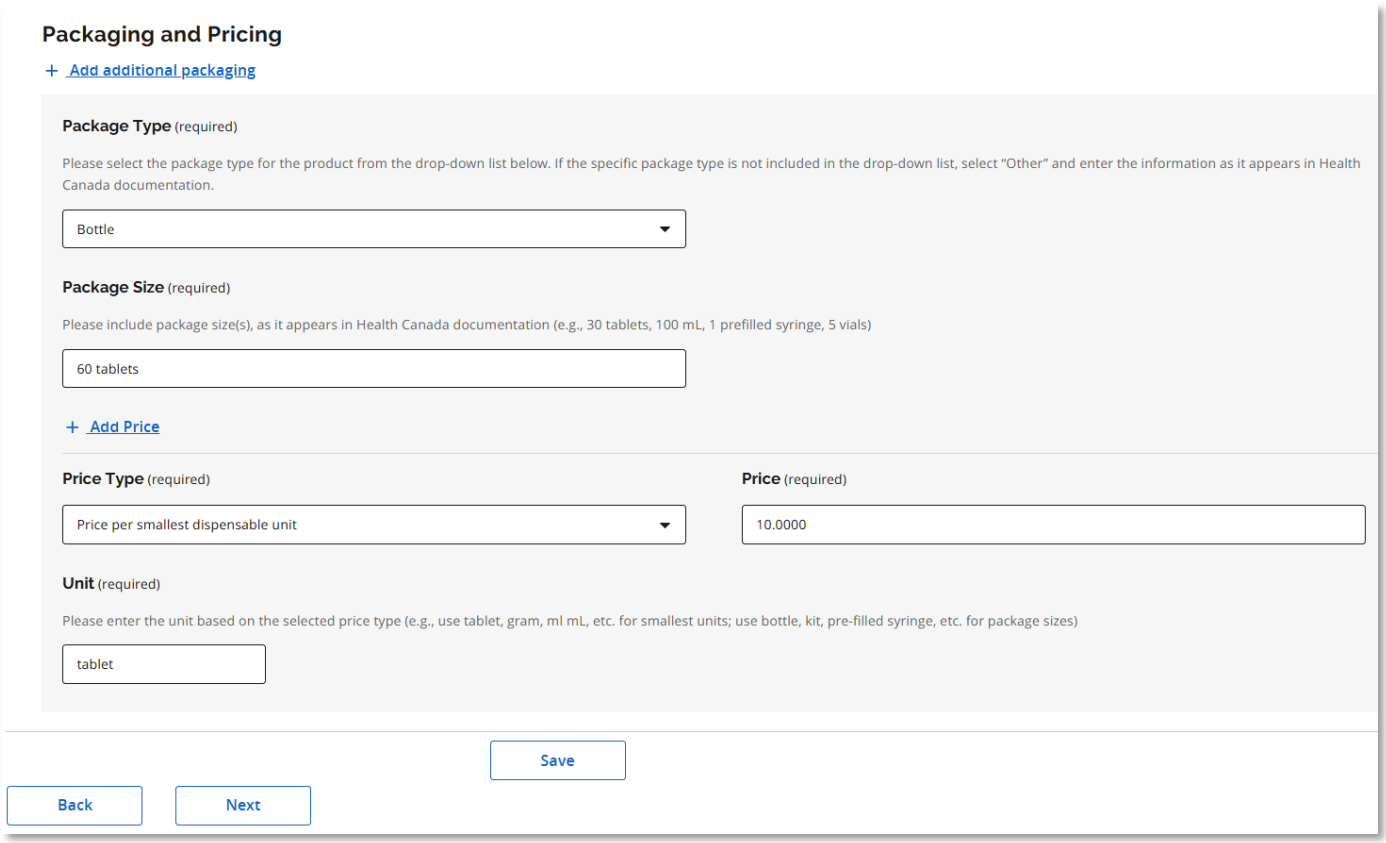


Figure 32 – Screenshot of the Product Classification section on the Product Details screen

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.

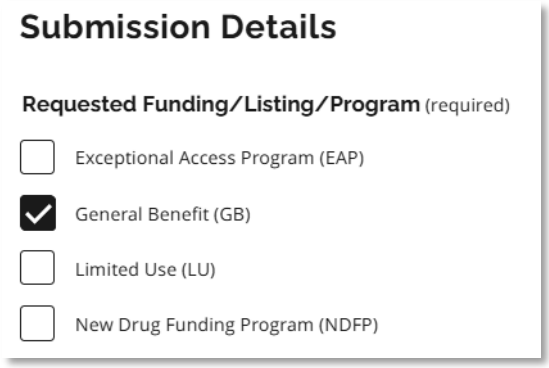


Figure 33 – Screenshot of the Requested Funding/Listing/Program section

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.

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.

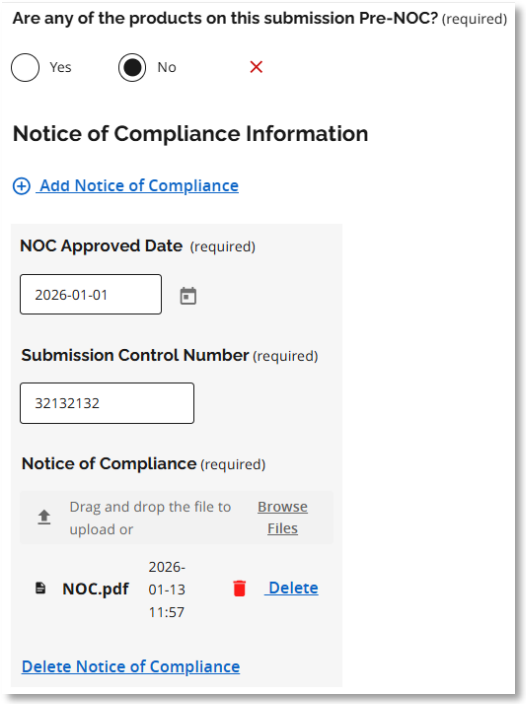


Figure 35 – Screenshot of the Notice of Compliance section

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.

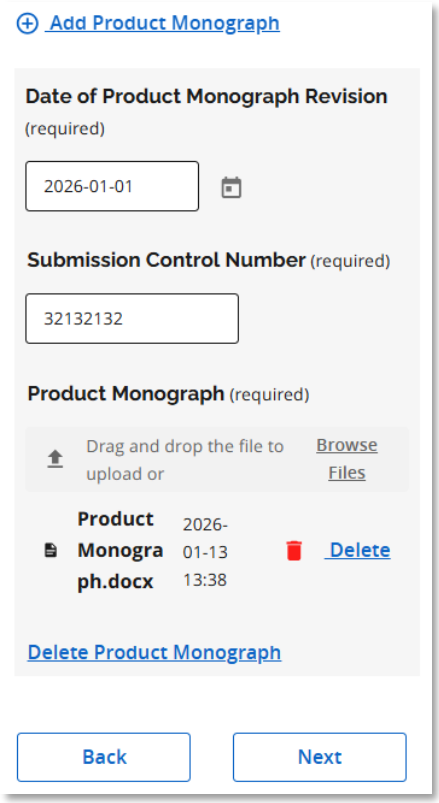


Figure 36 – Screenshot of the Product Monograph section

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.

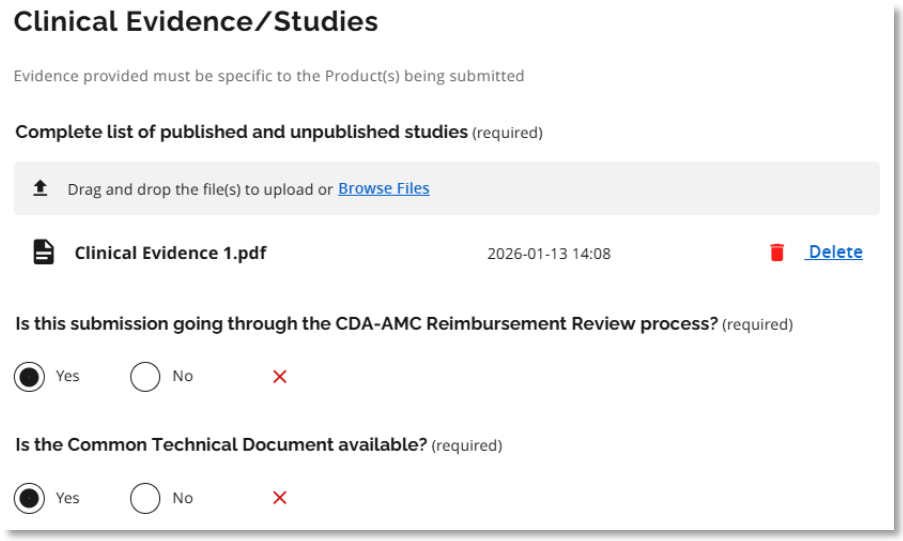


Figure 37 – Screenshot of the Clinical Evidence / Studies section

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.

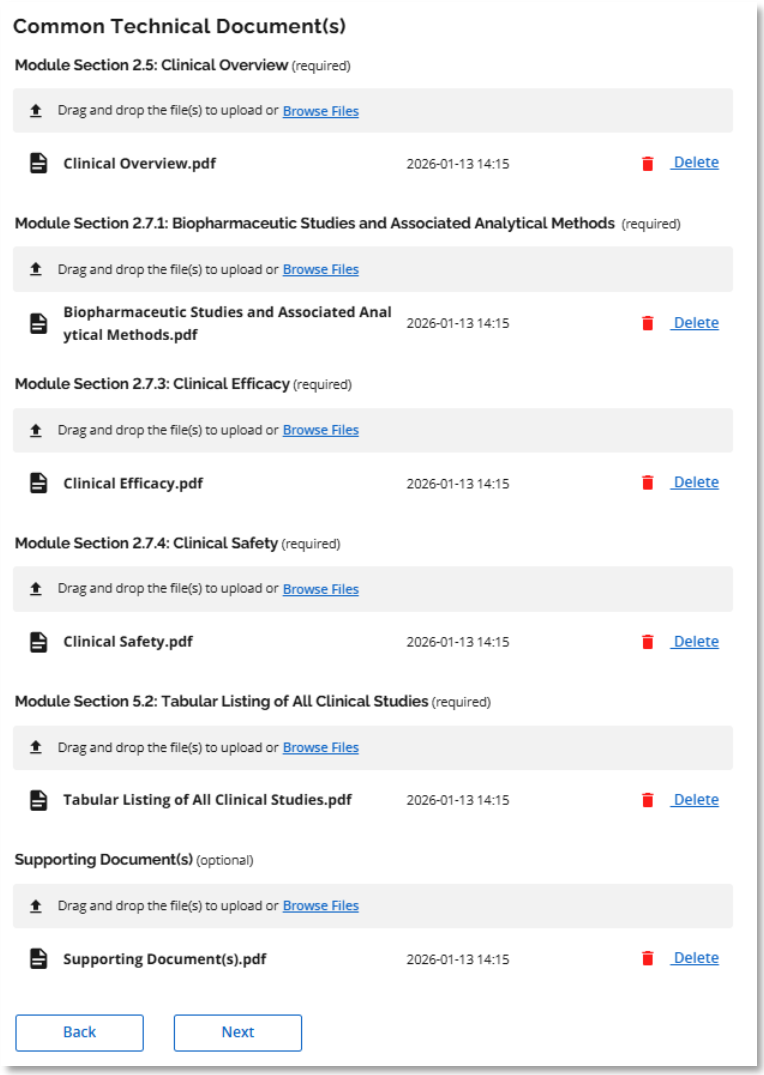


Figure 38 – Screenshot of the Common Technical Document(s) section

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.

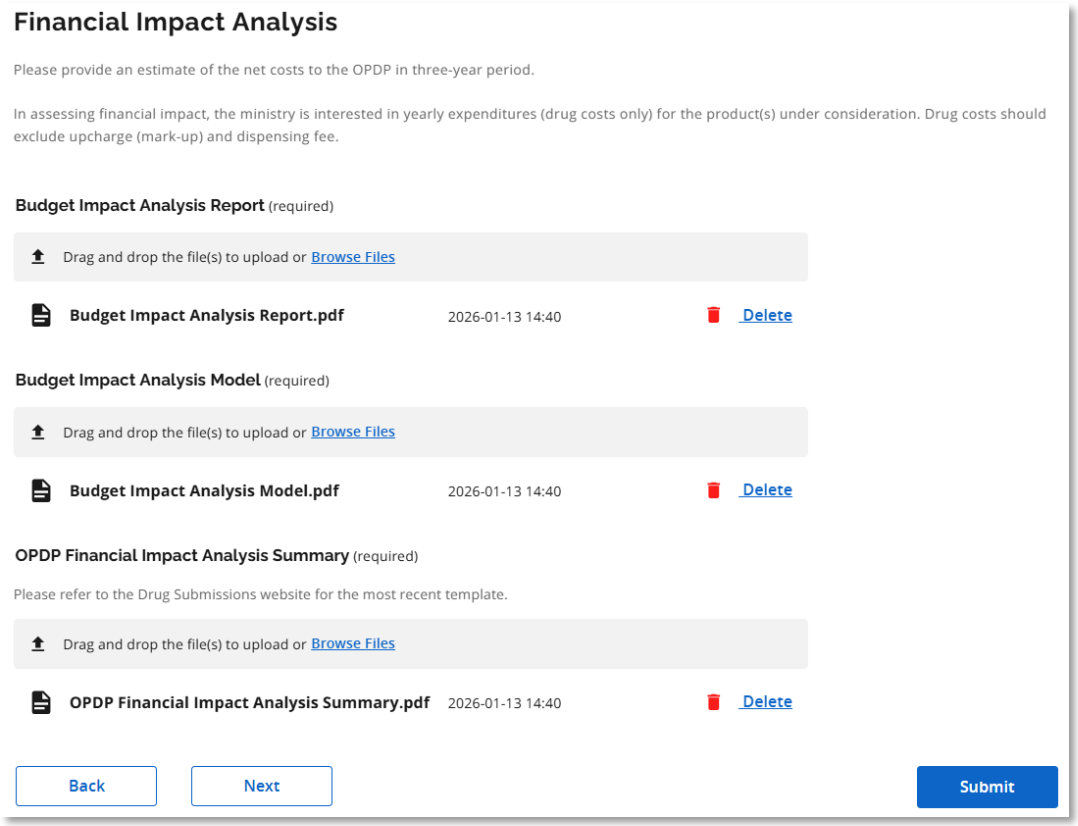


Figure 39 – Screenshot of the Financial Impact Analysis section

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.

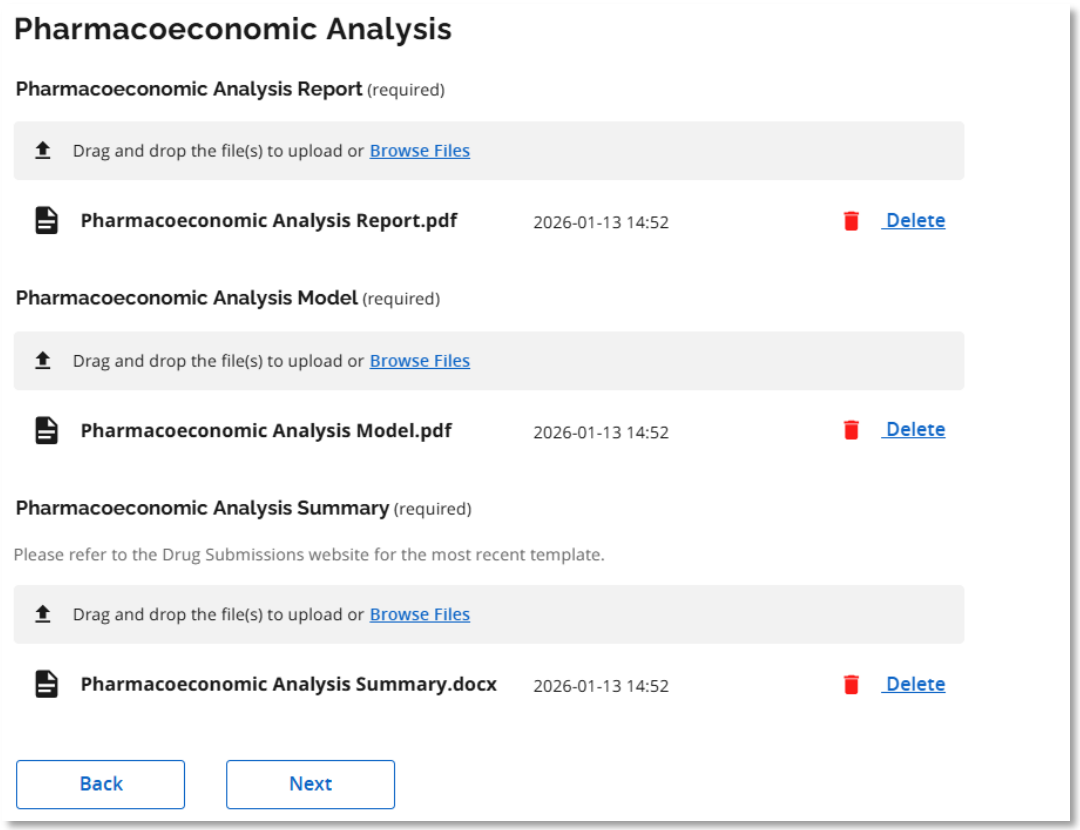


Figure 40 – Screenshot of the Pharmacoeconomic Analysis section

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).

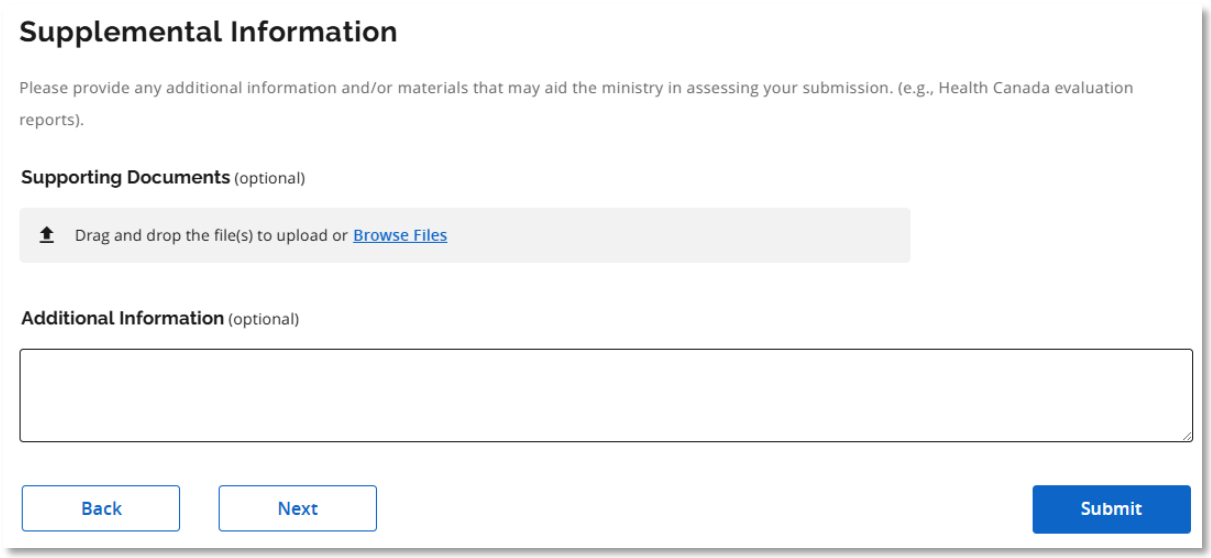


Figure 41 – Screenshot of the Supplemental Information screen

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.

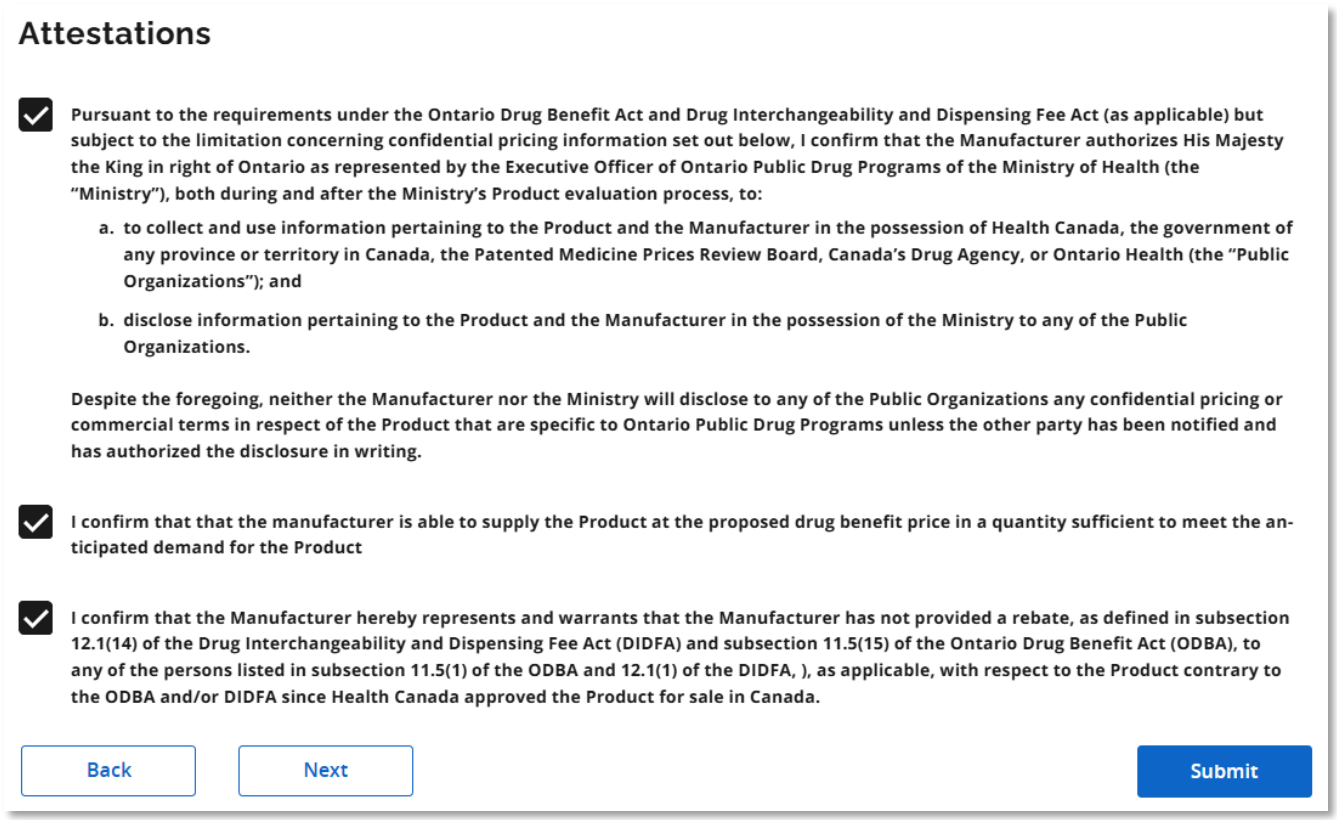


Figure 42 – Screenshot of the Attestations screen

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.

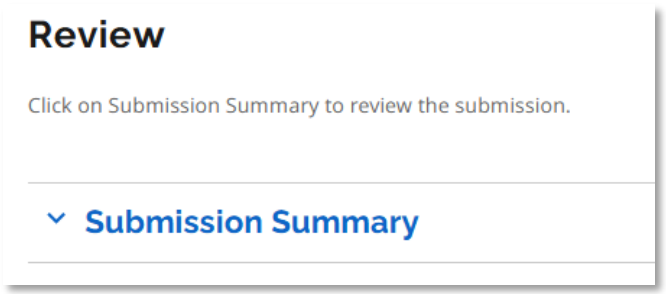


Figure 43 – Screenshot of the Submission Summary Link on the Review screen

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.

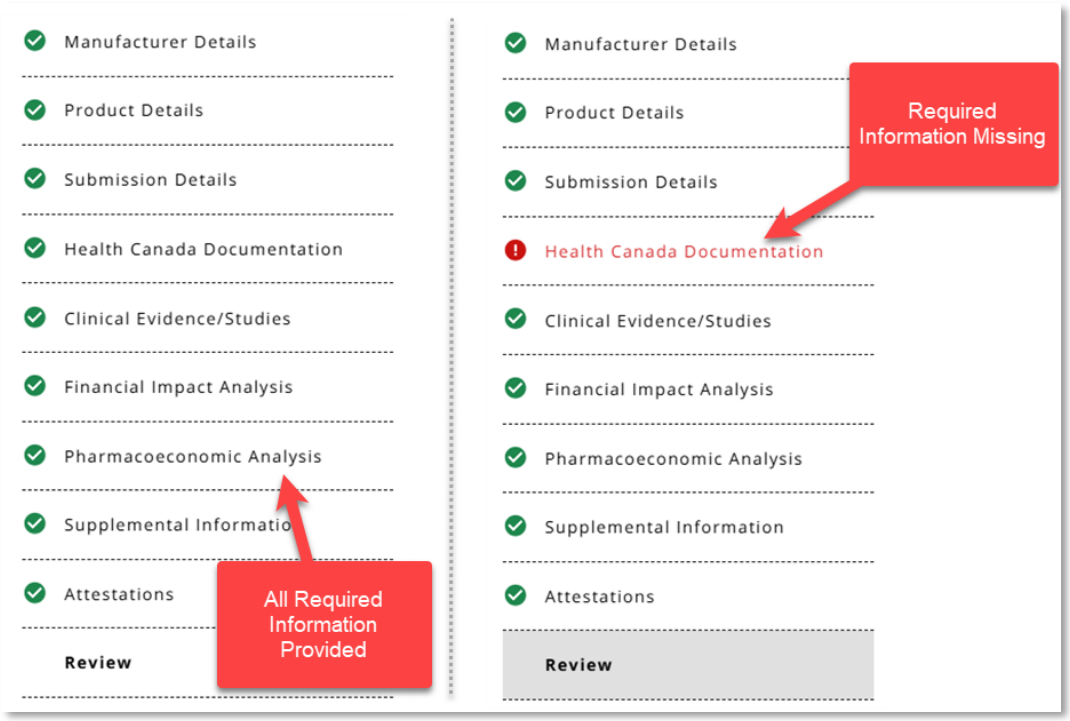


Figure 44 – Screenshot of the Left Menu Shown with All Required Information Provided (Left) and Required Information Missing (Right)

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.

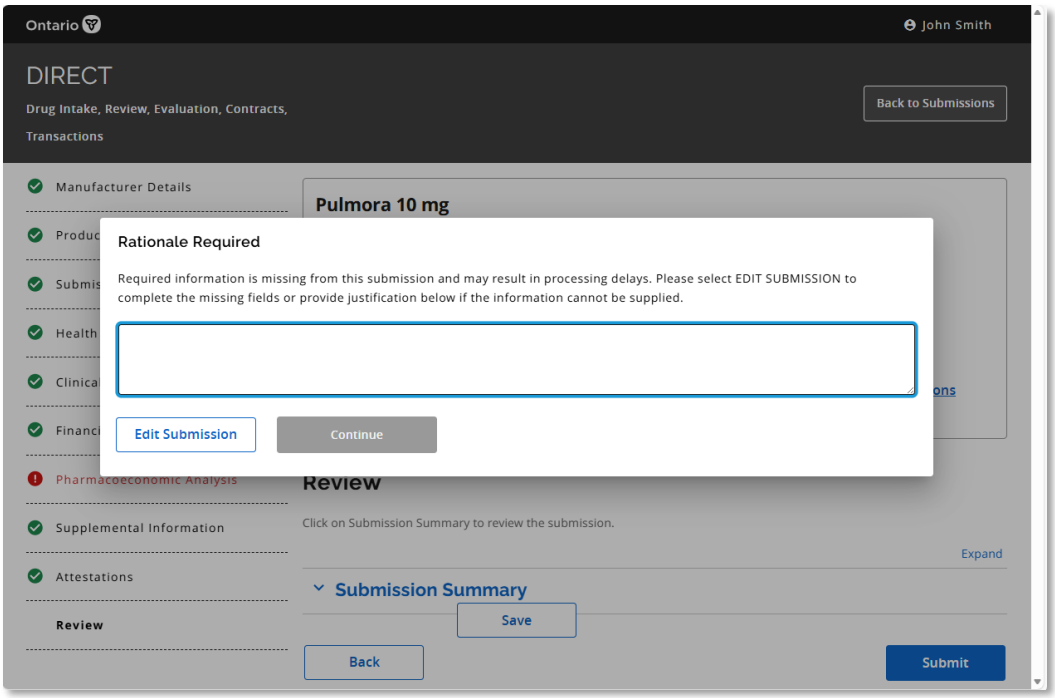


Figure 45 – Screenshot of the Rationale Required Window

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.

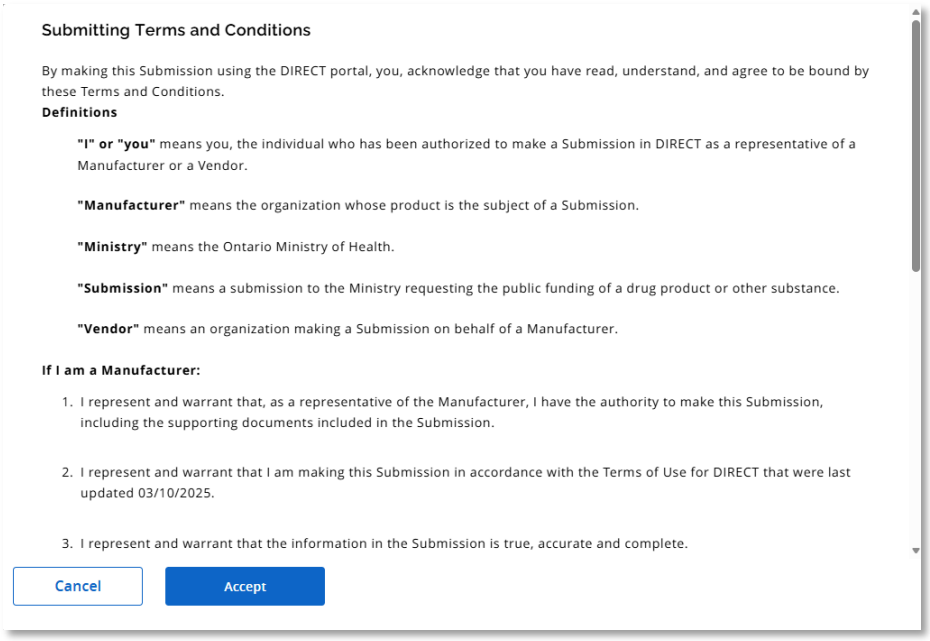


Figure 46 – Screenshot of the Submitting Terms and Conditions

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

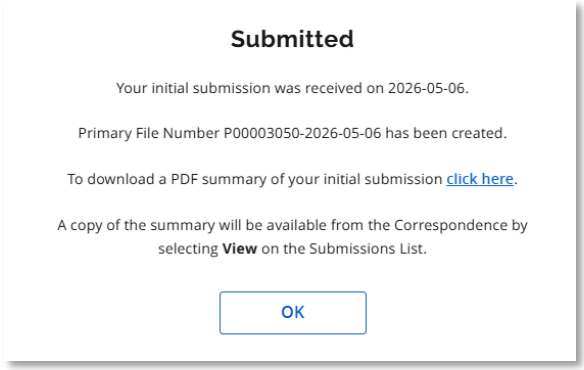


Figure 47 – Screenshot of the Submitted Message

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'.

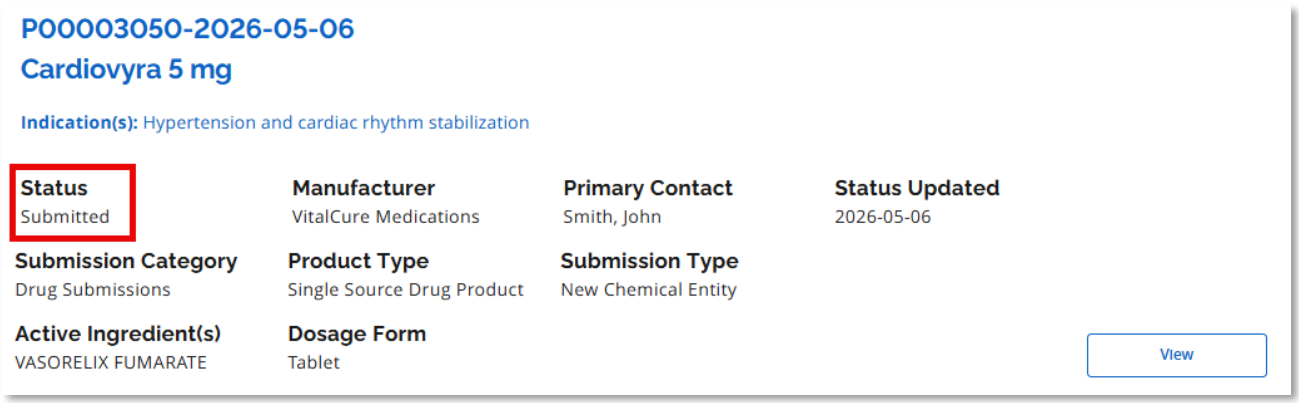


Figure 48 – Screenshot of the submission with a status of submitted in the Submission List

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'*.

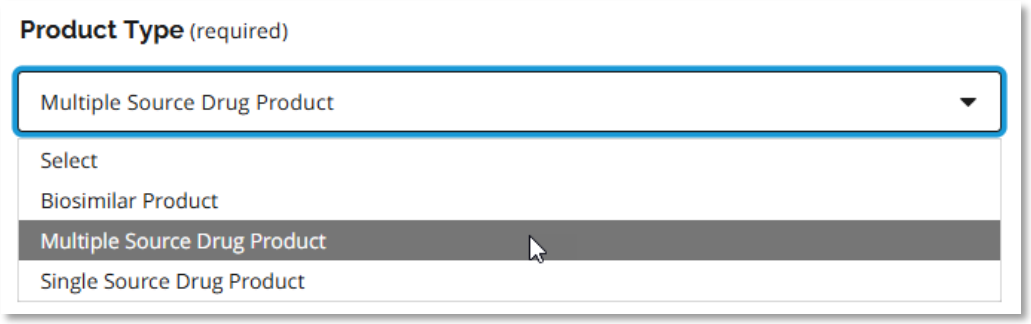


Figure 49 – Screenshot of the Product Type drop-down field

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.)

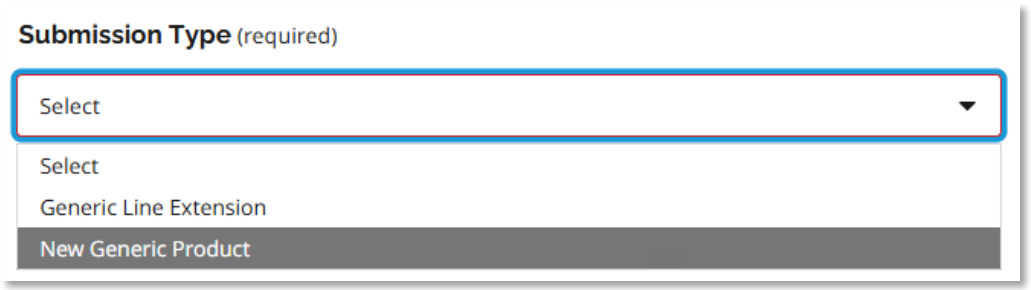


Figure 50 – Screenshot of the Submission Type drop-down field

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.)

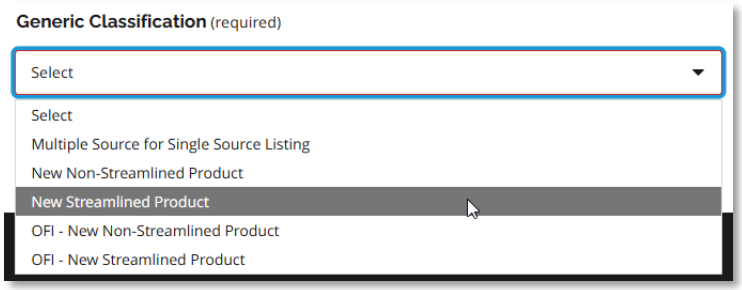


Figure 51 – Screenshot of the Submission Type drop-down field

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.

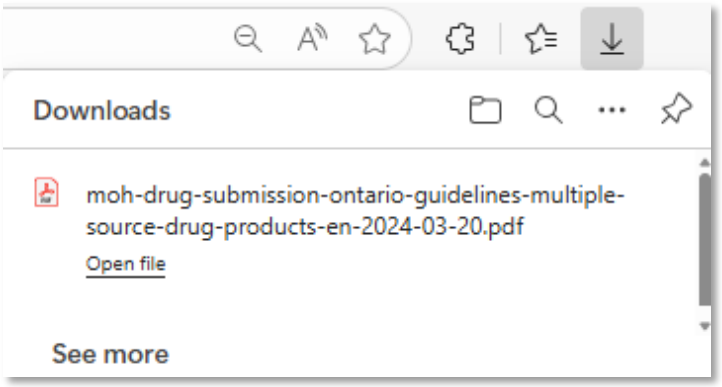


Figure 52 – Screenshot of a Downloaded Guidelines document as a PDF

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.

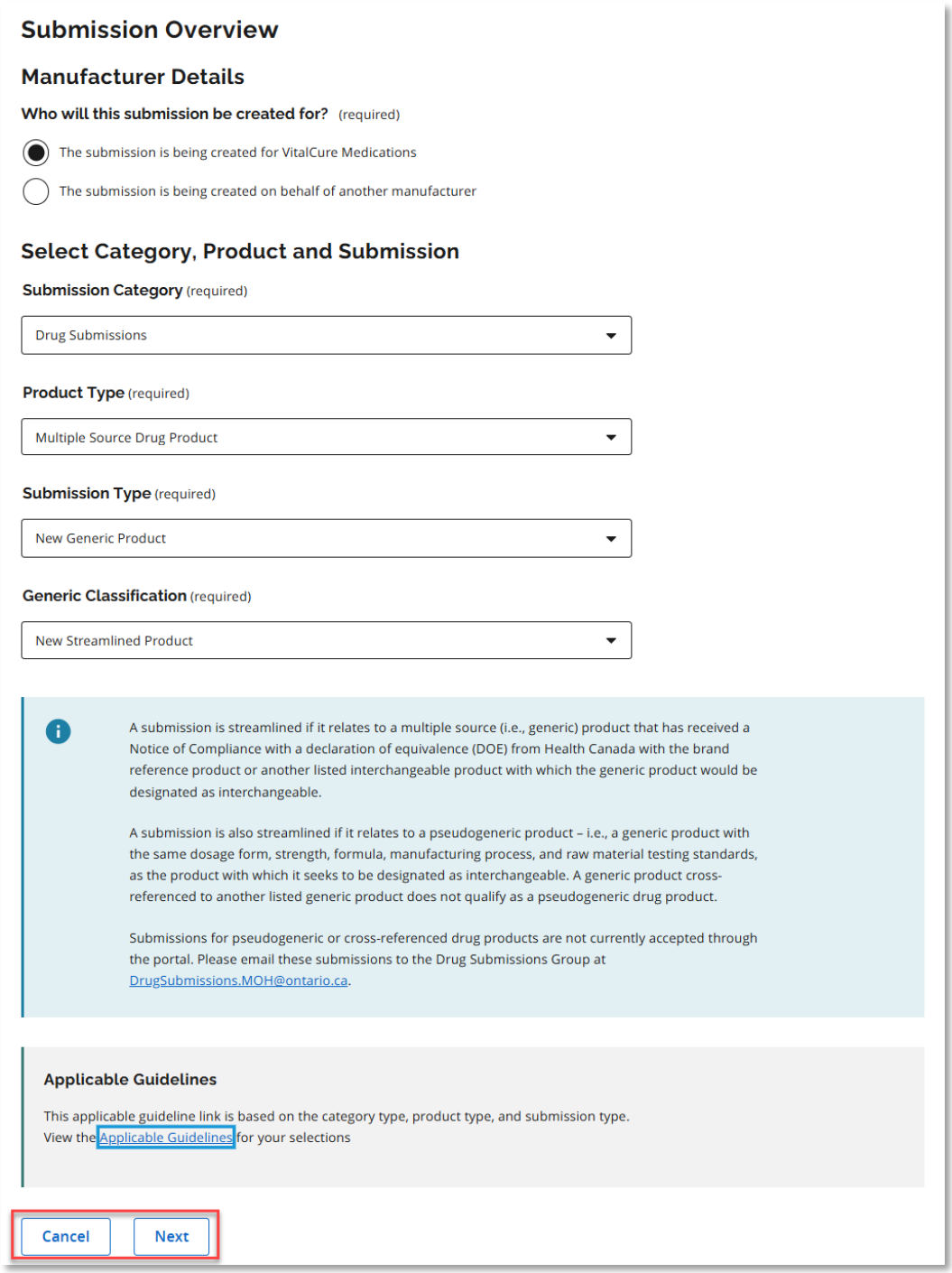


Figure 53 – Screenshot of the Submission Overview screen

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.

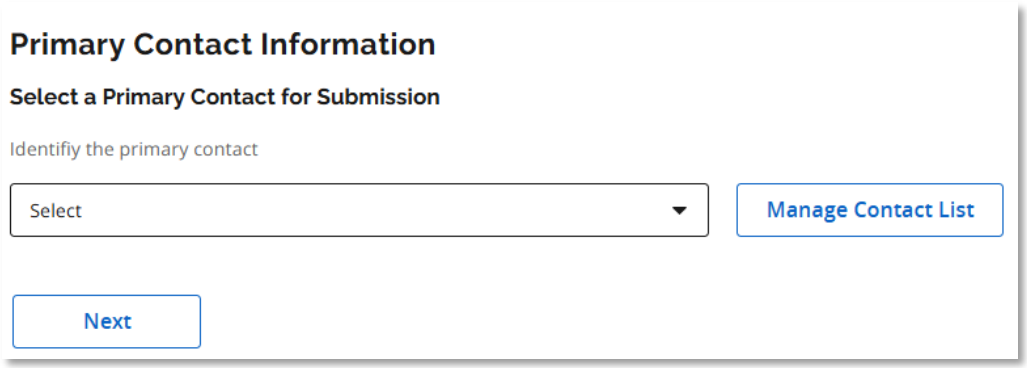


Figure 55 – Screenshot of the Primary Contact Information section

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.

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.

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.

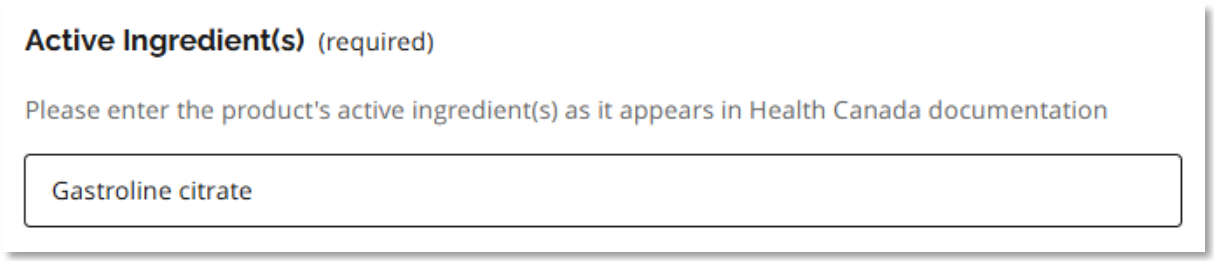


Figure 58 – Screenshot of the Active Ingredient(s) field on the Product Details screen

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

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.

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.

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).

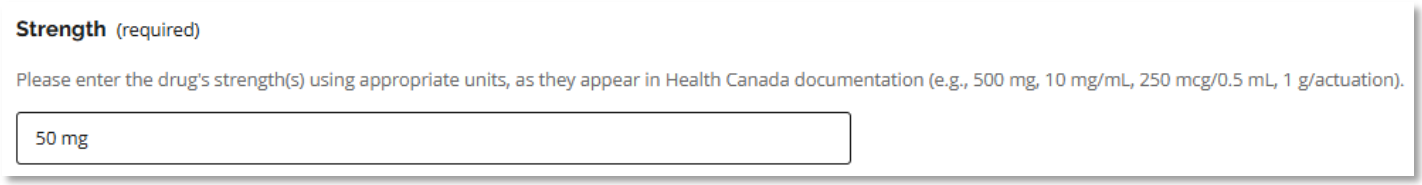


Figure 62 – Screenshot of the Strength field on the Product Details screen

3.4.21. Click in the **Route of Administration** drop-down field and select the applicable value. Multiple routes of administration can be added.

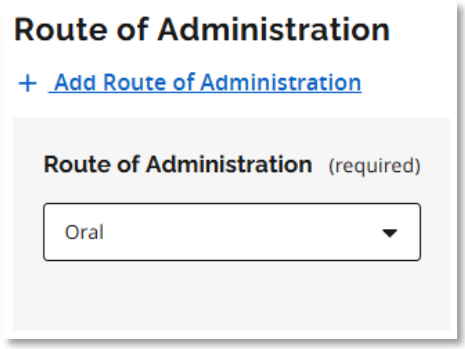


Figure 63 – Screenshot of the Route of Administration drop-down field on the Product Details screen

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'.

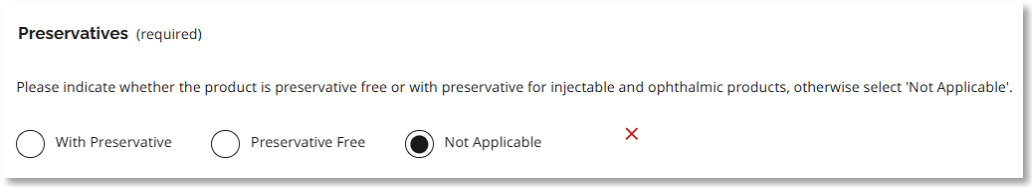


Figure 64 – Screenshot of the Preservative field on the Product Details screen

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.

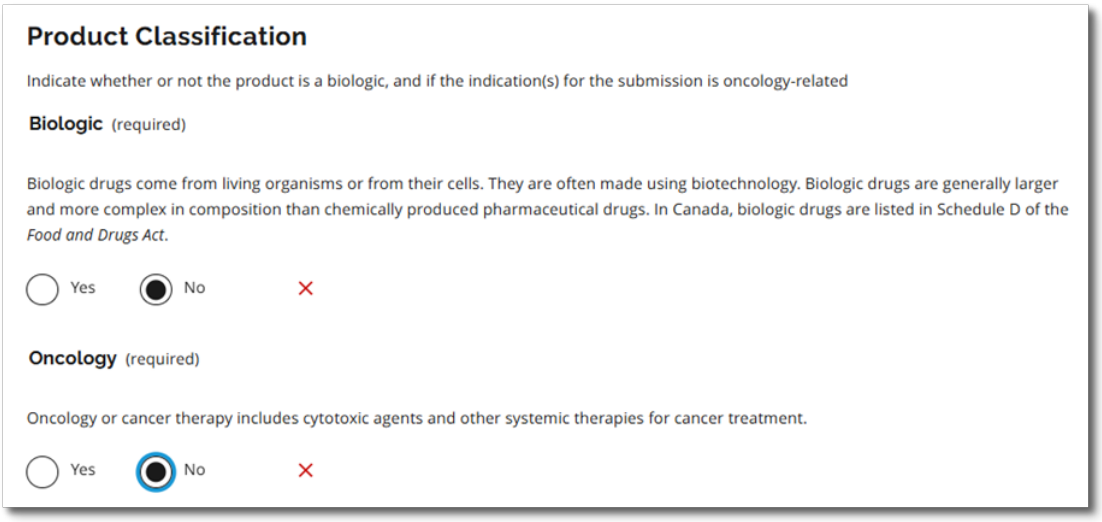


Figure 65 – Screenshot of the Product Classification section on the Product Details screen

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.

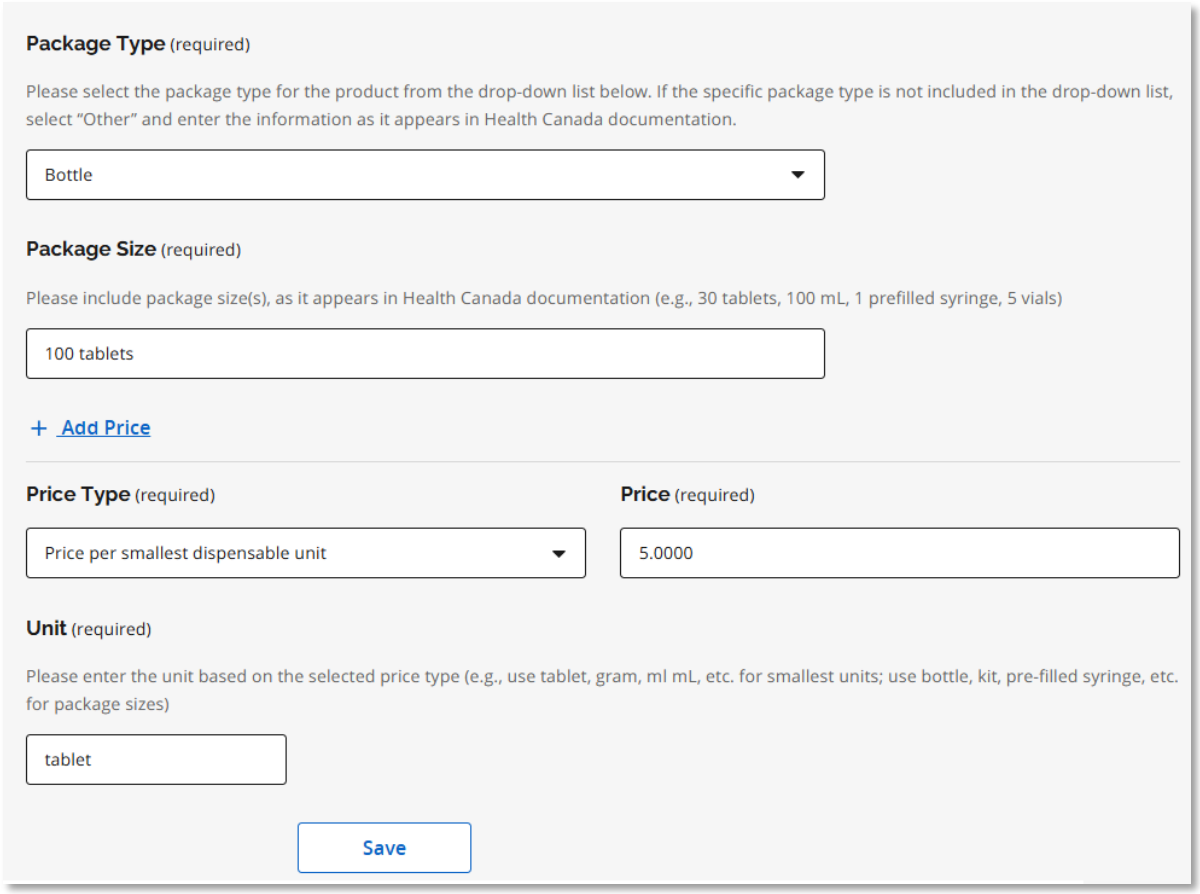


Figure 66 – Screenshot of the Packaging and Pricing section on the Product Details screen

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?

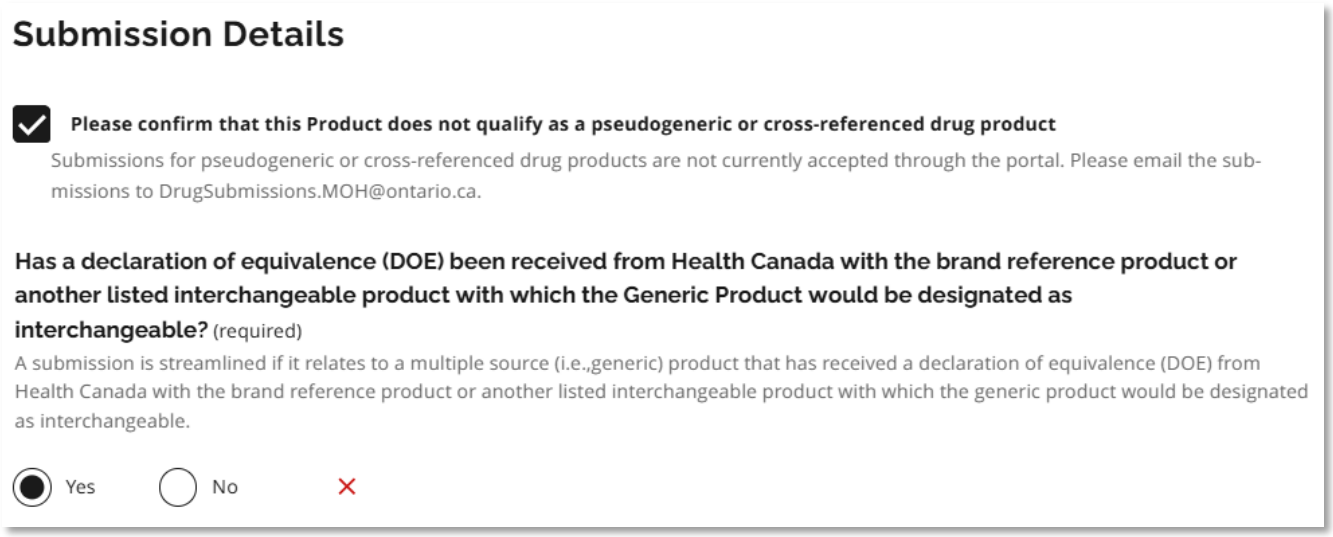


Figure 67 – Screenshot of the Submission Details screen

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.

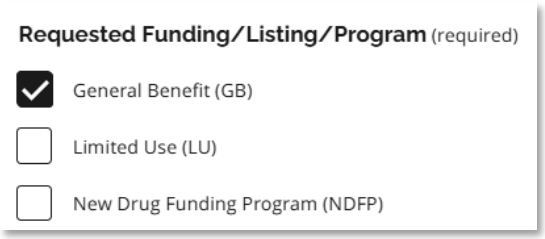


Figure 68 – Screenshot of the Requested Funding/Listing/Program section

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.

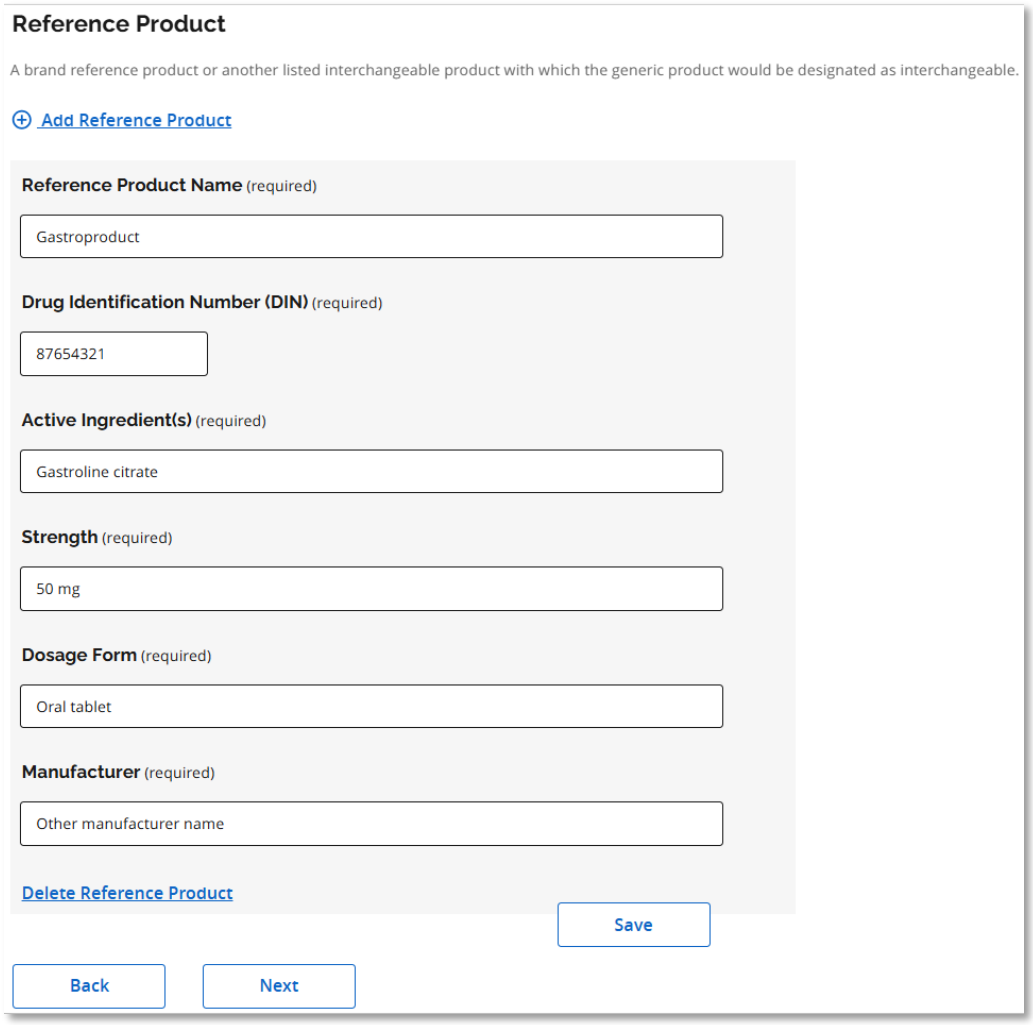


Figure 69 – Screenshot of the Reference Product section

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.

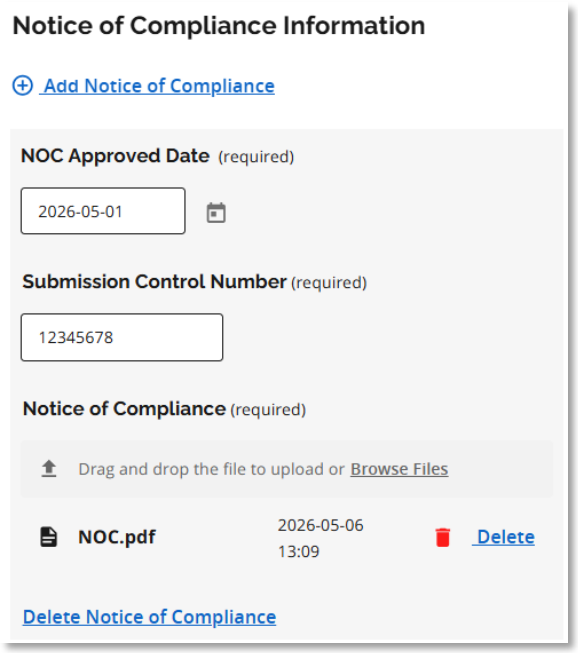


Figure 70 – Screenshot of the Notice of Compliance section

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.

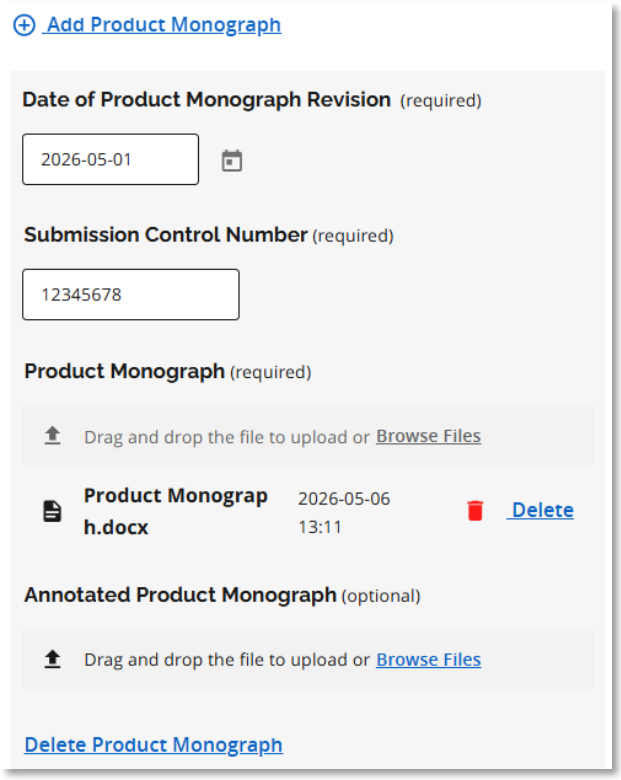


Figure 71 – Screenshot of the Product Monograph section

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).

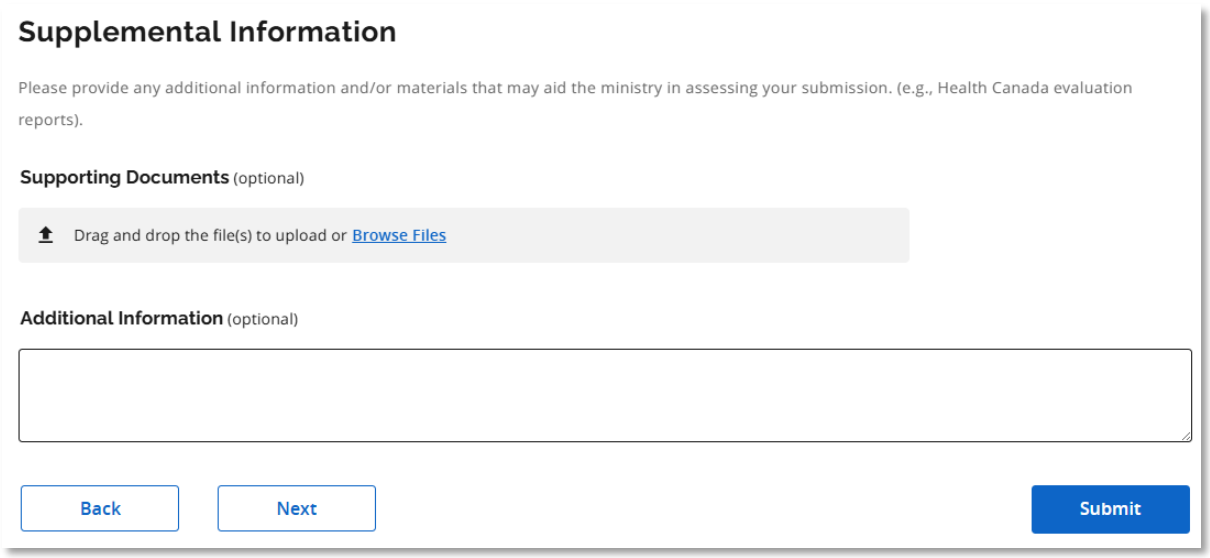


Figure 72 – Screenshot of the Supplemental Information screen

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.

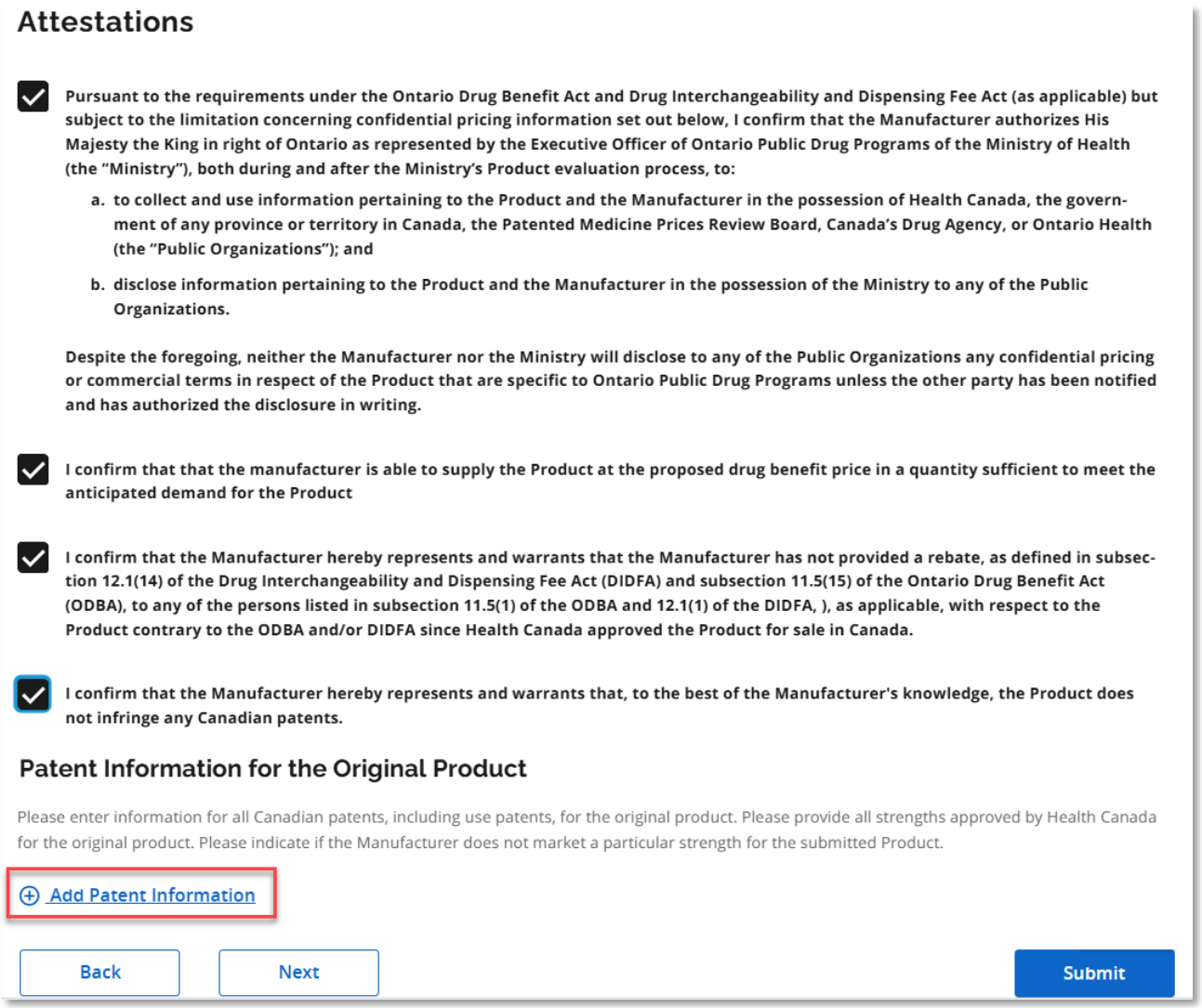


Figure 73 – Screenshot of the Attestations screen

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.

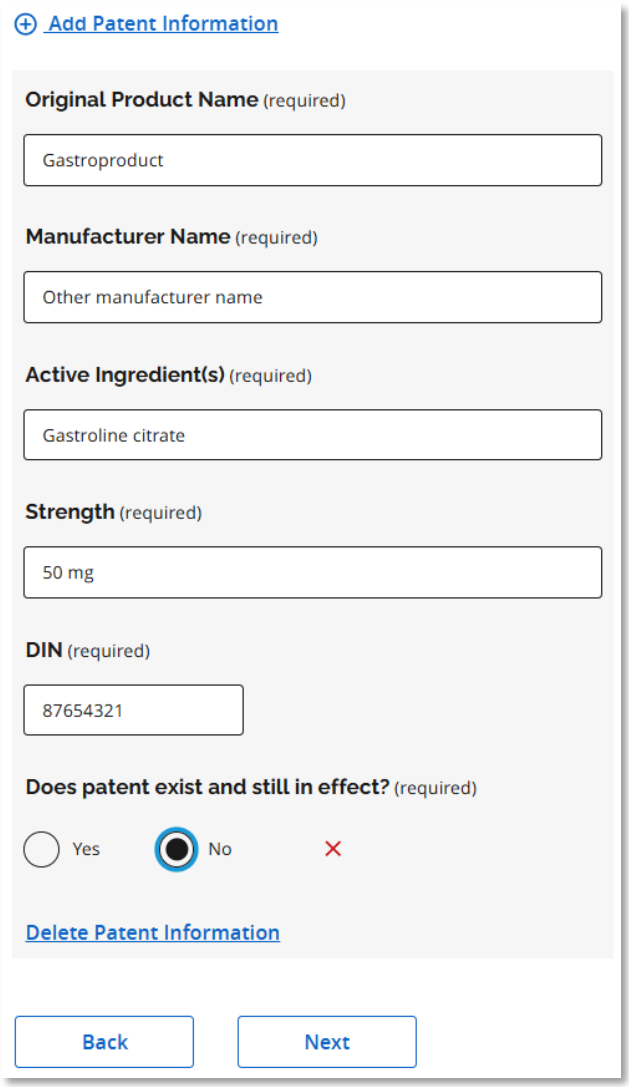


Figure 74 – Screenshot of the Patent Information section

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.

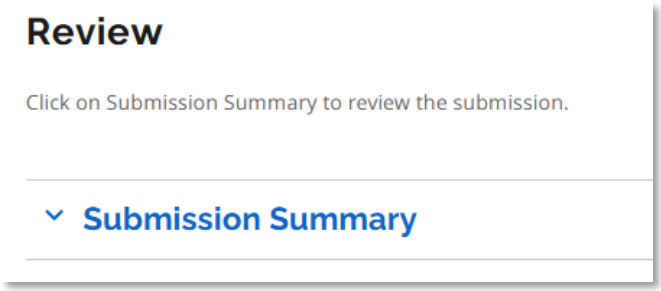


Figure 75 – Screenshot of the Submission Summary Link on the Review screen

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.

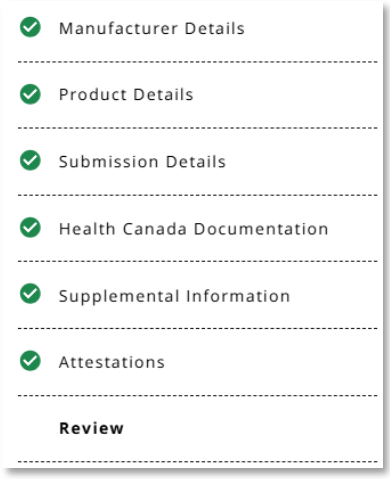


Figure 76 – Screenshot of the Left Menu

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.

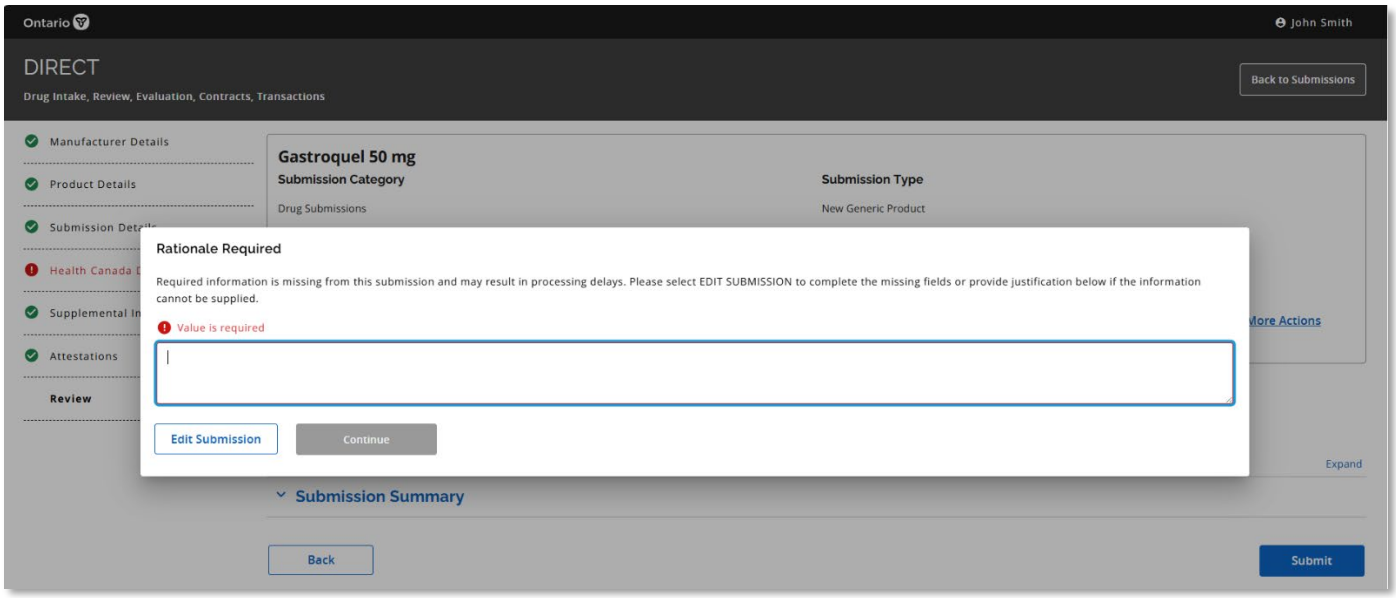


Figure 77 – Screenshot of the Rationale Required Window

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.

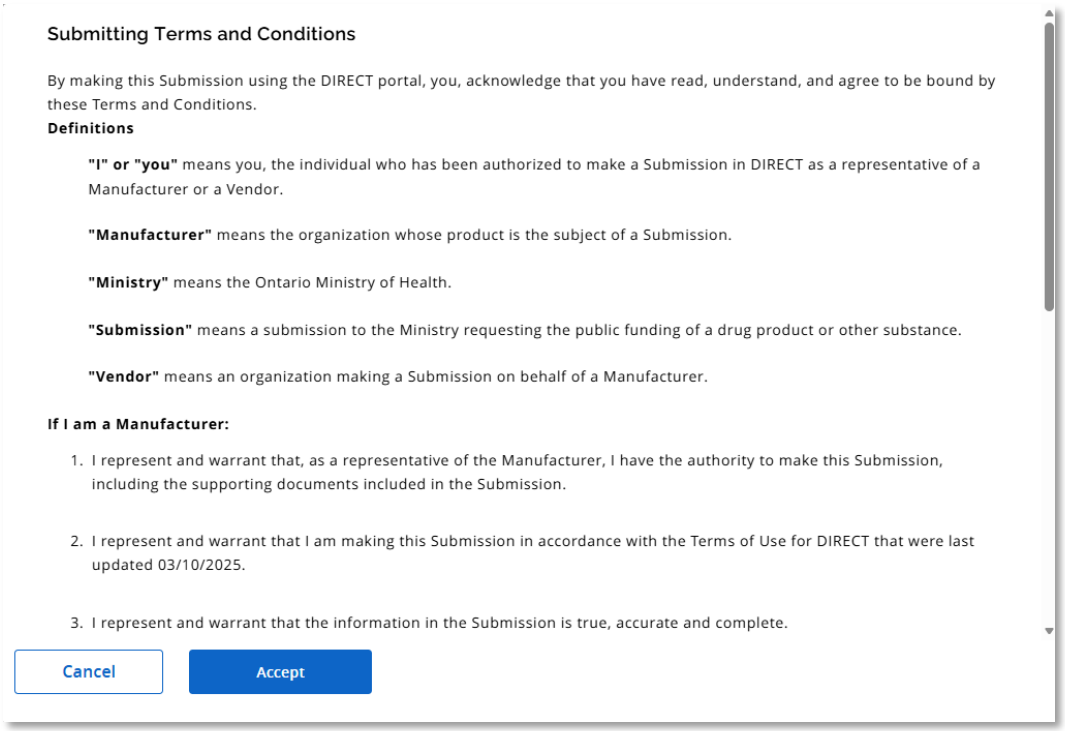


Figure 78 – Screenshot of the Submitting Terms and Conditions

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

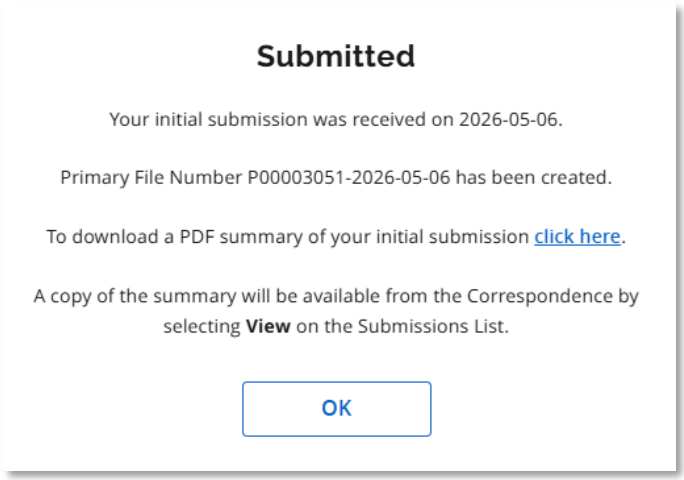


Figure 79 – Screenshot of the Submitted Message

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'.

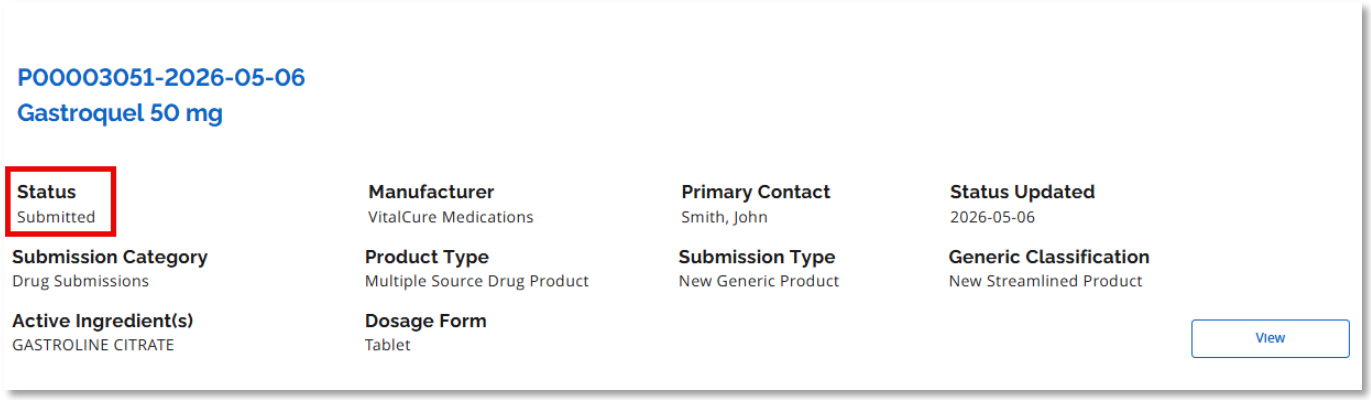


Figure 80 – Screenshot of the submission with a status of submitted in the Submission List

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.

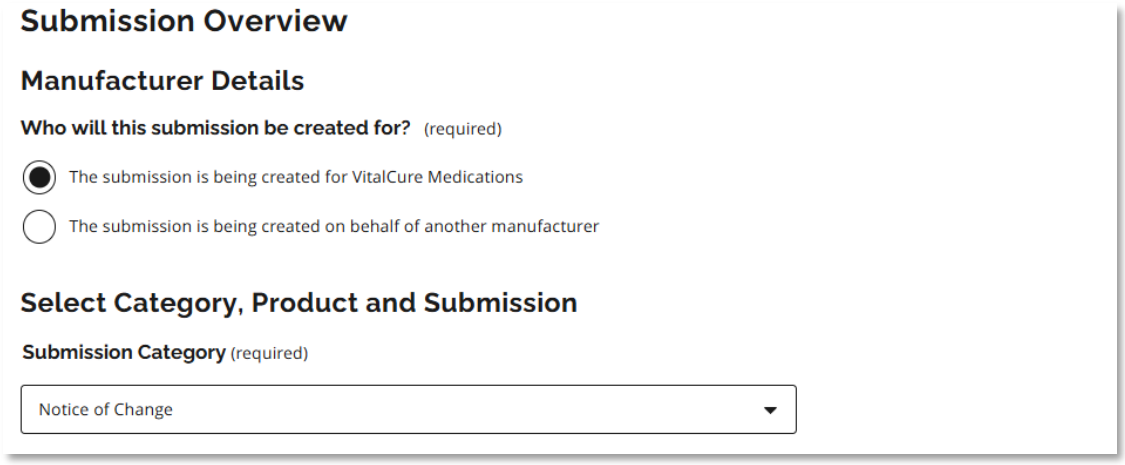


Figure 81 – Screenshot of the Submission Overview screen

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.

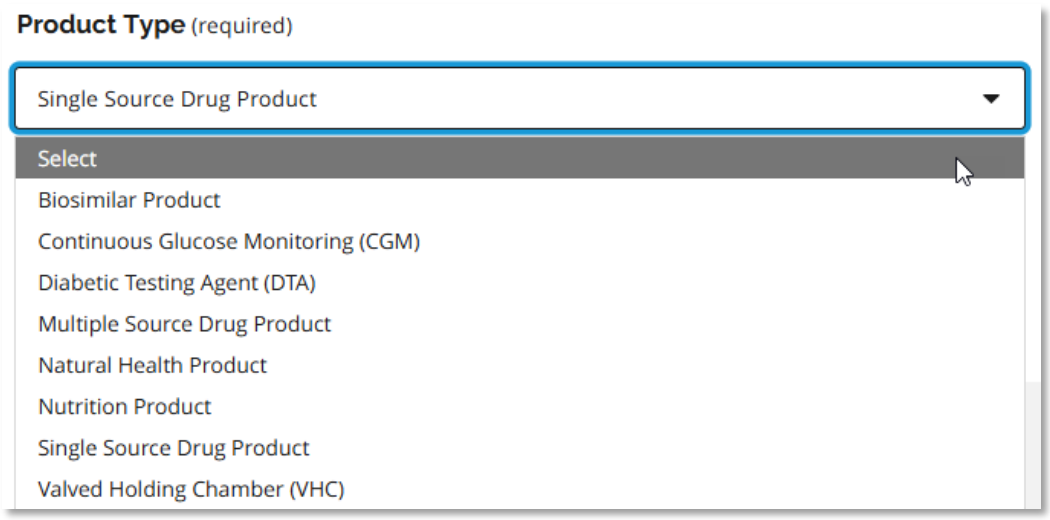


Figure 82 – Screenshot of the Product Type drop-down field

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**.**

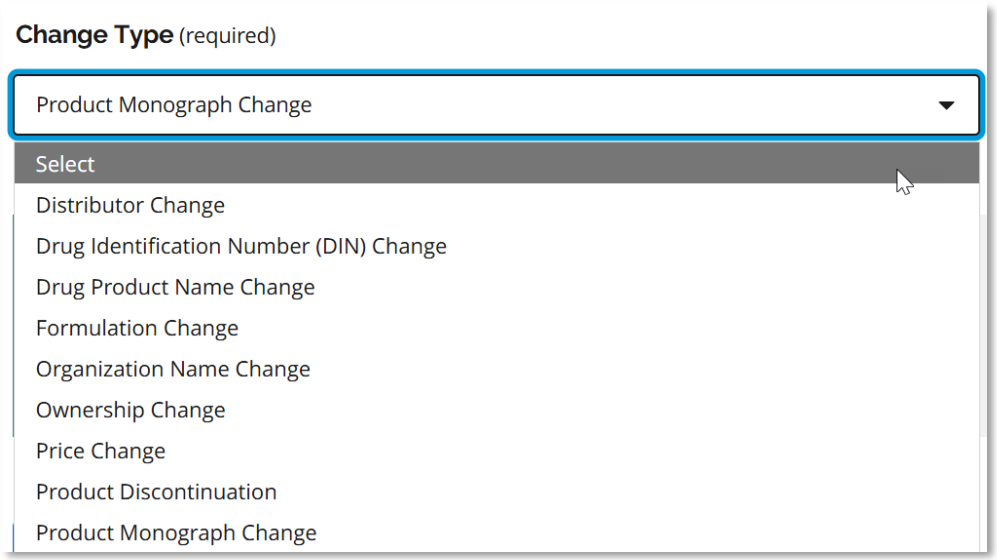


Figure 83 – Screenshot of the Change Type drop-down field

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.

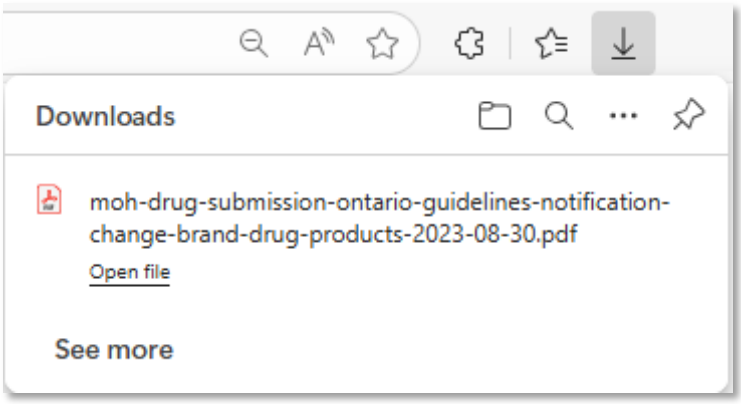


Figure 84 – Screenshot of a Downloaded Guidelines document as a PDF

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.

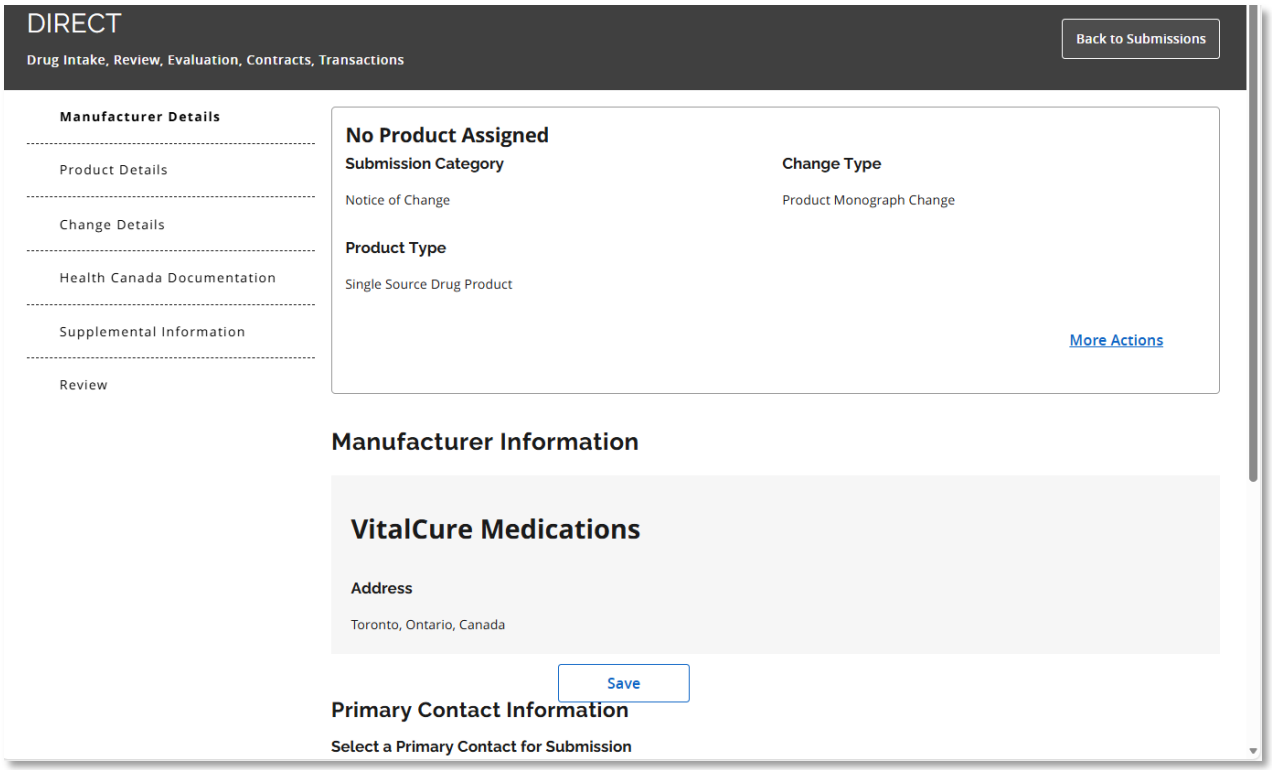


Figure 86 – Screenshot of the Manufacturer Details screen

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.

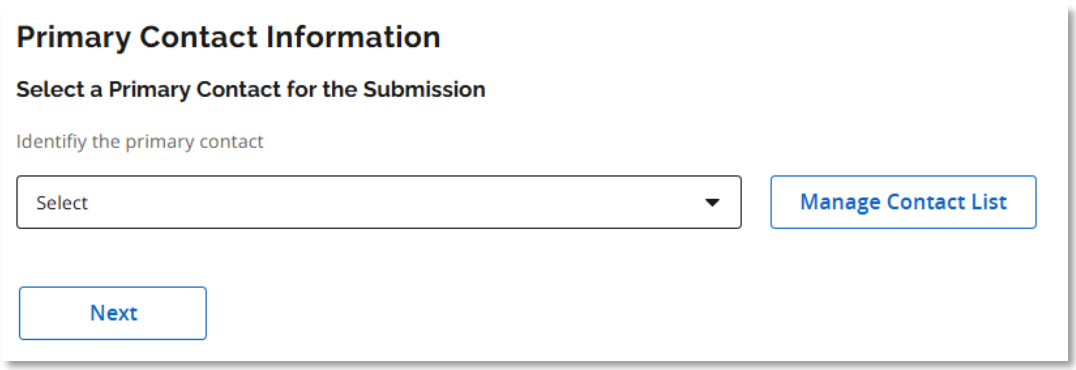


Figure 87 – Screenshot of the Primary Contact Information section

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.

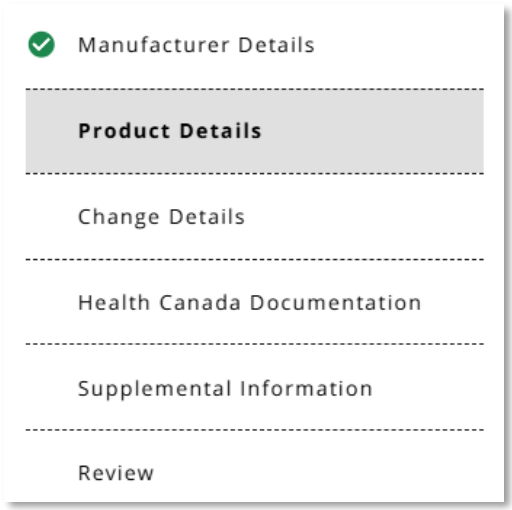


Figure 88 – Screenshot of the Left Menu Tabs on the Product Details screen

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.

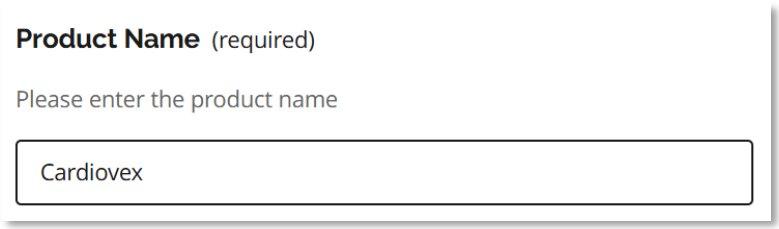


Figure 89 – Screenshot of the Product Name field on the Product Details screen

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

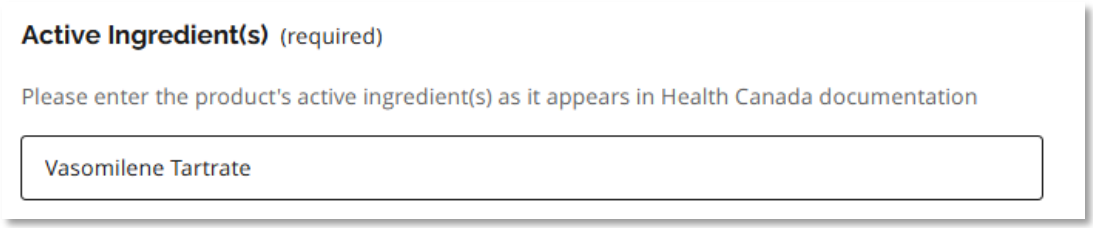


Figure 90 – Screenshot of the Active Ingredient(s) field on the Product Details screen

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'.)

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.

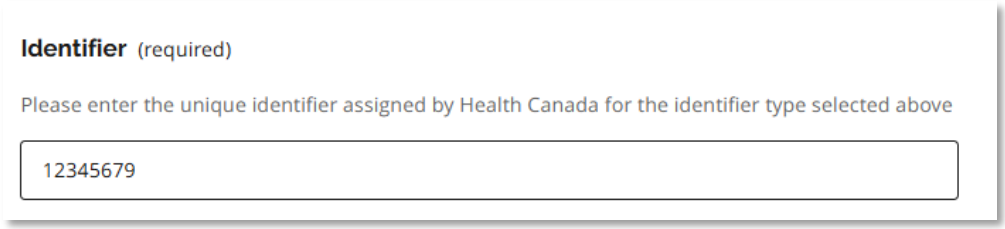


Figure 92 – Screenshot of the Identifier field on the Product Details screen

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

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).

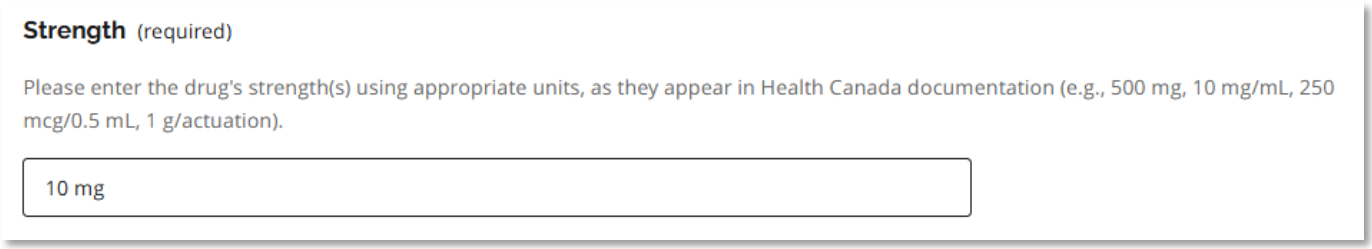


Figure 94 – Screenshot of the Strength field on the Product Details screen

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

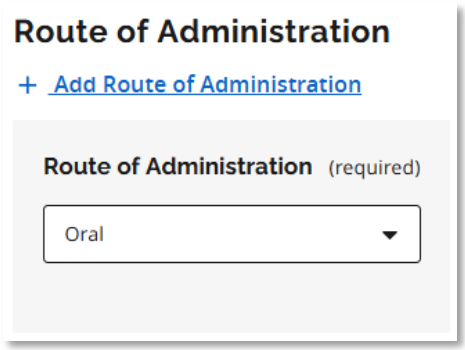


Figure 95 – Screenshot of the Route of Administration drop-down field on the Product Details screen

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'.

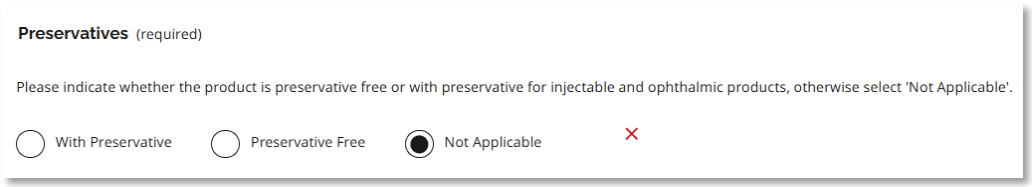


Figure 96 – Screenshot of the Preservative field on the Product Details screen

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.

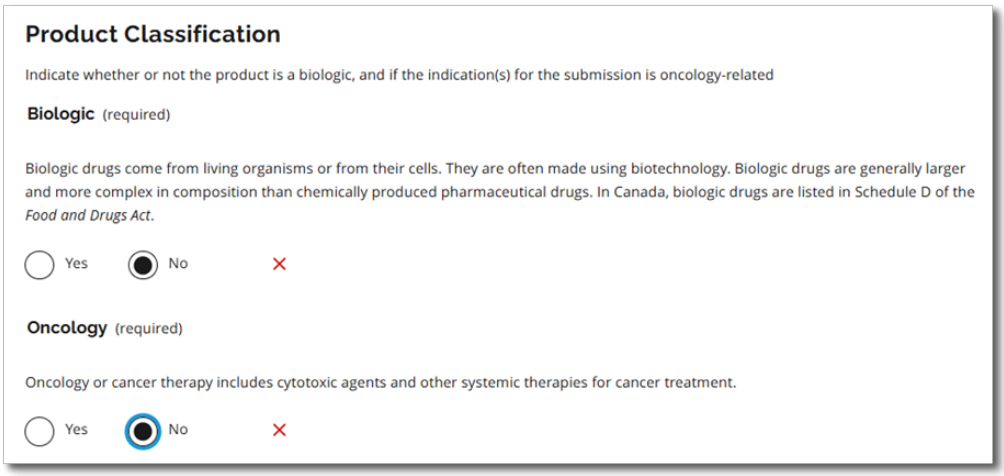


Figure 97 – Screenshot of the Product Classification section on the Product Details screen

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

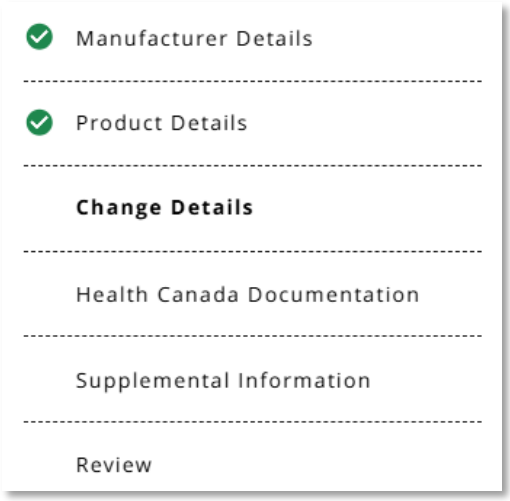


Figure 98 – Screenshot of the Left Menu Tabs on the Change Details screen

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

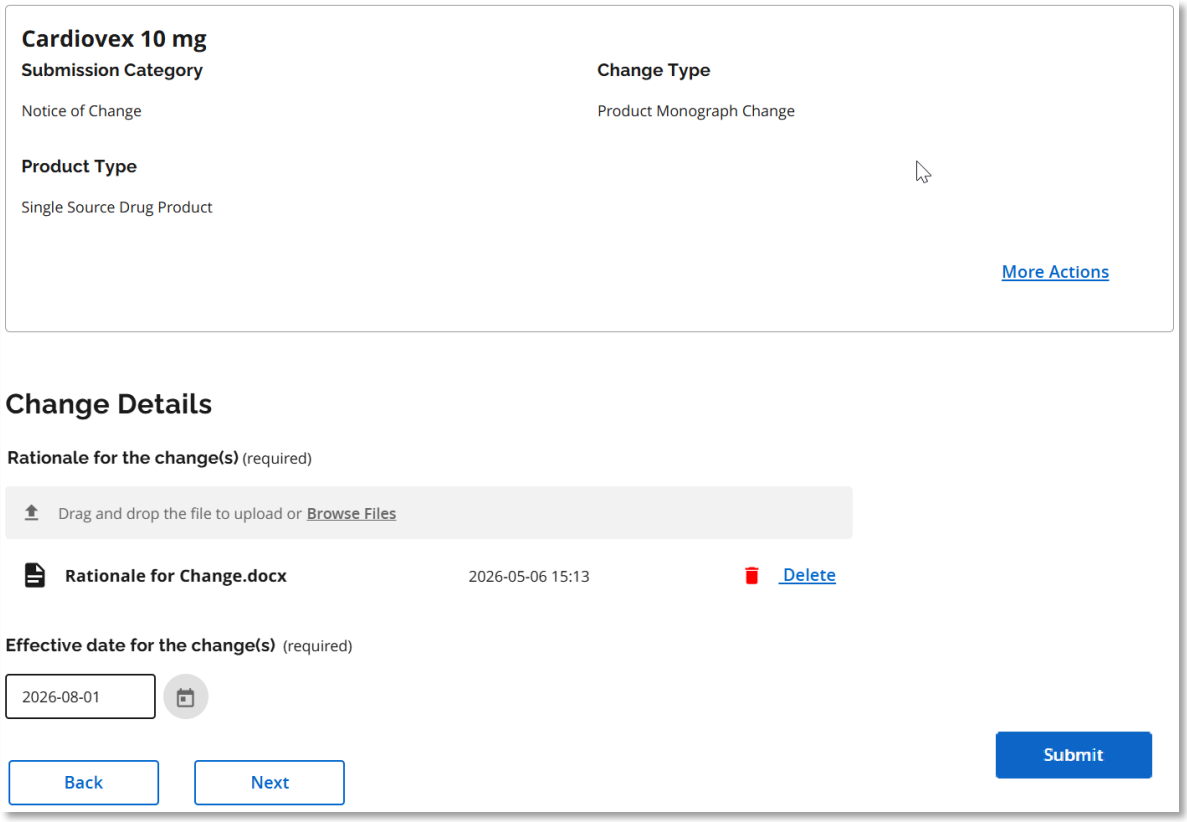


Figure 99 – Screenshot of the Change Details section

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.

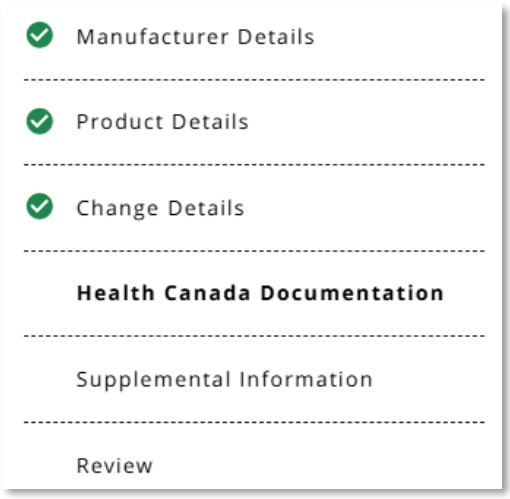


Figure 100 – Screenshot of the Left Menu Tabs on the Health Canada Documentation screen

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).

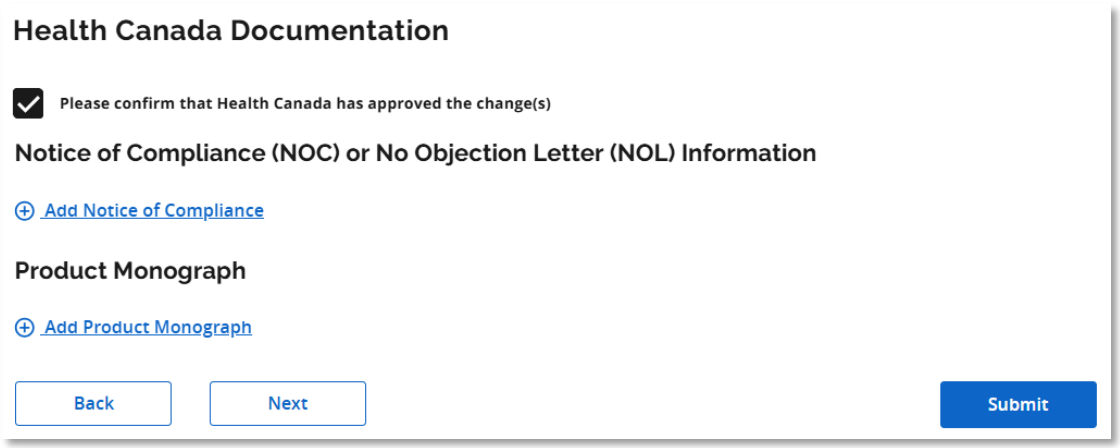


Figure 101 – Screenshot of the Health Canada Documentation screen

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.

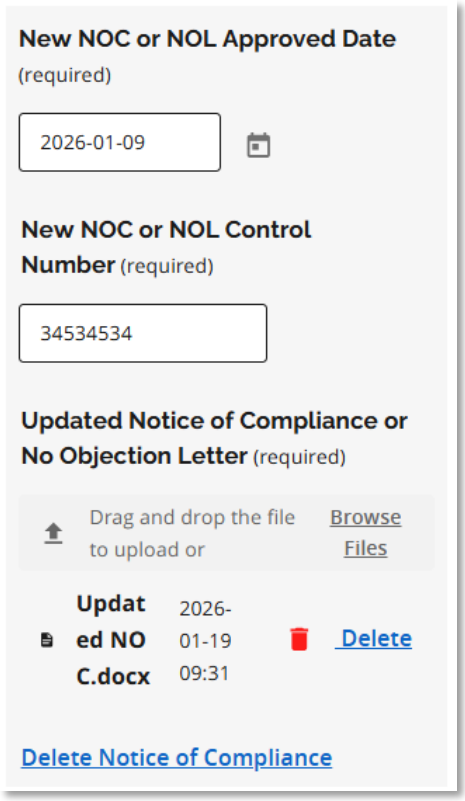


Figure 102 – Screenshot of the Notice of Compliance section

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.

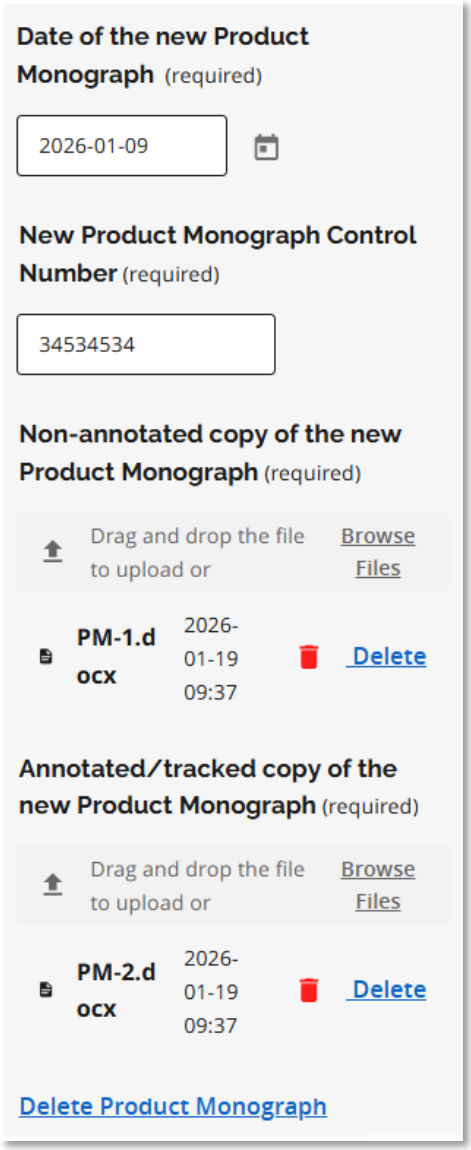


Figure 103 – Screenshot of the Product Monograph section

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).

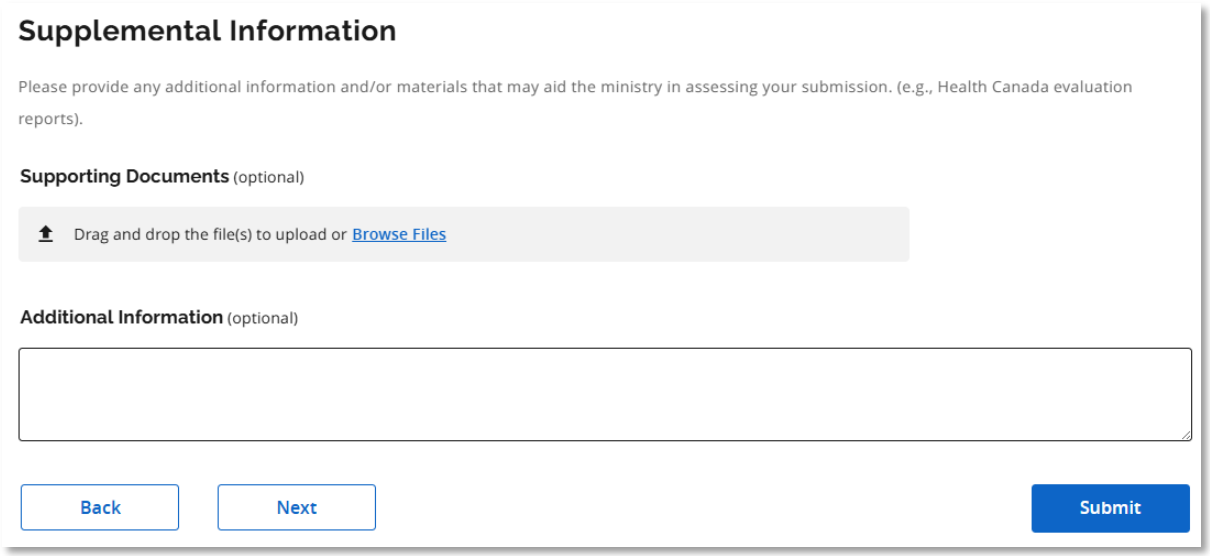


Figure 104 – Screenshot of the Supplemental Information screen

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.

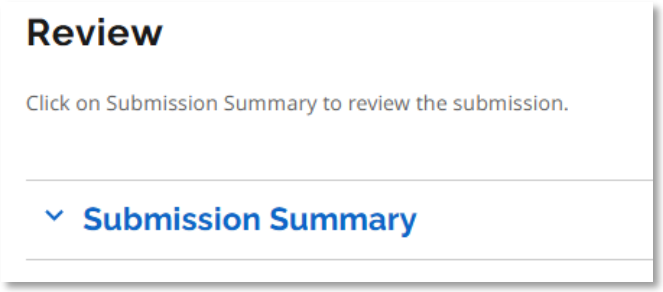


Figure 105 – Screenshot of the Submission Summary Link on the Review screen

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.

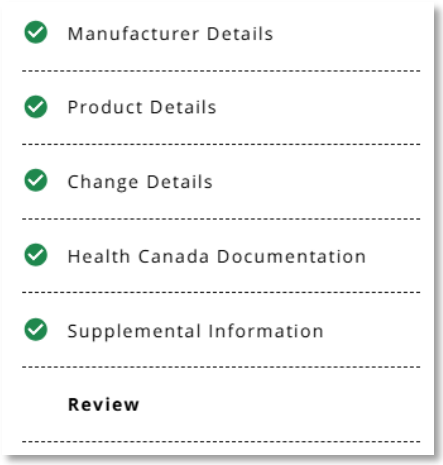


Figure 106 – Screenshot of the Left Menu

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.

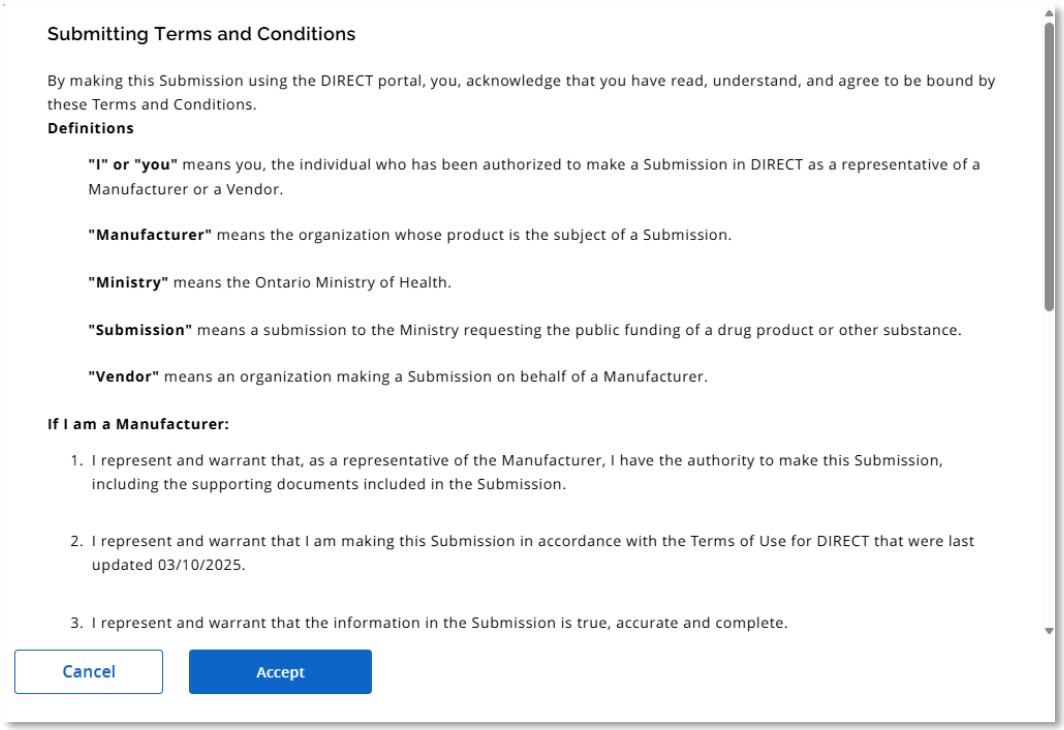


Figure 107 – Screenshot of the Submitting Terms and Conditions window

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

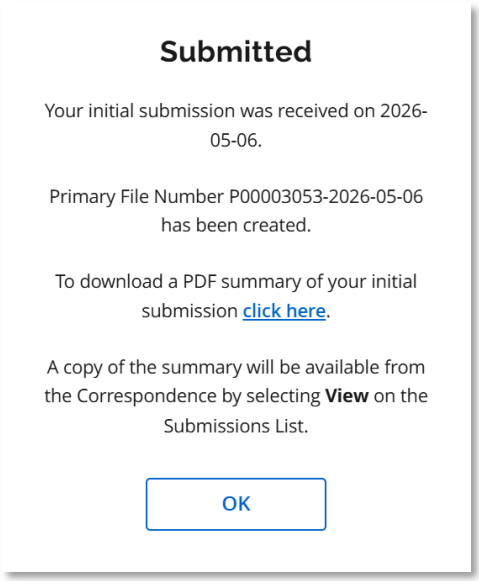


Figure 108 – Screenshot of the Submitted Message

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'.

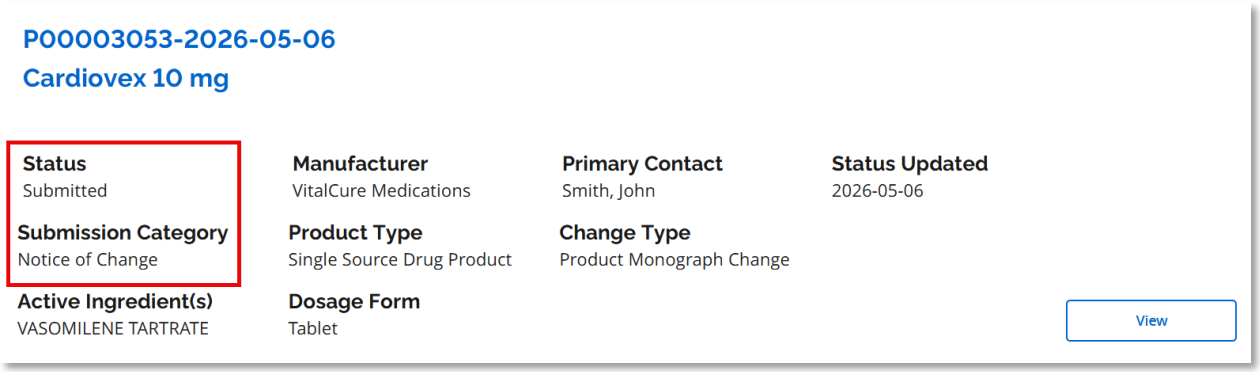


Figure 109 – Screenshot of the Notice of Change Submission in the Submission List

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**.

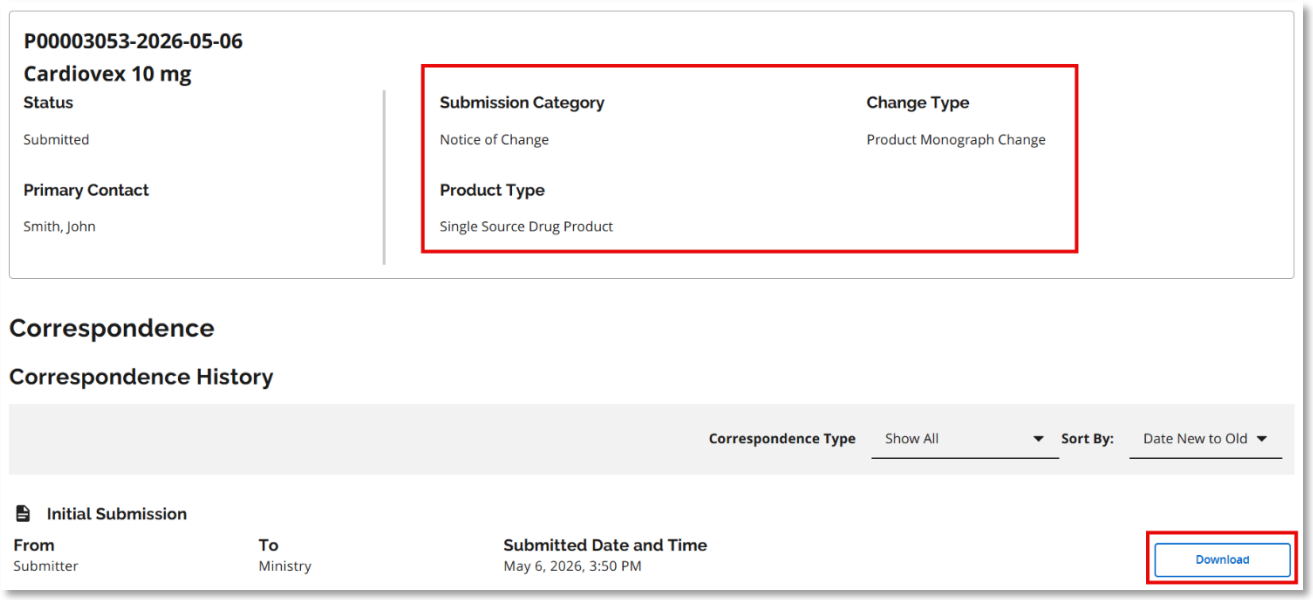


Figure 110 – Screenshot of the Notice of Change Submission Record

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.

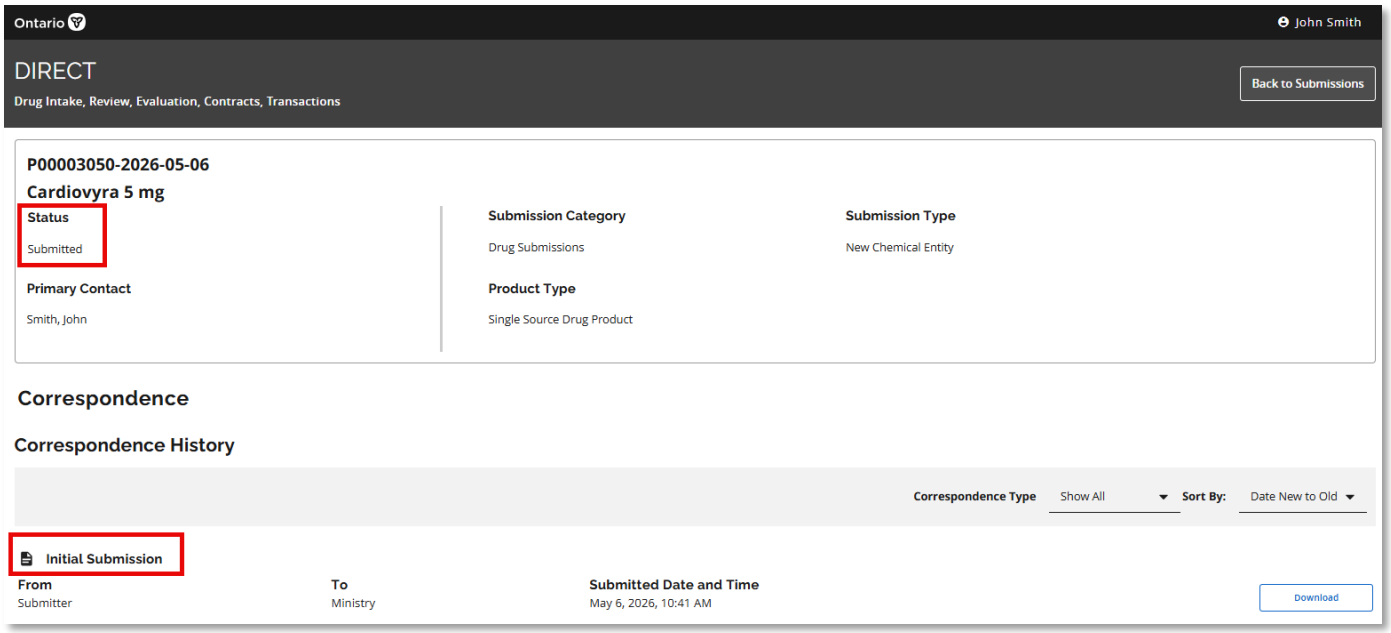


Figure 111 – Screenshot of the Submission Overview screen

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.

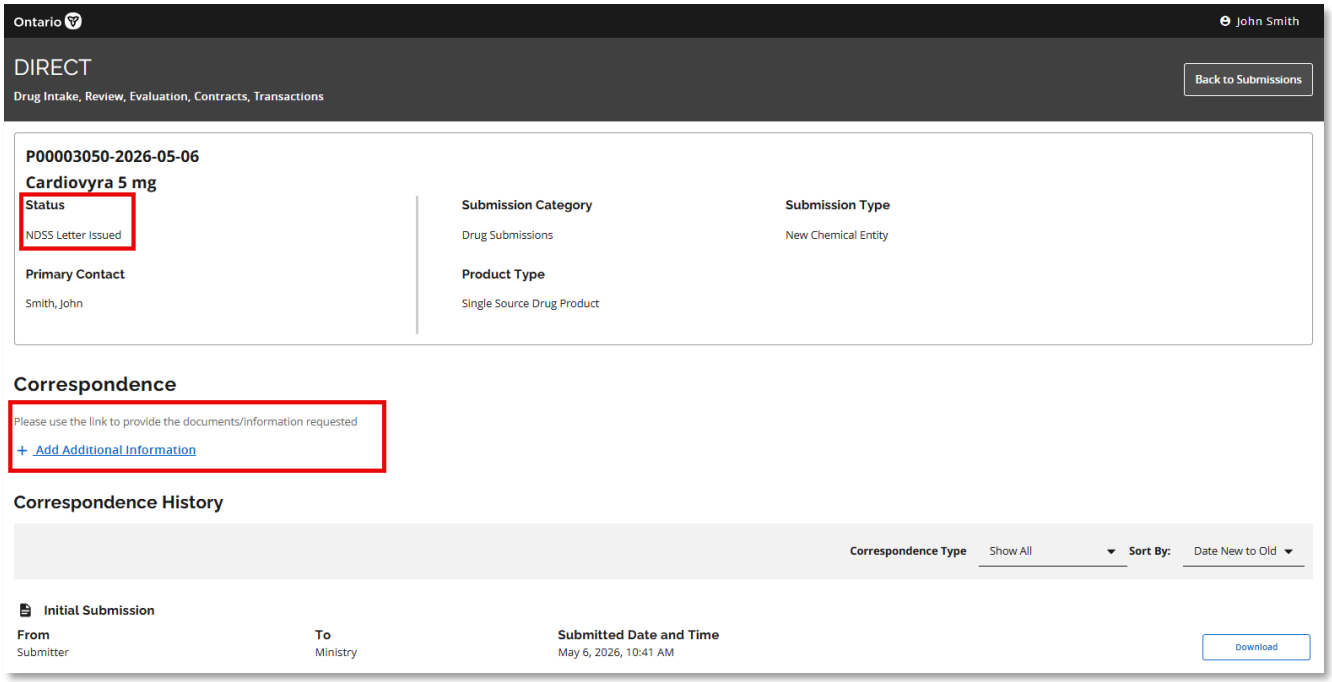


Figure 112 – Screenshot of the Submission Overview screen

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

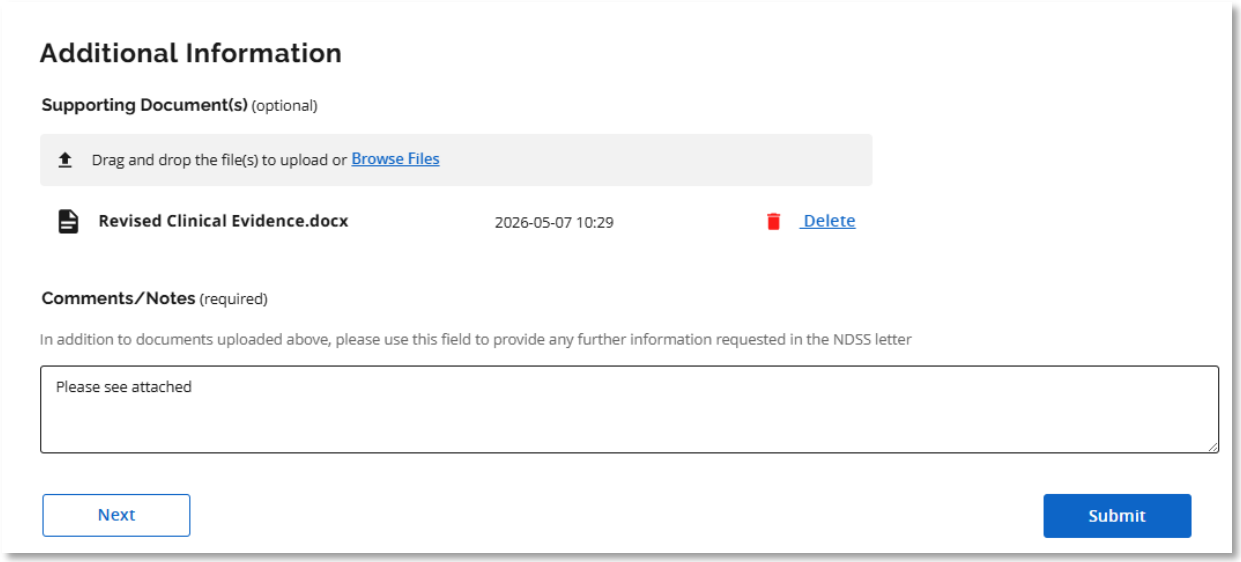


Figure 113 – Screenshot of the Additional Information screen

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.

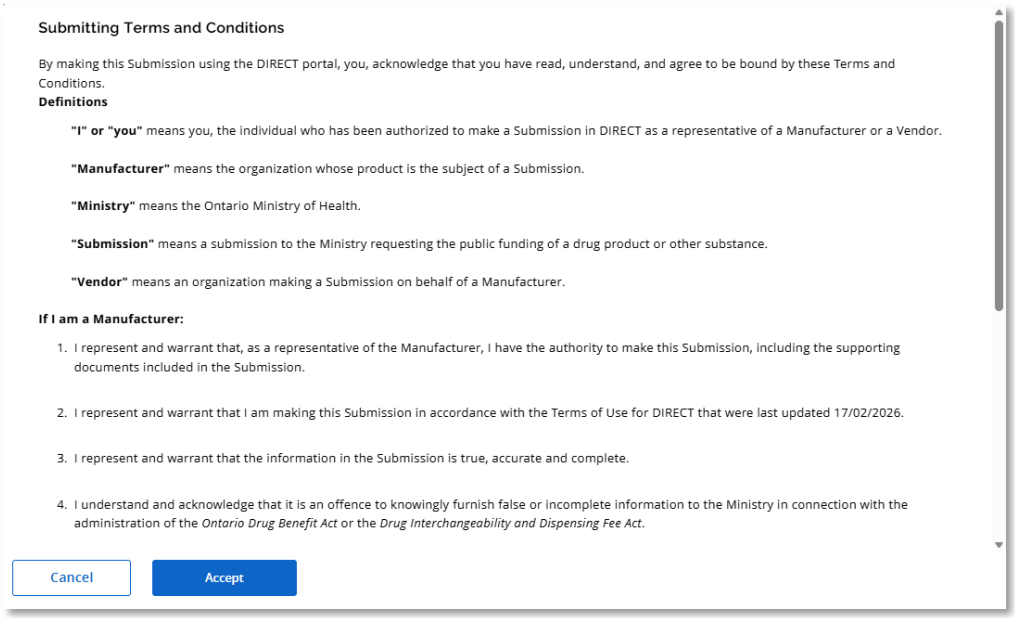


Figure 114 – Screenshot of the Submitting Terms and Conditions

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

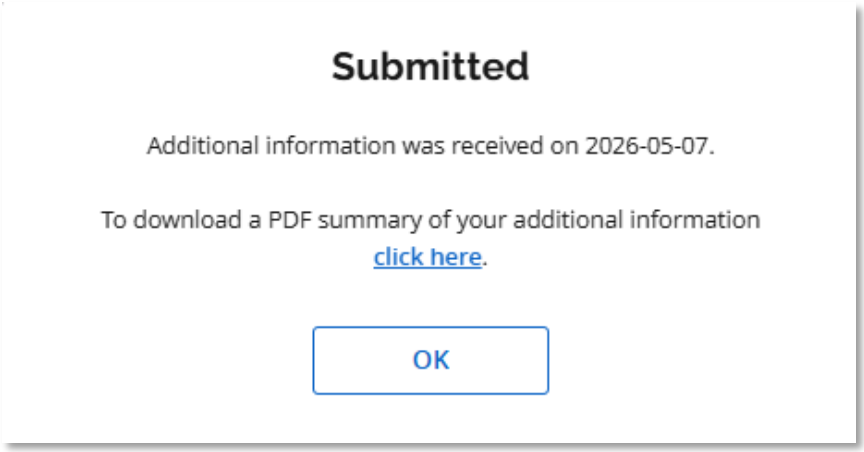


Figure 115 – Screenshot of the Successful Submission Message

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'.

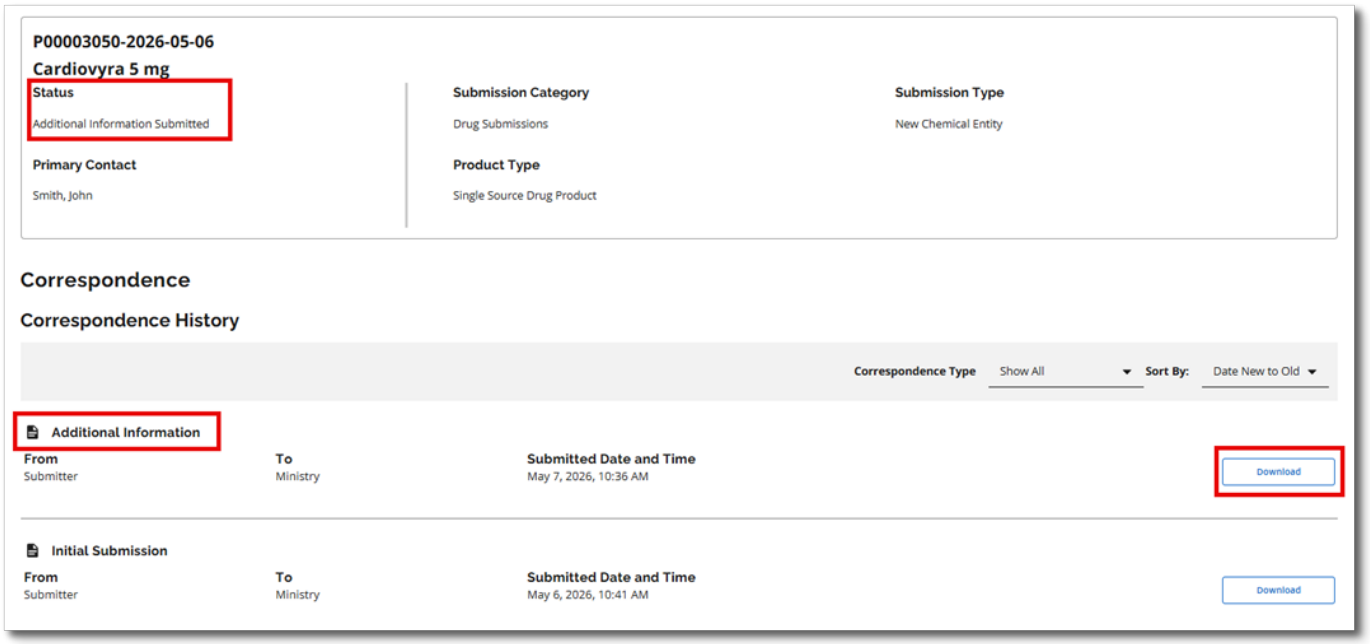


Figure 116 – Screenshot of the Submission Record with Additional Information Correspondence

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.

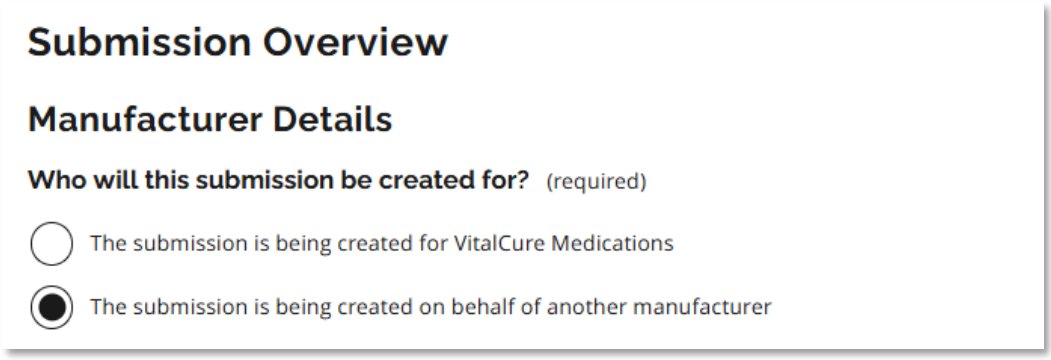


Figure 117 – Screenshot of the Submission Overview screen

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.

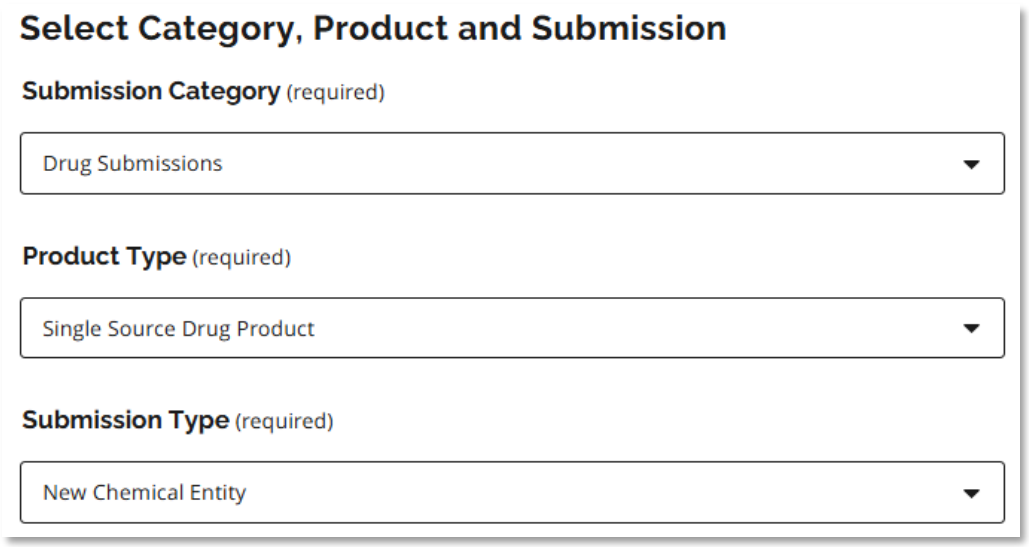


Figure 118 – Screenshot of the Category, Product and Submission section

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.

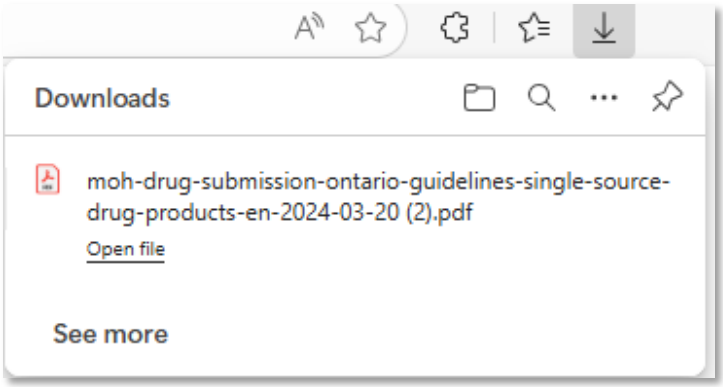


Figure 119 – Screenshot of a Downloaded Guidelines document as a PDF

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.

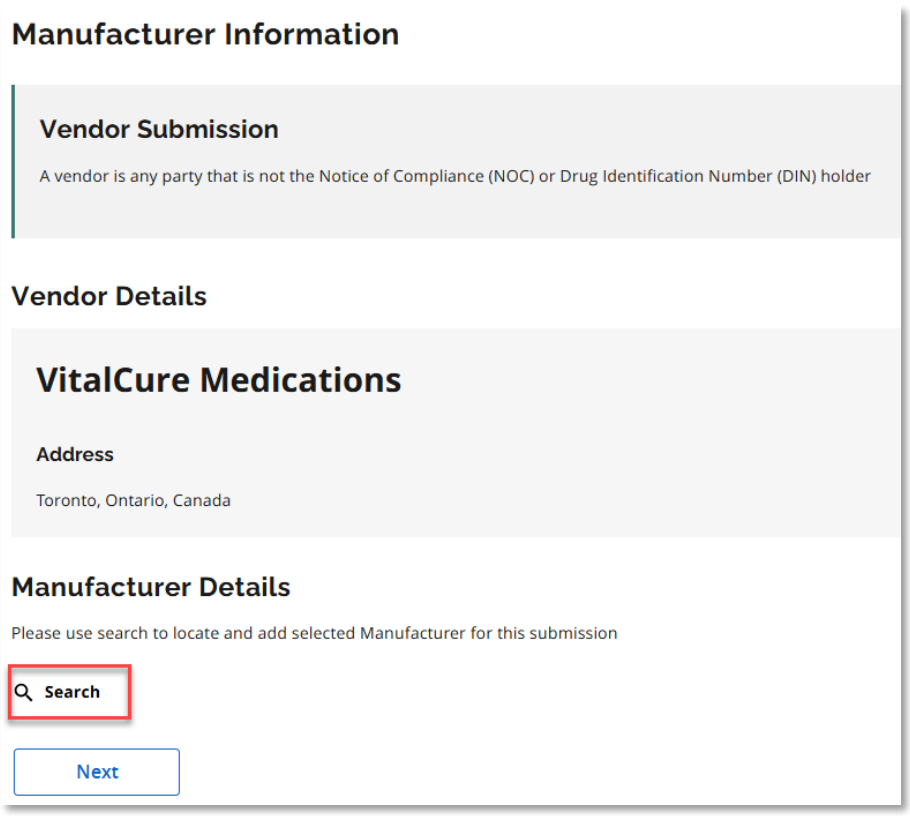


Figure 121 – Screenshot of the Manufacturer Details section

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.

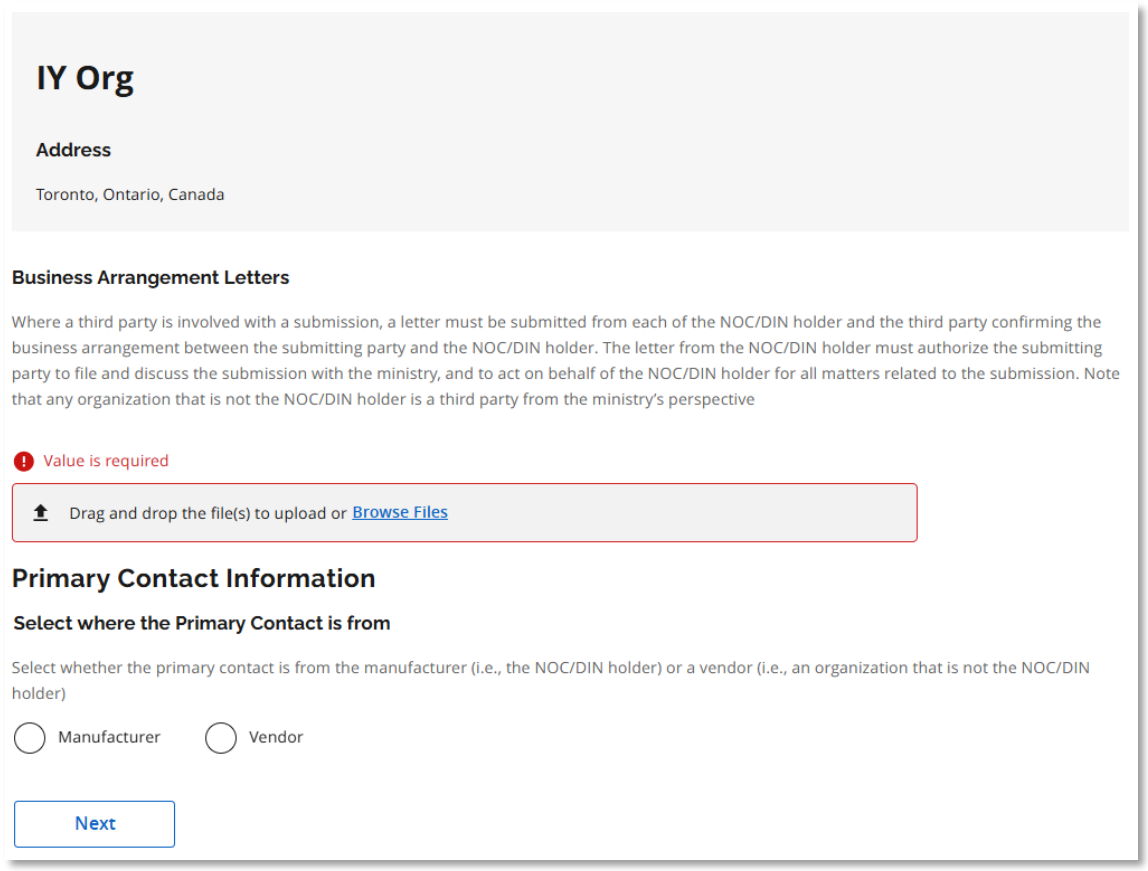


Figure 122 – Screenshot of the Business Arrangement Letter field

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.

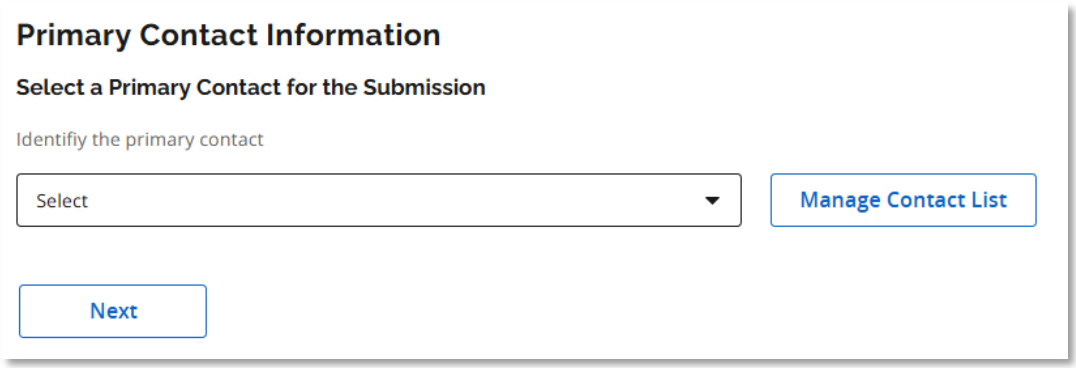


Figure 123 – Screenshot of the Primary Contact Information section

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.

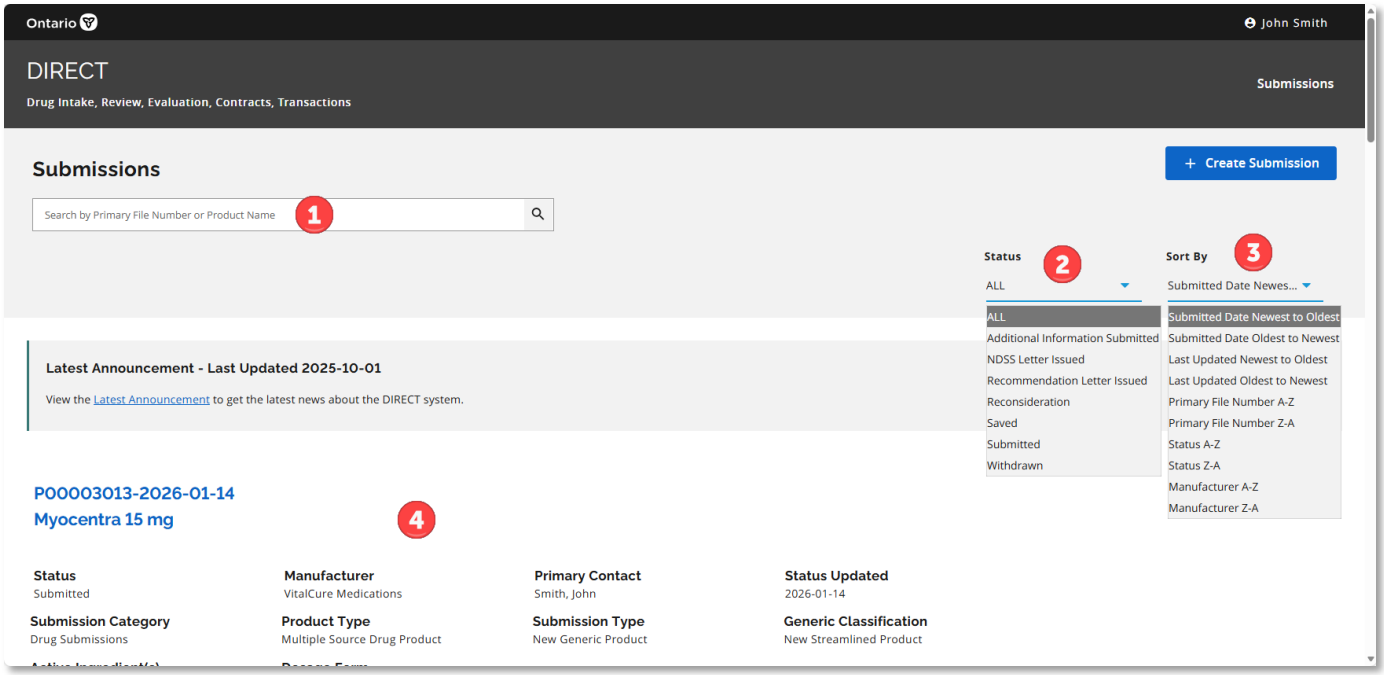


Figure 124 - Image of the Search, Sort, and Filter Options on the Submissions Screen

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.

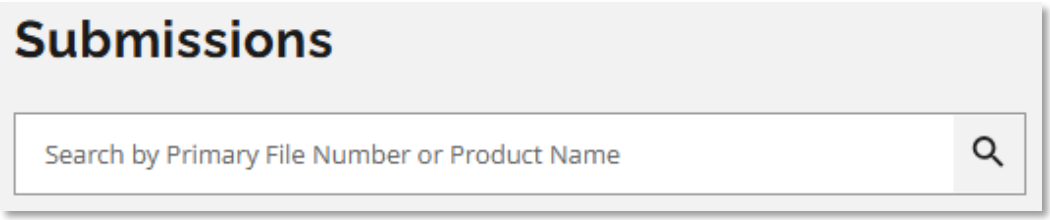


Figure 125 – Screenshot of the Submissions Search Field

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.

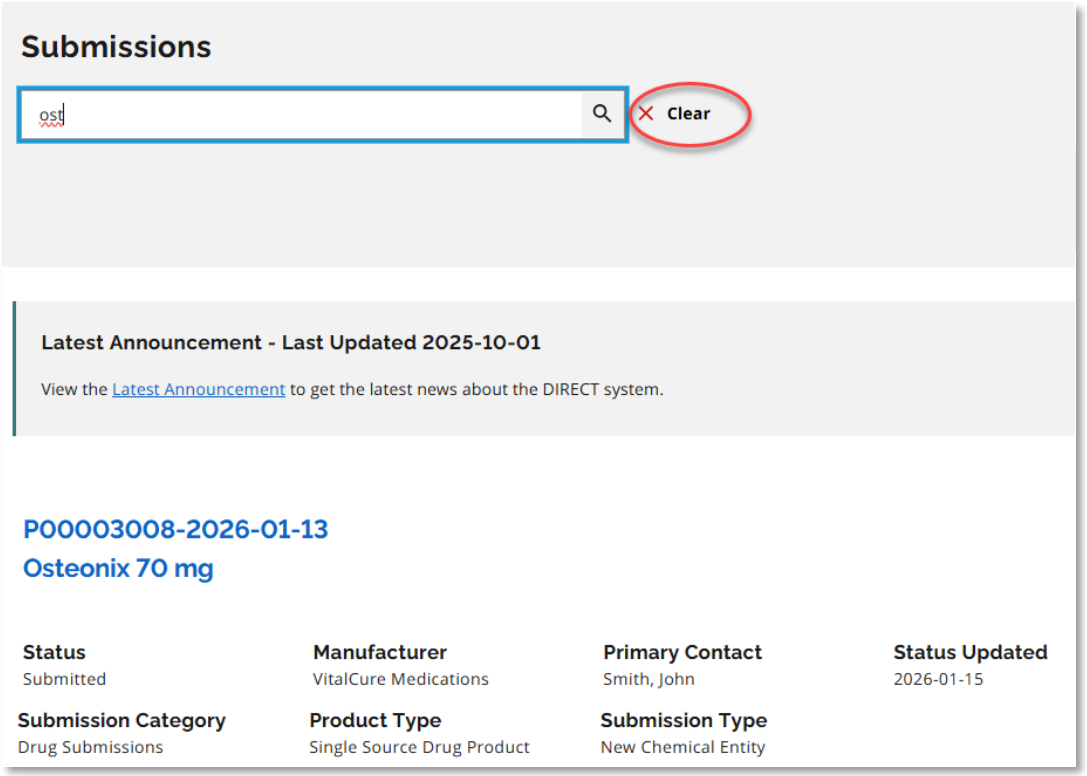


Figure 126 – Screenshot of the Submissions Search Field with Clear Link

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.

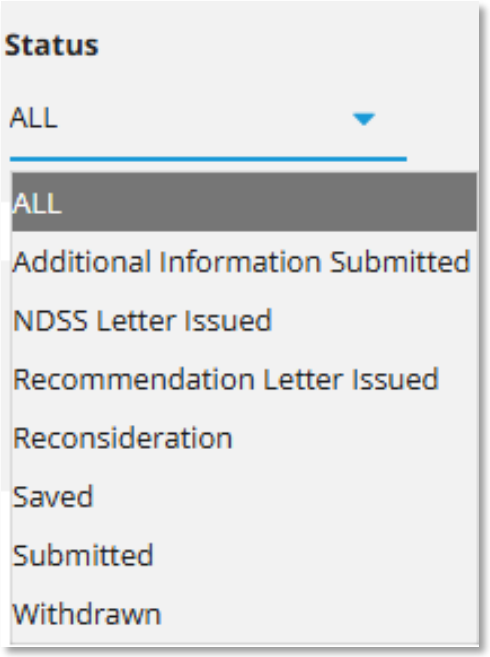


Figure 127 – Screenshot of the Status Filter Drop-down Field

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

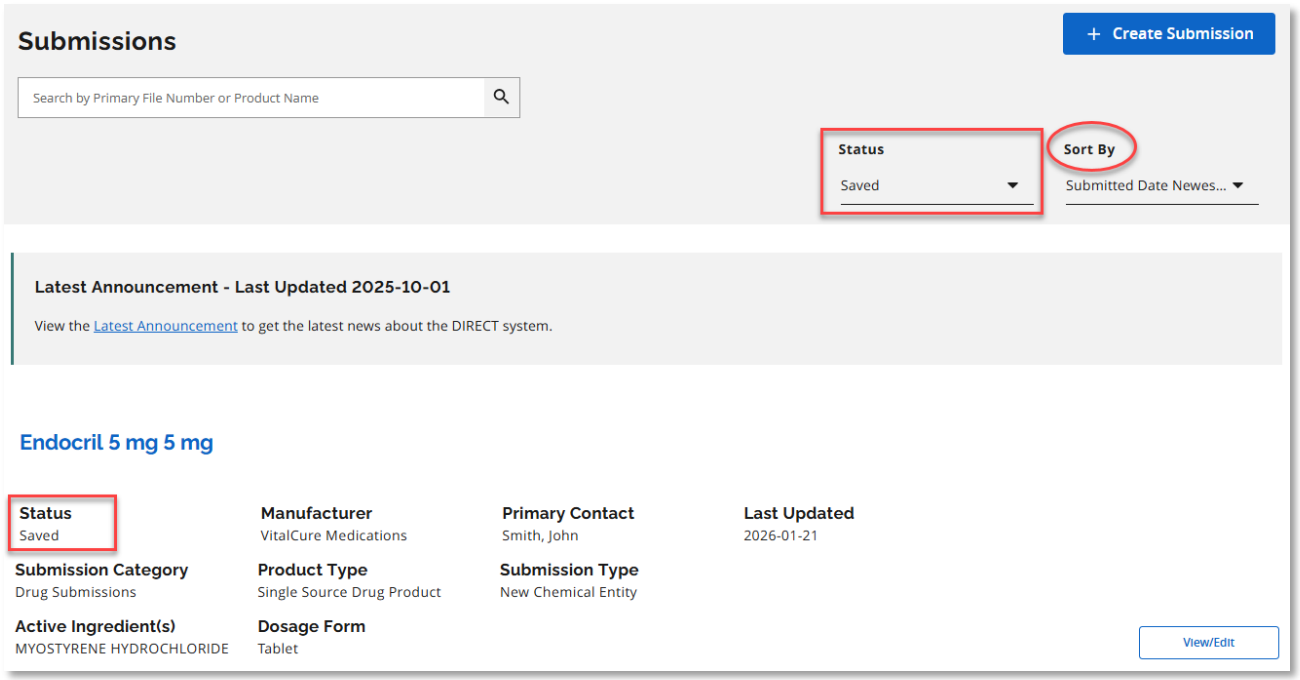


Figure 128 – Screenshot of the Status Filter Returned Results

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.

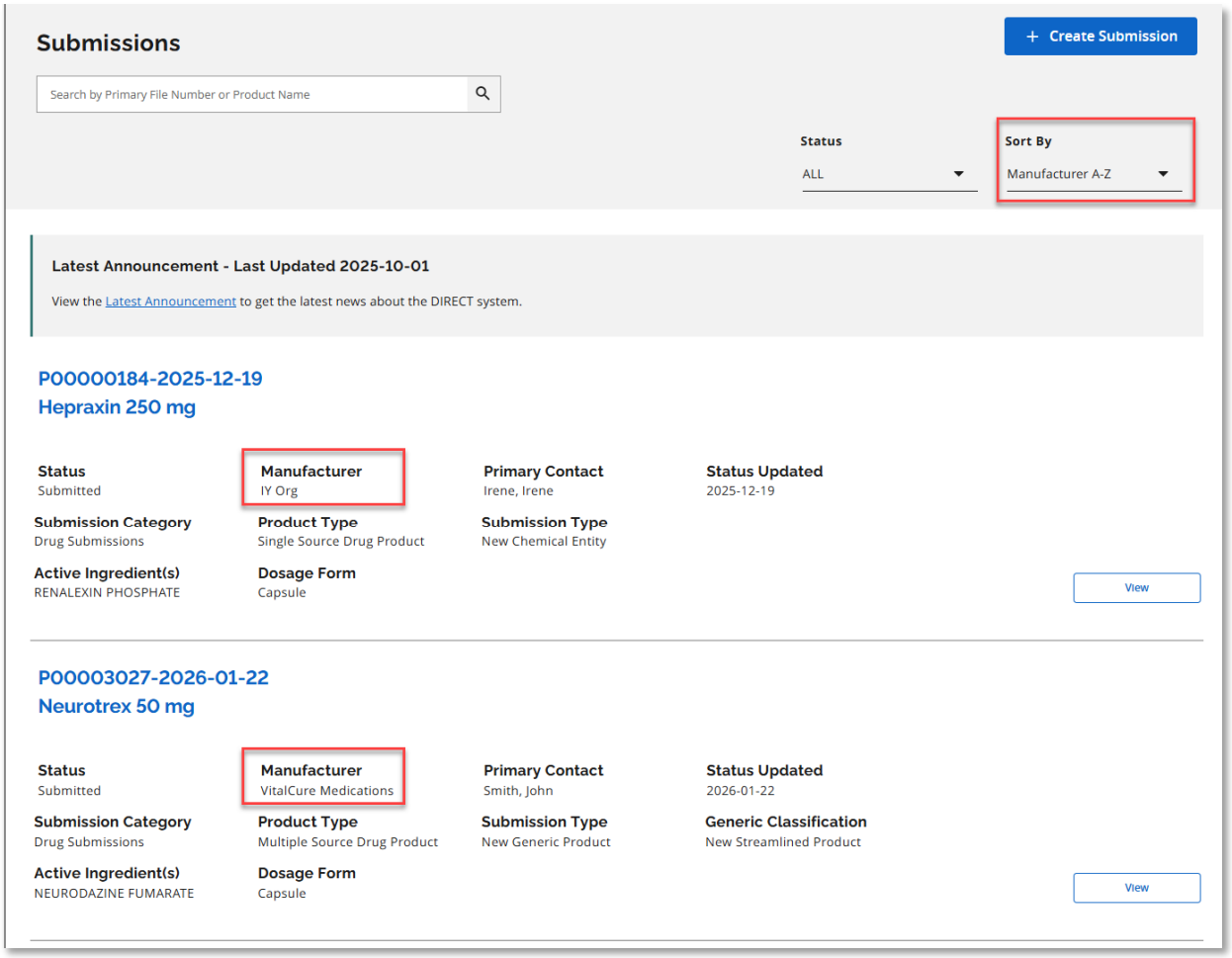


Figure 129 – Screenshot of the Sort by Filter Returned Results

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.

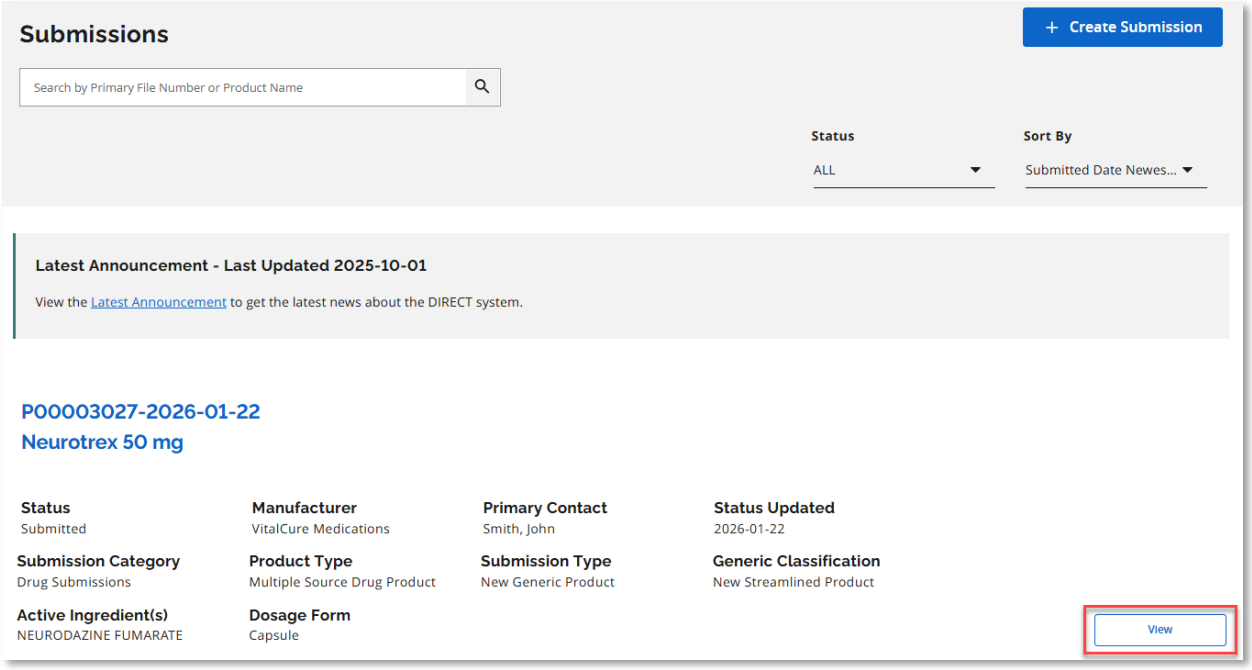


Figure 130 – Screenshot of the Submissions List

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.

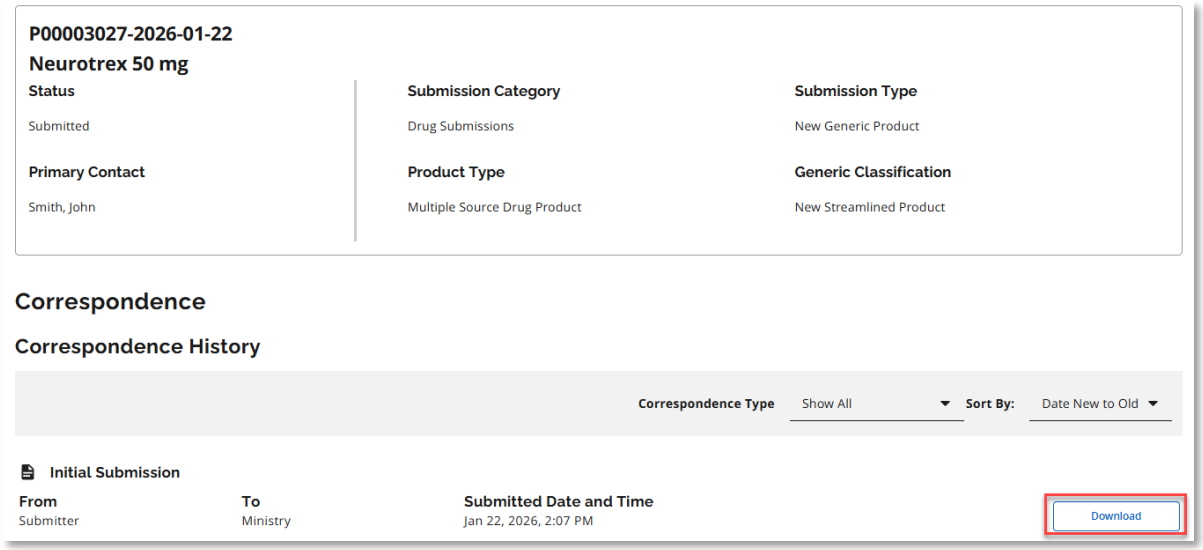


Figure 131 – Screenshot of the Submission Details screen

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

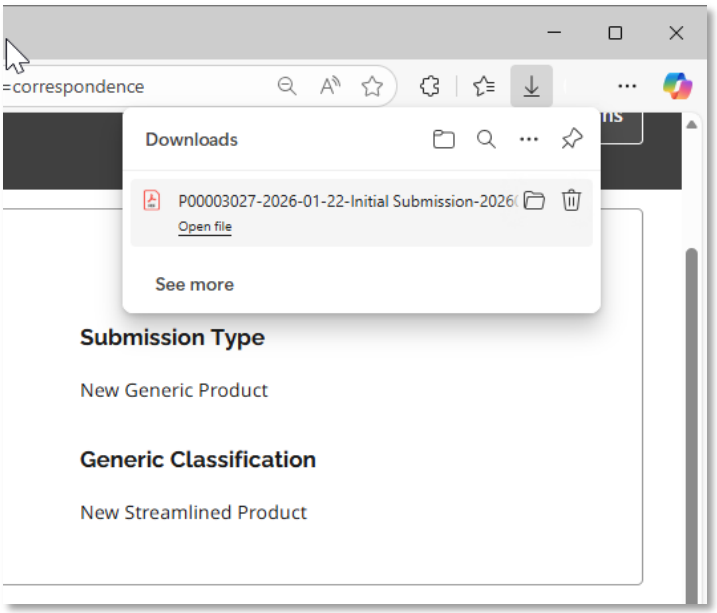


Figure 132 – Screenshot of the File Download

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

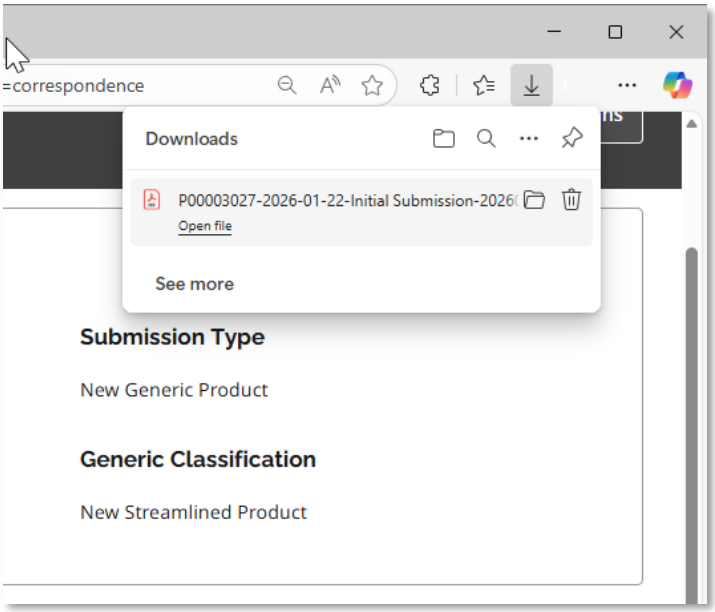
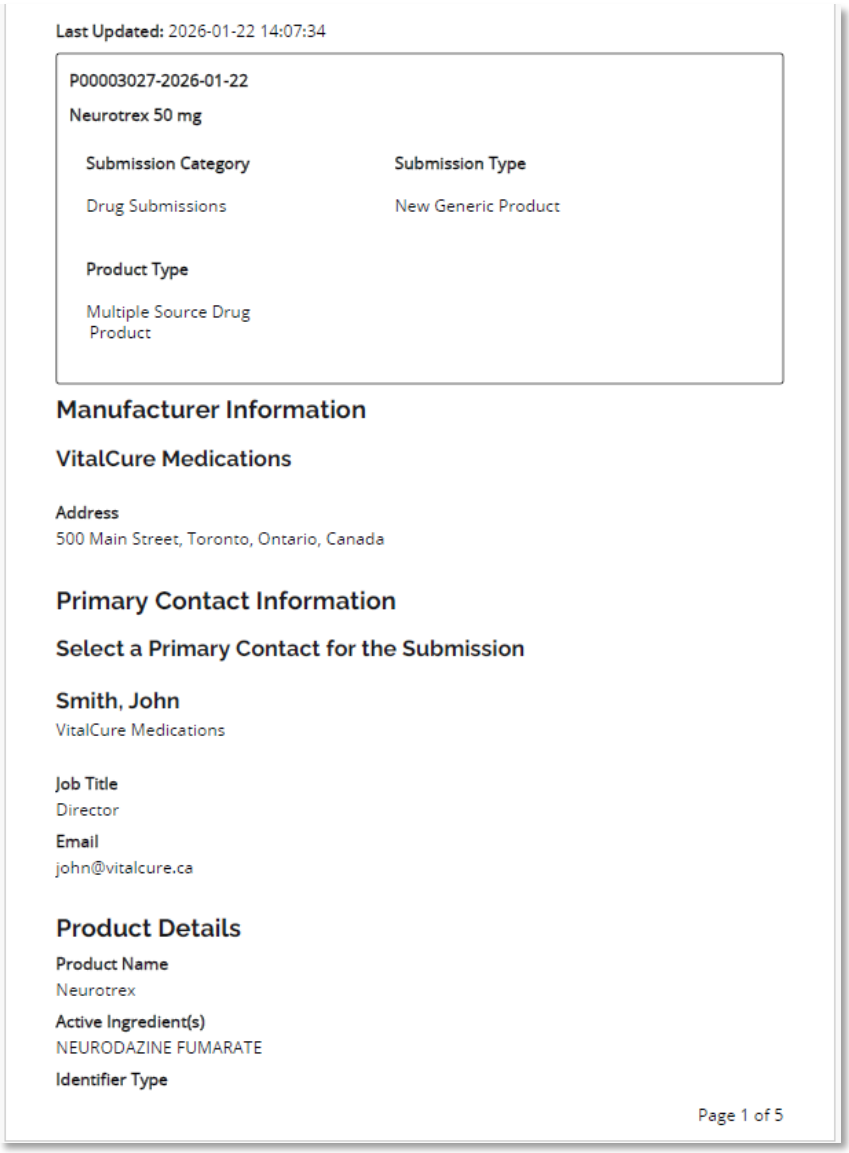


Figure 133 – Screenshot of the File Download

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

Drug Submissions

Submission Type

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.