

AMENDMENT APPLICATION FOR IMPORTER'S LICENCE FOR ACTIVE INGREDIENTS

Please note that companies must register with Client Registration and Identification Service (CRIS) and applicants must have valid CRIS user rights to submit applications on behalf of the company via apply@prism. For more information on CRIS, please refer to https://www.hsa.gov.sg/e-services/cris

The following amendments do not require submitting amendment application via this module:

- Amendment to change company's particulars such as company name and address has to be made via the "Amend Company Information" module.
- Amendment to change applicant's particulars such as name and contact details has to be made via the "Amend Applicant's Details for Licences and Applications" module.
- Both "Amend Company Information" and "Amend Applicant's Details for Licences and Applications" modules can be accessed at https://www.hsa.gov.sg/e-services/prism#AmendLicence.
- Please note that Importer's Licence granted for full scope activity is not allowed to be changed to restricted activity, and vice versa. For this case, you need to cancel the existing licence and submit a new application for new licence.
- 1. The online form may take an average of 10 minutes to fill in. The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network, internet performance, etc. Please note that the time stated above excludes the time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).
- 2. The following information/item(s) are required to complete the form:
 - (A) **Current layout plan for the premises**, specifying the storage area(s) (Mandatory) The layout floor plan will need to have the following information:
 - (i) The full address of the warehouse
 - (ii) The dimensions (length and width) of the warehouse
 - (iii) Indication of various storage areas, e.g. receiving bay, quarantined products area, released products area, rejected products area, returned products area, recalled products area, outgoing staging area, etc.
 - (B) **Pharmacist Practising Certificate** (applicable for a Responsible Person who is a pharmacist registered with the Singapore Pharmacy Council)
 - (C) List of Active Ingredient(s) handled by the company
 - (D) Standard Operating Procedures[^]
 - (E) Records or Recording Templates^

^Note: Documents should be prepared in accordance with the requirements stipulated in the <u>HSA Guidance Notes on Good Distribution Practice</u>

3. The applicant will require a Corppass* or Singpass before he/she can login to PRISM to retrieve the application form. A person who drafts an application on behalf of his/her company and is not a Singaporean Citizen, Permanent Resident or Employment Pass holder can apply for a



HSA PIN to login to PRISM. The Corppass* / Singpass or HSA PIN login is necessary for authentication and authorisation purposes.

*Note: From 11 April 2021, the login process for Corppass has been changed to verify the user's identity via Singpass first before accessing and transacting with government digital services. While Singpass is used for logins, Corppass will continue to be the authorisation system for access to government digital services.

For more information on Corppass, please refer to http://www.corppass.gov.sg/

4. Mode of payment

Please note that there will be no refund of any payment made in relation to applications submitted through PRISM.

The mode of payment available is as follows:

- GIRO (Preferred mode of payment)
- Non-GIRO: eNETS (Credit/Debit Card)

Payment by GIRO requires pre-registration. The <u>GIRO application form</u> is required to be submitted by post to the HSA Finance Department. The correspondence address can be found in the application form. The registration process will take around 3 to 4 weeks after the submission of the application form.



Amendment Application Form for Active Ingredients Importer's Licence

Fields marked with an asterisk * are mandatory.

This section allows the search for the Importer's Licence to be amended.

- (1) Select the **Licence Type** (Active Ingredients Importer's Licence).
- (2) Enter the **Licence Number** to be amended and click **'Search'** button. When the result is displayed, click **'Amend'** for the licence to be amended.

Important Notes: For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices. Search Criteria Licence/Permit/Certificate/Listing/Notification/Registration Select Licence Type V Type * Licence/Permit/Certificate/Listing/Notification/Registration No Product Name Search Reset Please do not create amendment application using the new window via right mouse click. 1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last] Active Pharmacy Licence S/No Licence No Start Date Expiry Date Action 1 Please do not create amendment application using the new window via right mouse click. 1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Part 1. Licence/Permit/Certificate/Listing Summary

The applicable Licence No., the start and expiry dates of the existing licence will be pre-populated.

This section requires the applicant to verify and fill in the following information.

(1) Amendment Details

PZ4001 AMEND@PRISM

Please provide the reason for the amendment in this entry.

(2) Technical assessment

The applicant is required to indicate if the amendment requires technical assessment.

Please find below some examples of amendments that require technical assessment and examples of amendments that do not require technical assessment.

(3) Click on **Next** button to go to the **Company Particulars** section.



1. Licence/Permit/Certificate/Listing Summary	
1.7 Licence/Permit/Certificate/Listing No.:	
1.2 Start Date:	
1.3 Expiry Date:	
1.4 Amendment Details:	
to the guidelines, available at the top	t requires technical assessment t does not require technical assessment
Examples of amendments that require technical assessment: • Inclusion of new warehouse or change in location/address of current warehouse for the	Examples of amendments that do not require technical assessment: Deletion of existing warehouse Addition or deletion of aspect of importation
 storage of active ingredients Inclusion of new storage conditions (e.g. Cold chain) to the warehouse 	Addition or deletion of Responsible Person While the aforementioned generally do not require technical assessment, the authority reserves the right to make the final decision and technical assessment may be required.

Note: For companies submitting amendment applications that require technical assessments for both Active Ingredients Importer's Licence (IL) and Active Ingredients Wholesaler's Licence (WL) concurrently, choose the option "This amendment requires technical assessment" for only one licence and select "This amendment does not require technical assessment" for the other licence.

If you are in doubt or encounter a situation which is not found in the above lists of examples, please contact us before submission.



Part 2. Company's particulars

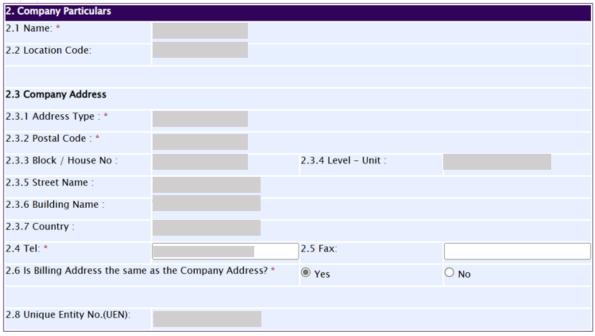
(1) The company name and address will be pre-populated based on the registered CRIS records. If you need to make changes to this information, please submit the change via the "Amend Company Information" module.

Input the information of Tel and/or Fax.

- (2) Indicate if the Billing Address is the same as Company Address.
- (3) If the Billing Address is not the same as Company Address, fill in the postal code and click on the **Retrieve Address** button. The Block/House No, Street Name and Building Name will be populated on screen. Fill in **Level-Unit** information if applicable. Fill in the other details.
- (4) Click on the **Next** button to go to the **Applicant Particulars** section.

Fields marked with an asterisk * are mandatory.

Please note that the billing address entered/amended will be updated to the central client database and will be used as the billing address for any subsequent billing to the company. This will apply to all other licenses/applications of the company.



Part 3. Applicant Particulars

This section requires the applicant to verify and fill in any other relevant information relating to the applicant particulars.

(1) Applicant details such as name, NRIC / FIN, designation, Telephone/Fax/Handphone number and e-mail address will be pre-populated based on the registered CRIS records.

If you need to makes changes to this information, please submit the changes via the "Amend Applicant's Details For Licences and Applications" module under the amend@prism on PRISM e-Service webpage.



(2) Select the type of Preferred Contact Mode

(Note: Please ensure that the relevant contact details above are entered for your preferred contact mode. Please note that the preferred contact mode is the mode which you will receive the final notification of this application.)

(3) Click on the **Next** button to go to the **Warehouse Particulars** section.

Fields marked with an asterisk * are mandatory.

3. Applicant Particulars				
3.1 Name: *		(as	s in NRIC/FIN)	
3.2 NRIC/FIN: *	(Example: S1234567A, F1234567A)			
3.3 Designation: *				
3.4 Contact Details				
3.4.1 Tel: *		3.4.2 Fax:		
3.4.3 Handphone:		3.4.4 Pager:		
3.4.5 Email:				
3.5 Preferences				
3.5.1 Preferred Contact Mode:	(Please ensure that the relevant of this preferred contact mode is the	e mode which you will rece ill receive our input reques	eive the final notifi sts (i.e. queries), if	erred contact mode. Please note that cation of this application. During the any, via email if you have indicated e.)

Part 4. Warehouse Particulars

This section requires the applicant to fill in the following information if there is an amendment to the warehouse particulars. Otherwise, please do not amend any details in this section.

Add new warehouse(s)

(1) Fill in Postal Code and click Retrieve Address.

The Block/House No, Street Name and Building Name will be populated on the screen.

- (2) Fill in **Level-Unit** information (if applicable) and any additional details relating to the premises in the **other address details** field (if applicable).
- (3) Fill in the Storage Condition of Warehouse.
- (4) Fill in **Approved By** information.
- (5) Click on the Add Warehouse button.

The screen will be automatically refreshed and the refreshed screen will display the warehouse particulars that were added.

- (6) Repeat steps (1) to (5) to add other warehouse(s) information.
 - Addresses of all warehouses where the products will be stored should be provided.
- (7) Click on the **Next** button to go to **Importer's Licence** section.



Update Warehouse(s)

- (1) Click on the warehouse requiring amendment from the **Warehouse List** table.
- (2) Make the required changes.
- (3) Click on the Update Warehouse button.

Remove Warehouse(s)

- (1) Click on the checkbox adjacent to the warehouse(s) from the Warehouse List table.
- (2) Click on the **Remove** button to delete the warehouse(s).

Fields marked with an asterisk * are mandatory. 4. Warehouse Particulars 4.1 Warehouse Address 4.1.1 Address Type: * Local 4.1.2 Postal Code: * 4.1.3 Block / House No: 4.1.4 Level - Unit: 4.1.5 Street Name: 4.1.6 Building Name: 4.1.7 Other address details: (To input specific identification number for the warehouse which is not reflected above, e.g. for address of 1, ABC Road, #01-01, XYZ Building, Annex A, SINGAPORE 123456, 'Annex A' can be entered in the 'Other Address Details') 4.1.8 Country: SINGAPORE 4.2 Storage Condition of Warehouse 4.2.1 Temperature: * Cold Chain (Not more than 8°C) ■ Non Cold Chain (Above 8°C) 4.2.1.1 Actual Temperature 15°C to 30°C (Room Temperature) Range: 8°C to 15°C (Cool) 2°C to 8°C (Refrigerate, Do not freeze) -10°C to -20°C (Freeze) Others 4.2.2 Relative Humidity (Cold Min % - Max % Chain): 4.2.3 Relative Humidity (Non Min % - Max 96 Cold Chain): 4.2.4 Approved By: Select One ✓ 4.3 This warehouse is Active Ingredients – Importers Licence applicable for: * Active Ingredients – Wholesalers Licence Add Warehouse Approved SN Select All Address of Warehouse Storage Relative Applicable Condition Humidity Licence(s) Remove



Part 5. Importer's Licence Details

This section requires the applicant to fill in the following information if there is an amendment to the aspect of importation. Otherwise, please do not amend any details in this section.

Amend Aspect of Importation

Select Aspect of Importation.

If the existing Active Ingredients IL is for full scope, you are not allowed to change to limited scope, and vice versa. For this case, you need to cancel the existing licence and submit a new application for a new licence.

- (1) Select Aspect of Importation.
- (2) Click on the **Next** button to go to the **Responsible Person** section.

5. Importers Licence Details	t - are mandatory.
5.1 Aspect of Importation: *	☐ Active Ingredients supplied for the manufacture of therapeutic product, CTGT product or medical device intended for any application of or use by humans in Singapore ☐ Active Ingredients solely for export
	☐ Active Ingredients imported for purposes other than in the manufacture of therapeutic products, cell, tissue or gene therapy products, or medical devices
	☐ Active Ingredients imported for manufacturing of therapeutic products, cell, tissue or gene therapy products, or medical devices, for non-clinical purposes
	Other specific activity

Part 6. Responsible Person

This section requires the applicant to fill in the following information if there is an amendment to the Responsible Person appointed by the company. Otherwise, please do not amend any details in this section.

Add Responsible Person(s)

- (1) Fill in the details of the **Responsible Person** and contact information.
- (2) If more than 1 Responsible Person is appointed by your company and the Responsible Persons are in charge of the GDP aspects for different Division, site, etc., you can input the relevant information into the field of "Scope". This portion may also be left empty if there is no differentiation of scope and duties of the Responsible Person.
- (3) Click on the **Add Responsible Person** button.

The screen will be automatically refreshed and the refreshed screen will display the Responsible Person particulars that were added.

- (4) Repeat steps (1) to (3) to add other responsible person(s) information.
- (5) Click on the Next button to go to Supporting Attachments section.

Update Responsible Person(s)

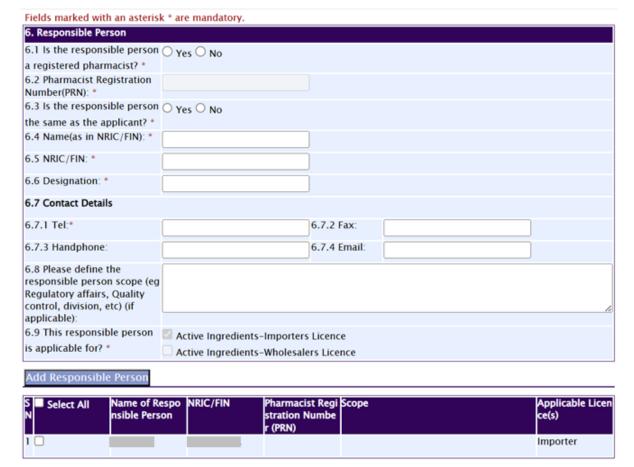
- (1) Click on the Responsible Person required amendment from the **Responsible Person List** table.
- (2) Make the required changes.



(3) Click on the **Update** button.

Remove Responsible Person(s)

- (1) Click on the checkbox adjacent to the Responsible Person from the **Responsible Person List** table.
- (2) Click on the **Remove** button to delete the Responsible Person.



Part 7. Supporting Attachments

This section allows the attachment of the supporting documents for the application.

Add Attachment

- 1) Click 'Choose File' button to select the required file for attachment.
- Select the required file.
- 3) Click 'Open' button in the pop-out window.
- 4) Click on the 'Attach File' button for the file to be attached to this application.
- 5) Fill in the remarks in the 'Remark' field with regards to the file attached (if required).
- 6) Repeat steps (1) to (5) to add other documents. All supporting documents should be provided.



Remove Attachment

- 1) Click on the checkbox beside the attachment or attachments from the List of Attachments table.
- 2) Click on the 'Remove' button to delete the attachment.

The file extensions, which are acceptable and supported for attachments, are:

- tif (Black & White)
- jpg (graphics files)
- pdf (Adobe Acrobat files)
- doc (Microsoft Word files)
- xls (Microsoft Excel files)
- ppt (Microsoft Powerpoint files)
- avi (audio visual, if required)
- mpeg (audio visual, if required)

Note:

If the file size is big (estimate about 2MB and above), the uploading time may be longer.

Documents to be submitted	Applicable for amendments to be made
Current Store layout plan for premise(s) specifying storage area(s)	Yes, for addition of a new warehouse or change in location/address of current warehouse
Pharmacist Practising Certificate	Yes, for addiction of a new Responsible Person or change of the current Responsible Person to a new person who is a pharmacist
List of Active Ingredients handled by the company	Optional
Safety Data Sheet of the Active Ingredients handled by the company	Optional
GDP Operating Procedures	Optional
GDP Records or Recording Templates	Optional
Store Approval Letter	Optional



7. Supporting Documents To add an attachment, type in the path or hit the browse button. Then hit the Attach Files button to save the attachment to the list below. Please click here for guideline on document attachment. Documents 7.1 Store Layout Plan Choose File No file chosen 7.2 Pharmacist Practising Choose File No file chosen Certificate (applicable for responsible person who is a registered pharmacist) 7.3 List of Active Ingredient(s) han Choose File No file chosen dled by the company 7.4 Material Safety Data Sheet or Choose File No file chosen Safety Data Sheet of the Active Ingredient(s) handled by the company 7.5 Good Distribution Practice Stan Choose File No file chosen dard Operating Procedures 7.6 Good Distribution Practice Choose File No file chosen Records or Recording Templates 7.7 Store Approval Letter Choose File No file chosen 7.8 Other Supporting Documents: Choose File No file chosen Attach Files Supporting Attachments previously submitted with corresponding New or Amendment application Sn Attachment Name Attachment Type Size (Kb) Remarks

Part 8. Confirmation

Fields marked with an asterisk * are mandatory.

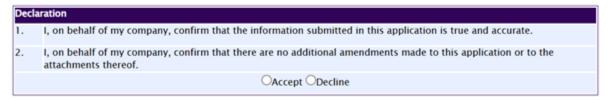
Once all the relevant sections are completed the confirmation page would display all the information from the sections earlier. Click **Validate** to check if all fields are filled up correctly.

Alternatively you may select **Save** to save a copy of the draft application if you wish to complete the application at a later time.

Part 9. Declaration

After validation is successful, you can read through the declaration section carefully before accepting to undertake the conditions. Then click **Submit**.

All applicants under the Health Product Act (HPA) must comply with HPA and their regulations. This is to ensure that all active ingredients in Singapore meet the required standards. Applicants must also comply with all other applicable laws and their regulations.

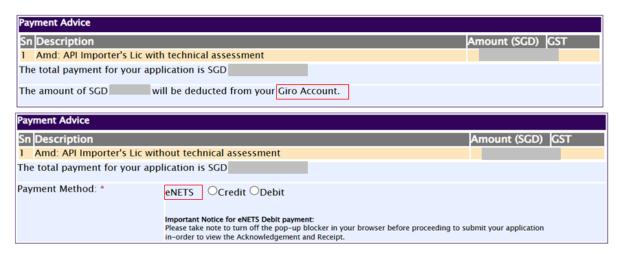




Payment Advice

This section shows the application fee for the licence applied. There are 2 modes of payment available:

- GIRC
- Non-GIRO: eNETS (Credit/Debit Card)



For eNETS payment, please choose the applicable (Credit or Debit). The page will be re-directed to the relevant screen for the applicant to make payment.

If the payment made via eNETS is not completed successfully, the applicant will need to contact HSA HelpDesk (contact information on final page) for assistance.

Acknowledgment

This section acknowledges that the application has been submitted to HSA for processing. An application number will be generated for the application.

PQ1001 AMENDMENT OF ACTIVE INGREDIENTS - IMPORTER'S LICENCE

Acknowledgement	
Your application have been successfully submitted	
Please note that your licence applied is Active Ingredients – Importers Licence Only	
Please note that your application number is	
Client Code : Licensee Name Amount :	

You may wish to print a copy of this acknowledgement page or take note of the application number for ease of reference. You also need to provide the application number if you wish to communication with HSA.



Input Request

This section illustrates how the applicant can respond to an Input Request raised to the application.

An Input Request arises when the reviewing HSA officer requires further clarification from the applicant regarding the Importer's Licence Amendment Application Form.

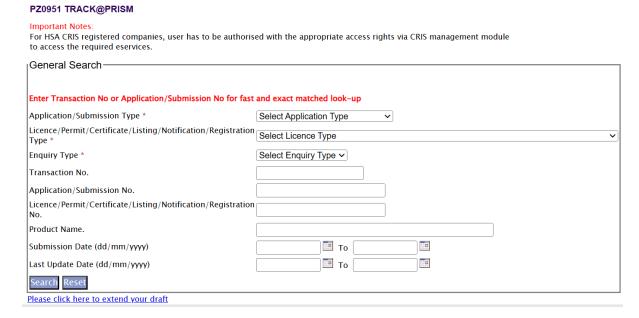
A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

Input request can be classified as Primary or Secondary.

- Primary Input Request requires changes to be made directly in the application form.
- <u>Secondary Input Request</u> requires applicant's explanation to certain matters pertaining to the application form submitted.

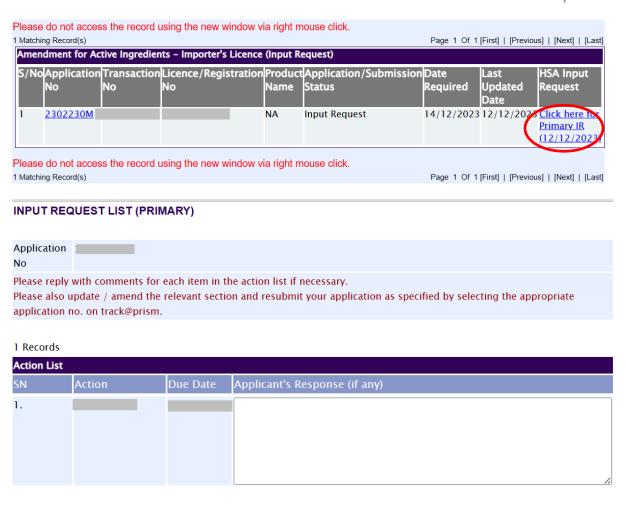
Responding to Primary Input Request

(1) Log on to track@prism. Enter the mandatory fields of 'Application/Submission Type', 'Licence/Permit/Certificate/Listing/Notification/Registration Type', 'Enquiry Type' and any other information relating to the application. Click the 'Search' button.



(2) Click on the 'HSA Input Request' to view if any reply is required from the applicant. Click the 'Submit' button and an alert message will pop up to prompt you to make the necessary changes in the application form.





(3) Click on the 'Application No.' to make changes directly on the Importer's Licence Amendment Application for response to Primary Input Request.



(4) The webpage will display the application form as per previously submitted.

Effective Date: 18 December 2023

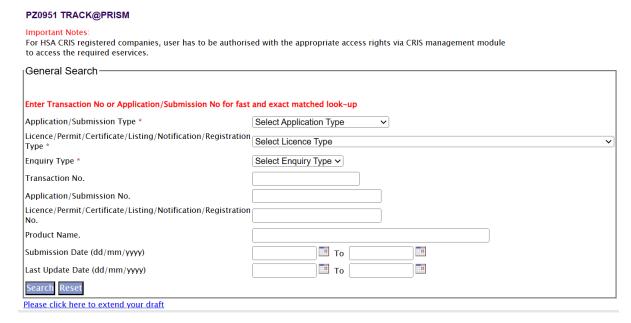
Cancel



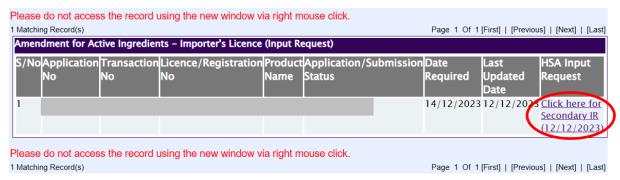
(5) Proceed to make the necessary changes for the section(s) that required amendment and submit the revised application form.

Responding to Secondary Input Request

(1) **Enter** the **Application Number** of the Importer's Licence Application to retrieve the application that requires amendment to the submitted information in track@prism.



(2) Click on the 'HSA Input Request' to view the comments left by the HSA officer and the necessary action to be taken with regards to the Importer's Licence Amendment Application.



(3) Fill in any response in the text box for response to Secondary Input Request and click the 'Submit' button.



INPUT REQUEST LIST (SECONDARY)



Other useful information

1. You may check on the status of your application upon submission at track@prism.

2. Kindly contact the HSA Helpdesk if you encounter any technical issues (IT problems) during the application submission, or any enquiry relating to the CRIS account.

HSA HelpDesk

Hotline: 6776 0168 (from 7:00 am to midnight daily)

Email: helpdesk@hsahelp.gov.sg

3. For general enquiries or questions related to the importation and wholesaling of TP, please contact the Audit and Licensing Division.

Audit & Licensing Division

Tel: 6866 1111

Email: hsa_gdp@hsa.gov.sg