AMENDMENT APPLICATION FOR WHOLESALER'S LICENCE FOR THERAPEUTIC PRODUCTS

Please note that companies must register with Client Registration and Identification Service (CRIS) and applicants must have valid CRIS user rights in order to be able to submit applications on behalf of the company via amend@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/therapeutic-products

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 premise(s),** 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 product area, released product area, rejected product area, returned product area, recalled product area, outgoing staging area, etc.
    (B) **Authorisation Letter from Product Registrant** (Mandatory for products not registered under your company)
    (C) **Pharmacist Practising Certificate** (applicable for a Responsible Person who is a pharmacist registered with Singapore Pharmacy Council)
    (D) **Good Distribution Practice (GDP) Standard Operating Procedures**
    (E) **Good Distribution Practice (GDP) Records or Recording Templates**

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:

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

Payment by GIRO requires pre-registration. The GIRO application form 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.

Application Form

Fields marked with an asterisk * are mandatory.

This section allows the search for the licence to be amended.

(1)   Select the **Licence Type** (Therapeutic Products Wholesaler's Licence).
(2)   Enter the **Licence Number** and click **'Search'** button.
      When the search result is displayed, click **Amend**.

PZ4001 AMEND@PRISM

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 Type *	Select Licence 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				Amend

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 effective 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**

      Please provide the reason for the amendment in this entry.

(2)   **Site Inspection**

      The applicant is required to indicate if the amendment requires site inspection.

      Please find below some examples of amendments that require site inspection and examples of amendments that do not require site inspection.

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

1. Licence/Permit/Certificate/Listing Summary

1.1 Licence/Permit/Certificate/Listing No.:	
1.2 Start Date:	
1.3 Expiry Date:	
1.4 Amendment Details:	
1.5 Site Inspection (Please refer to the guidelines, available at the top right hand corner, before selection):	⦿ This amendment requires site inspection ○ This amendment does not requires site inspection
1.7 Licence Type	
1.7.1 Wholesaler: *	Term (Annual)
1.8 Licence Duration	
1.8.1 Wholesaler:	1 Year

Next   Reset

Examples of amendments that require site inspection:
- Inclusion of new warehouse or change in location/address of current warehouse for the storage of therapeutic products
- Inclusion of new storage conditions (e.g. Cold chain) to the warehouse

Examples of amendments that do not require site inspection:
- Deletion of existing warehouse
- Addition or deletion of aspect of wholesaler dealing
- Addition or deletion of forensic classification of products to be sold by wholesale
- Addition or deletion of Responsible Person

While the aforementioned generally do not require site inspection, the authority reserve the right to make the final decision and site inspection may be required.

Note: For companies submitting amendment applications that require site inspection for both Therapeutic Products Importer's Licence (TPIL) and Therapeutic Products Wholesaler's Licence (TPWL), choose the option 'This amendment requires site inspection' for one licence and 'This amendment does not require site inspection' for the other licence.

Examples for Company holding TPIL and TPWL

1.5 Site Inspection (Please refer to the guidelines, available at the top right hand corner, before selection):	⦿ This amendment requires site inspection ○ This amendment does not requires site inspection	Therapeutic Products Importer's Licence

1.5 Site Inspection (Please refer to the guidelines, available at the top right hand corner, before selection):	○ This amendment requires site inspection ⦿ This amendment does not requires site inspection	Therapeutic Products Wholesaler's 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 **'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 **'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 licences/applications of the company.

2. Company Particulars			
2.1 Name: *	Auto Populated		
2.2 Location Code:	1		
2.3 Company Address			
2.3.1 Address Type: *	Local		
2.3.2 Postal Code: *	Auto Populated		
2.3.3 Block / House No:	Auto Populated	2.3.4 Level – Unit:	Auto Populated
2.3.5 Street Name:	Auto Populated		
2.3.6 Building Name:	Auto Populated		
2.3.7 Country:	SINGAPORE		
2.4 Tel: *		2.5 Fax: Your Fax No. is necessary for our future correspondence	
2.6 Is Billing Address the same as the Company Address? *	● Yes	○ No	
2.8 Unique Entity No.(UEN):	Auto Populated		

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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.

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 at 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.

(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 **'Next'** button to go to **Wholesaler's Licence** section.

Update Warehouse(s)

(1) Click on the warehouse required amendment from the **Warehouse List** table.

(2) Make the required changes.

(3) Click **'Update Warehouse'** button.

Remove Warehouse(s)

(1) Click on the checkbox adjacent to the warehouse(s) from the **Warehouse List** table.

(2) Click **'Remove'** button to delete the warehouse(s).

Part 5. Wholesaler's Licence Details

This section requires the applicant to fill in the following information if there is an amendment to the products to be imported by the company. Otherwise, please do not amend any details at this section.

(1)   Select **Aspect of Wholesaler Dealing**.

      If 'Registered Therapeutic Products' is selected, proceed to (2). Otherwise, proceed to (3).

(2)   Select **Forensic Classification of Registered Products**.

(3)   Click **'Next'** button to go to the **Responsible Person** section.

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 at this section.

Add Responsible Person(s)

(1)   Fill in the details of the **Responsible Person** and contact information.

      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 RP

(2)   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.

(3)   Repeat steps (1) to (2) to add other responsible person(s) information.

(4)   Click **'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 **'Update'** button.

Remove Responsible Person(s)

(1)   Click on the checkbox adjacent to the Responsible Person from the **Responsible Person List** table.

(2)   Click **'Remove'** button to delete the Responsible Person.

For more information on Responsible Person, please refer to the <u>Guidance Notes on Duties of Responsible Persons Named In The Importer's Licence and Wholesaler's Licence</u> and Frequently Asked Questions (FAQ) for Responsible Person. These should be read in conjunction with the <u>Health Products (Therapeutic Products) Regulations 2016</u>.

Fields marked with an asterisk * are mandatory.

6. Responsible Person	
6.1 Is the responsible person a registered pharmacist? *	○ Yes ○ No
6.2 Pharmacist Registration Number(PRN): *	
6.3 Is the responsible person the same as the applicant? *	○ Yes ○ No
6.4 Name(as in NRIC/FIN): *	
6.5 NRIC/FIN: *	
6.6 Designation: *	

6.7 Contact Details

6.7.1 Tel:*		6.7.2 Fax:	
6.7.3 Handphone:		6.7.4 Email:	

6.8 Please define the responsible person scope (eg Regulatory affairs, Quality control, division, etc) (if applicable):	
6.9 This responsible person is applicable for? *	☐ Therapeutic Products–Importer's Licence ☑ Therapeutic Products–Wholesaler's Licence

Add Responsible Person

SN	☐ Select All	Name of Responsible Person	NRIC/FIN	Pharmacist Registration Number (PRN)	Scope	Applicable Licence(s)
1	☐					Wholesaler

Remove

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Part 7. Supporting Documents

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.

(2) Select the required file.

(3) Click **'Open'** button in the pop-up window.

(4) Click **'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 Step (1) to (5) to add other documents. All supporting documents should be provided.

(7) Click **'Next'** button to proceed to **Confirmation and Declaration** section.

Remove Attachment

(1) Click on the checkbox beside the attachment or attachments from the **List of Attachments** table.

(2) Click **'Remove'** button to delete the document.

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

- tif (Black & White)
- pdf (Adobe Acrobat files)
- xls (Microsoft Excel files)
- avi (audio visual, if required)
- jpg (graphics files)
- doc (Microsoft Word files)
- ppt (Microsoft PowerPoint files)
- 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 addition of a new Responsible Person or change of the current Responsible Person to a new person who is a pharmacist
List of product to sell by wholesale	Optional
GDP Operating Procedures	Optional
GDP Records or Recording Templates	Optional
Store Approval Letter	Optional

denotes mandatory items

Part 8. Confirmation

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.
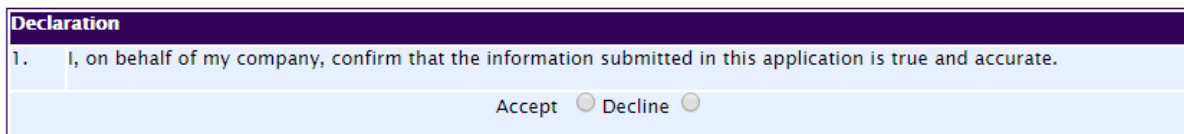
Part 9. Declaration

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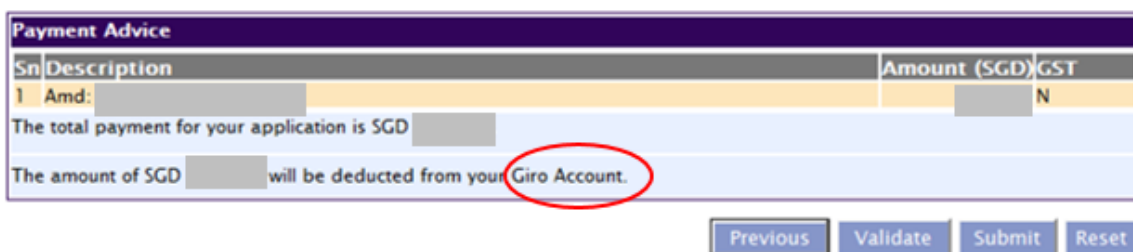
Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO (deducted from the relevant bank account)

- eNETS (Credit Card or Debit Card)
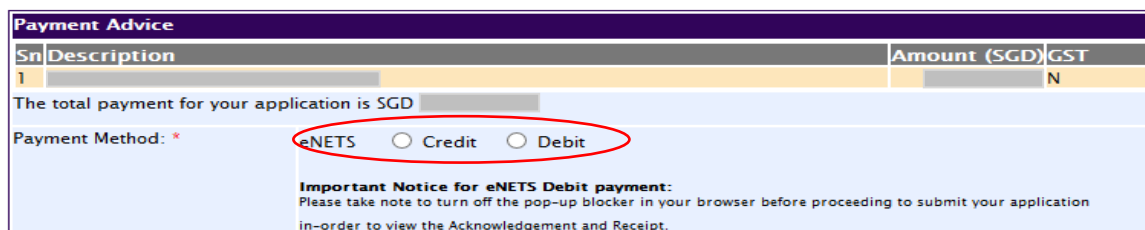
or

If the eNETS option is selected and then the Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.

If the eNETS option is selected and then the Debit option is selected, the page will be re-directed to the relevant screen for the applicant to select the bank first before being re-directed to input the debit card details.

Upon successful transaction, an eNETS official receipt and a HSA tax invoice will be generated.

If the payment was made via eNETS and was not completed successfully, the system will prevent retrieval of the draft application and the applicant will need to contact HSA HelpDesk for assistance.

To submit the completed application, click the **'Submit'** button. Applicant will be prompted to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

Acknowledgment

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

Applicant may wish to print a copy of this acknowledgement page or take note of the application number for ease of reference. Applicant may provide the application number if he/she wishes to communicate with HSA.

Note: Applicant can click 'Show Printer-Friendly version' to print or view the application.

Input Request

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

Input Request arises when the reviewing HSA officer requires further clarification from the applicant regarding the Application Form.
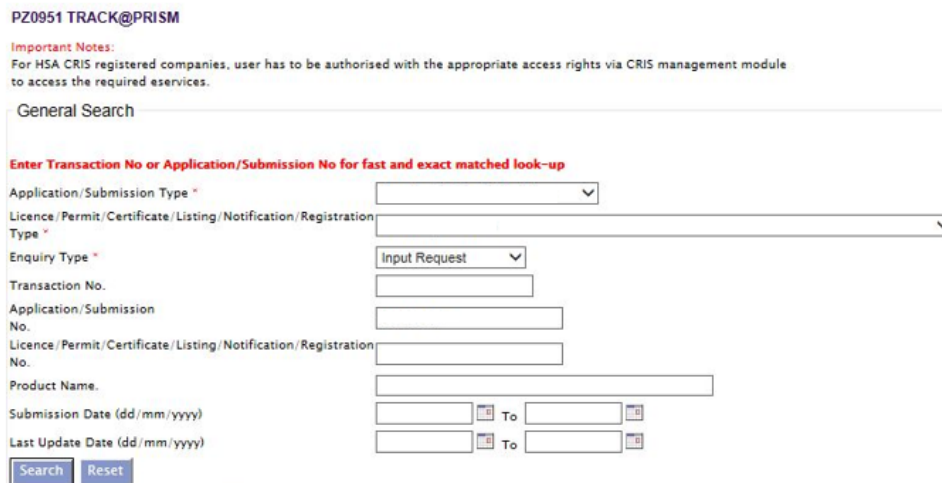
A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

Input request can be classified as Primary or Secondary.

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

Responding to Primary Input Request

(1) Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click **'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. When the search result is displayed, click the 'Application No.'

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

(4) Proceed to make the necessary changes for the section(s) that required amendment, click **'Save'** button and submit the revised application form.

Responding to Secondary Input Request

(1)   Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click **'Search'** button.

(2)   When the search result is displayed, click under the 'HSA Input Request' to view the comments left by the HSA officer and the necessary action to be taken with regards to the Application.

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

Other useful information

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

2. Kindly contact the HSA Helpdesk if any technical issues (IT problems) during the application submission are encountered.

    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 licences and certificates of manufacturers, importers and wholesalers, please contact the Audit and Licensing Division at Tel: 6866 1111.