

AMENDMENT APPLICATION FOR IMPORTER'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
- 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 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.

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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 <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.

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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 Importer'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 $Licence/Permit/Certificate/Listing/Notification/Registration \\ \boxed{Select\ Licence\ Type}$ ~ 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. Page 1 Of 1 [First] | [Previous] | [Next] | [Last] 1 Matching Record(s) Active Pharmacy Licence Amend Please do not create amendment application using the new window via right mouse click. 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.

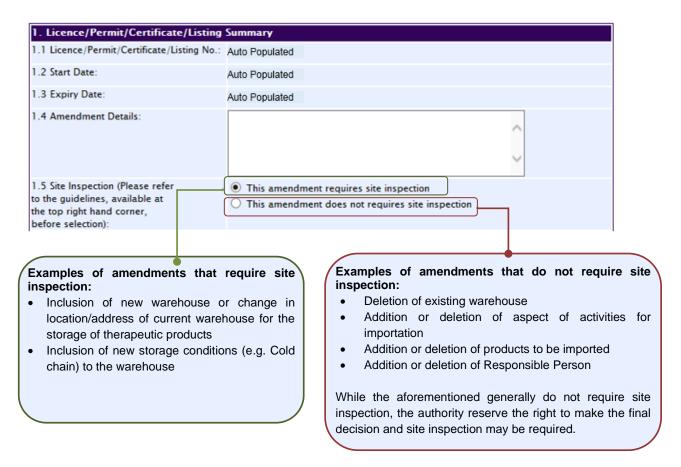
(2) Site Inspection

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.

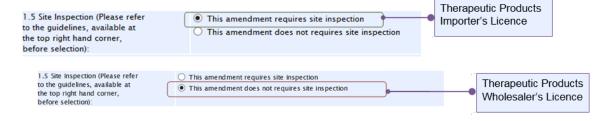
(3) Click on 'Next' button to go to the Company Particulars section.





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



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

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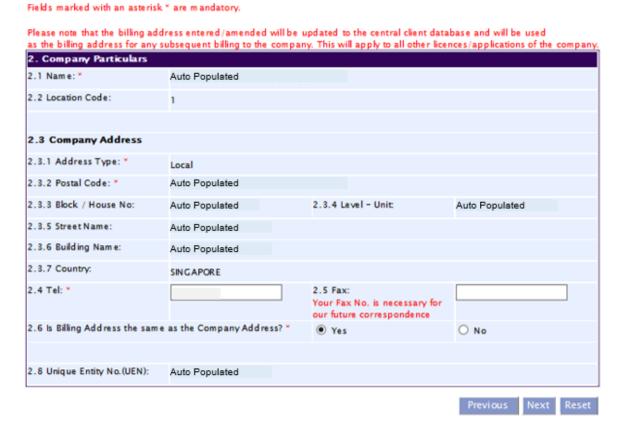


Part 2. Company's particulars

(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 under the amend@prism on PRISM e-Service webpage.

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 'Next' button to go to the Applicant Particulars section.



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.

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(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' button.
 The Block/House No, Street Name and Building Name will be populated on the screen.
- (2) Fill in **Level-Unit** information and any additional detail relating to the store in the **Other Address Detail** field if applicable.
- (3) Fill in the Storage Condition of Warehouse.
- (4) Fill in Approved By information.
- (5) Click '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 Importer's Licence section.

Update Warehouse(s)

- (1) Click on the warehouse required amendment from the Warehouse List table.
- (2) Make the required changes.

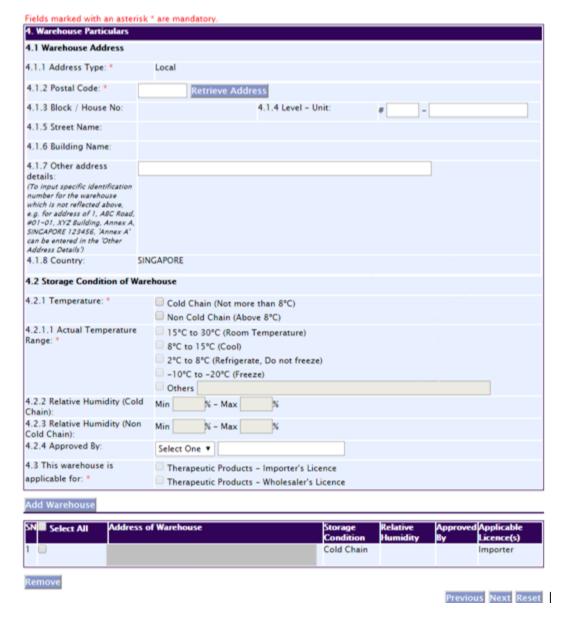
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(3) Click 'Update Warehouse' button.

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. Importer'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.



Amend Aspect of Importation

Select Aspect of Importation.

Note – "Other Specific Activity" is not applicable for Importer's Licence (Limited Scope).

If the existing TPIL 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 new licence.

Add registered product (s)

If "Registered Therapeutic Products" is selected, proceed to (1) to (3). Otherwise, proceed to (4).

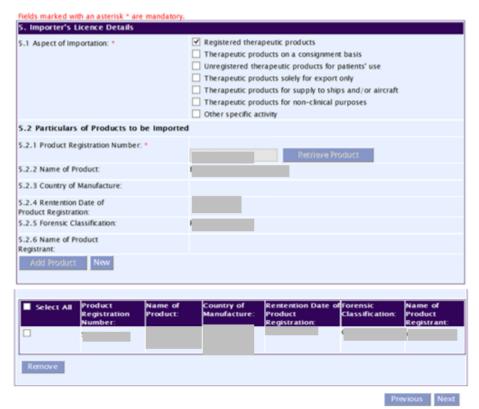
- (1) Fill in Product Registration Number and click on the 'Retrieve Product' button. The details of the product will be populated on the screen.
- (2) Click 'Add Product' button.

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

- (3) Repeat steps (1) to (2) to add other product particulars.
 All details for the products to be imported should be provided.
- (4) Click 'Next' button to go to Responsible Person section.

Remove Product(s)

- Click on the checkbox adjacent to the product(s) from the List of Products To Be Imported table.
- (2) Click 'Remove' button to delete the product(s).



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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 '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 Documents 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>.

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Fields marked with an asterisk *	are mandatory.				
6. Responsible Person					
6.1 Is the responsible person a	● Yes ○ No				
registered pharmacist? *					
6.2 Pharmacist Registration					
Number(PRN): *					
6.3 Is the responsible person	O Yes No				
the same as the applicant? *					
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 I	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					²
applicable):					
6.9 This responsible person is	✓ Therapeutic Products	-Importer's Licence			
applicable for? *	Therapeutic Products	-Wholesaler's Licence			
Add Responsible Person					
S Select All Name of Resp nsible Person		acist Reg Scope on Numb N)			Applicable Lice nce(s)
					porter
Remove					
				Previ	ous Next Reset

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 on the **Remove** button.

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Fields marked with an asterisk " a	ire mandatory.				
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 products to sell by	Choose File No file chosen				
wholesale :					
7.4 Good Distribution Practice	Choose File No file chosen				
Standard Operating					
Procedures :					
7.5 Good Distribution Practice	Choose File No file chosen				
Records or Recording					
Templates :					
7.6 Store Approval Letter :	Choose File No file chosen				
7.7 Other Supporting Documents	Choose File No file chosen				
1					
Attach Files					
Select All to delete all attachment records					
Sn Attachment Name A	ttachment Type Size Remarks				
	(Kb)				
1 🗆					
To remove an attachment, click on the checkbox. Then hit the Remove button to remove the attachment from the list.					
Remove					

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)

Previous Next Reset

• 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
Authorization Letter from Product Registrant	Yes *, for addition of a new product not registered under your company
GDP Operating Procedures	Optional
GDP Records or Recording Templates	Optional
Store Approval Letter	Optional

^{*} denotes mandatory items

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Part 8. Confirmation

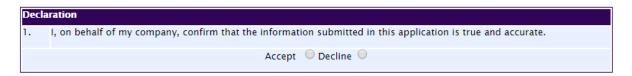
Once all the relevant sections are completed the confirmation page would display all the information from the sections earlier. Click "Validate" to check if all fields are filled up correctly.

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**.

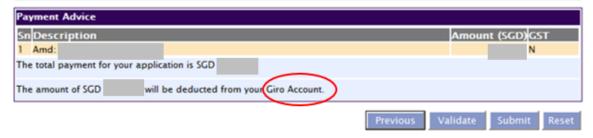


Payment Advice

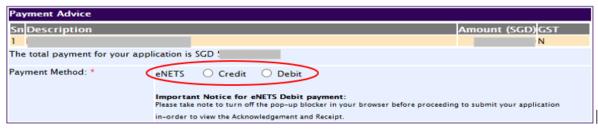
This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO (deducted from the relevant bank account)
- eNETS (Credit Card or Debit Card)



or



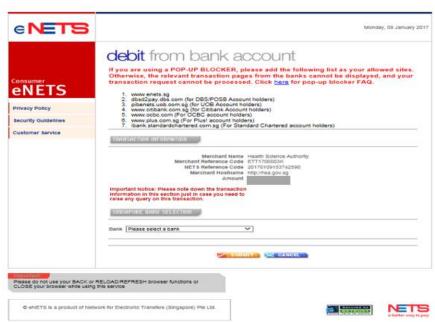


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If the eNETS option is selected and then Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.



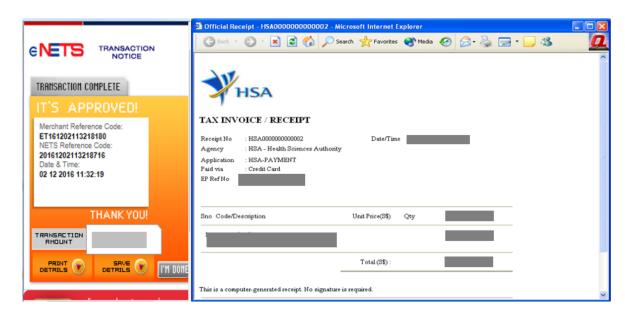
If the eNETS option is selected and then the Debit option is selected, the page will be re-directed to the relevant screen for the applicant to select the bank first before being re-directed to input the debit card details.







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



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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.

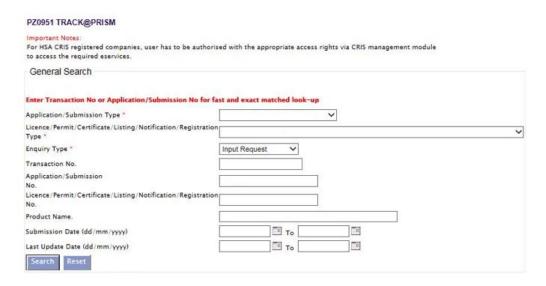
A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

Input request can be classified as Primary or Secondary.

- Primary Input Request requires changes to be made directly in the application form.
- <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 -> 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 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.

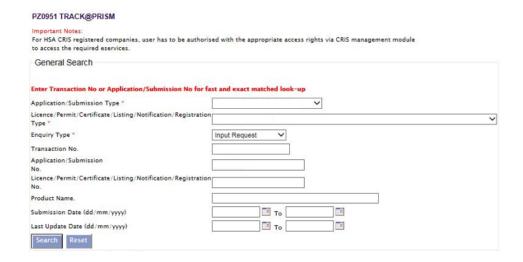
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Responding to Secondary Input Request

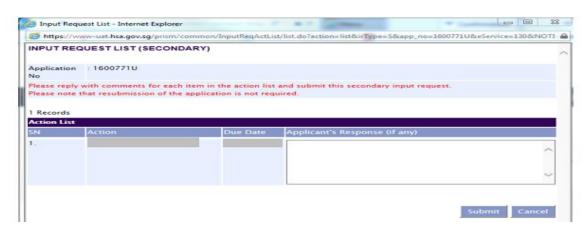
(1) Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click 'Search' button.



(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: (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.

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