

NEW APPLICATION FOR IMPORTER'S LICENCE AND/OR 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 apply@prism. For more information on CRIS, please refer to https://www.hsa.gov.sg/e-services/cris

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 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) Standard Operating Procedures^
- (E) Records or Recording Templates^

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

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 <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.

Part 1. Application Details

This section allows the selection of the licence for submission.

(1) Select **Licence Applied.** The screen will be refreshed accordingly.

You can refer to the following table when selecting the licence:

Selection of Licence	Applicable for Companies
Therapeutic Products – Importer's Licence ¹ (TPIL) Only	 Conduct import of TP only Only importing for Restricted Activities ² such as: a) Import TP solely for re-export only; b) Import TP for supply to ships/aircraft c) Import TP for non-clinical use
Therapeutic Products – Wholesaler's Licence (TPWL) Only	Only Wholesaling of TP
Therapeutic Products – Importer's Licence and Wholesaler's Licence (TPIL & TPWL)	 Importing of unregistered TP for patients' use Conduct both import and wholesaling of TP, and others (see a, b, & c above)

Note: - [1] Please refer to the ICA website for details on the checkpoints where the therapeutic products may be imported.

[2] Do not need to apply for TPWL.

Fields marked with an asterisk * are mandatory.

1. Application Details	
1.1 Licence Applied: *	Therapeutic Products – Importer's Licence Only
	Therapeutic Products – Wholesaler's Licence Only
	Therapeutic Products – Importer's Licence and Wholesaler's Licence

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- (2) If you are applying for 'Importer's Licence and Wholesaler's Licence' or 'Wholesaler's Licence Only', the subsections (3) and (4) are not applicable. Please proceed to (5).
- (3) If you are applying for 'Importer's Licence Only', select 'Full Scope' or 'Limited Scope' for the Importer's Licence.

Selection of Licence Scope	Applicable for Companies
Full Scope	 Importing of registered TP and others, such as a) Import TP solely for re-export only; b) Import TP for supply to ships/aircraft c) Import TP for non-clinical use
Limited Scope	Importing of unregistered TP for patients' use and others Only Importing for Restricted Activities (see a, b, & c above)

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Therapeutic Products – Importer's Licence Only

Fields marked with an asterisk * are mandatory.

1. Application Details	
1.1 Licence Applied: *	Therapeutic Products - Importer's Licence Only
	Therapeutic Products - Wholesaler's Licence Only
	Therapeutic Products - Importer's Licence and Wholesaler's Licence
1.2 Licence Type	
1.2.1 Importer: *	Full Scope Limited Scope
	Term (Annual) Consignment (per consignment only)
1.3 Licence Duration	
1.3.1 Importer:	

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(4) Select 'Term (Annual)' or 'Consignment (per consignment only)' if you have selected 'Limited Scope' in (3) above.

Selection of Licence Type	Applicable for Companies	Validity of Licence
Term (Annual)	 Importing of registered TP Importing of unregistered TP for patients' use Importing for Restricted Activities for more than 1 occasion in a year 	1 year (renewable)
Consignment (per consignment only)	Importing for Restricted Activities on a one-off occasion	Valid for the specific consignment

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

Part 2. Company Particulars

(1) Details such as **Name** of company and **Company Address** will be populated on screen based on the registered CRIS records.

If you need to make changes to this information, please submit the changes via the "Amend Company Information" module under the amend@prism on PRISM e-Service webpage.

Input the information of Tel and/or Fax.

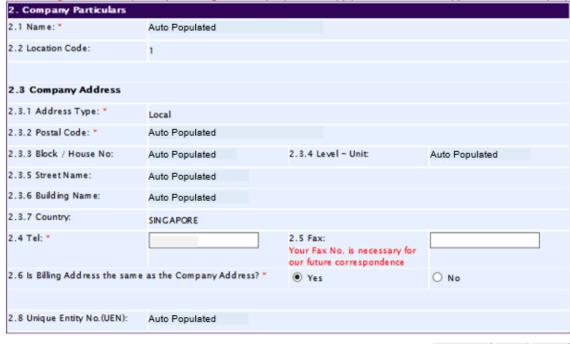
- (2) Indicate if the Billing Address is the same as Company Address.
- (3) If the Billing Address is not the same as Company Address, fill in the postal code and click on the **Retrieve Address** button. The Block/House No, Street Name and Building Name will be populated on screen. Fill in **Level-Unit**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

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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.



Part 3. Applicant Particulars

This section allows the input of applicant particulars.

- (1) Fill in Name, ID No and Designation.
- (2) Fill in the Contact Details and Preferred Contact Mode.
- (3) Click 'Next' button to go to Warehouse Particulars section.

Fields marked with an asterisk * are mandatory 3. Applicant Particulars 3.1 Name: * (as in NRIC/FIN) 3.2 NRIC/FIN: * (Example: \$1234567A, 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: OEmail OFax OSMS (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

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Part 4. Warehouse Particulars

This section allows the input of warehouse particulars.

Add 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** field and any additional detail relating to the warehouse 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.

(Note: If you are applying for TPWL only, the next section will be Wholesaler's Licence section.)

<u>Update Warehouse(s)</u>

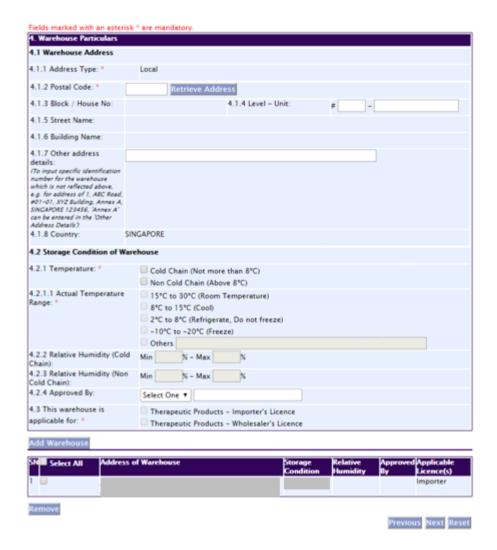
- (1) Click on the warehouse required amendment from the Warehouse List table.
- (2) Make the required changes.
- (3) Click 'Update Warehouse' button.

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).

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Part 5. Importer's Licence Details

This section allows the input of particulars of products to be imported.

(1) Select Aspect of Importation.

Note – 'Other Specific Activity' is <u>not applicable</u> for Importer's Licence (Limited Scope).

If 'Registered Therapeutic Products' is selected, proceed to (2) to (4). Otherwise, proceed to (5).

(2) Fill in Product Registration Number and click 'Retrieve Product' button.

The details of the product will be populated on the screen.

(3) Click 'Add Product' button.

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

(4) Repeat steps (2) to (3) to add other product particulars.

All details for the products to be imported should be provided.

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

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Remove Product(s)

- 1) 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).

Fields marked with an asterisk * are mandatory. 5. Importer's Licence Details 5.1 Aspect of Importation: * Registered therapeutic products Therapeutic products on a consignment basis Unregistered therapeutic products for patients' use Therapeutic products solely for export only Therapeutic products for supply to ships and/or aircraft Therapeutic products for non-clinical purposes Other specific activity 5.2 Particulars of Products to be Imported 5.2.1 Product Registration Number: * Retrieve Product 5.2.2 Name of Product: 5.2.3 Country of Manufacture: 5.2.4 Rentention Date of Product Registration: 5.2.5 Forensic Classification: 5.2.6 Name of Product Registrant: Add Product New



Part 6. Wholesaler's Licence Details

This section allows the input of wholesale dealing particulars.

- (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.

Fields marked with an asterisk * are mandatory.



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Part 7. Responsible Person

This section allows the input of details of Responsible Person.

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 RP
- (3) Click '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 'Next' button to go to the 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.

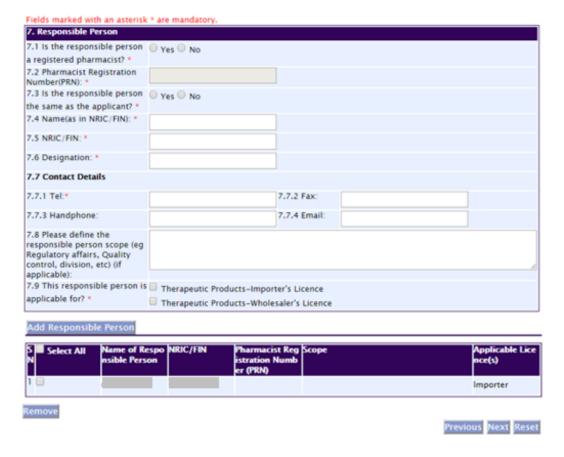
Remove Responsible Person(s)

- (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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Part 8. 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-out 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.

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 attachment.

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8. 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		
8.1 Store Layout Plan : *	Choose File No file chosen	
8.2 Pharmacist Practising Certificate (applicable for responsible person who is a registered pharmacist);	Choose File No file chosen	
8.3 Authorisation letter from product registrant ;	Choose File No file chosen	
8.4 List of products to sell by wholesale :	Choose File No file chosen	
8.5 Good Distribution Practice Standard Operating Procedures :	Choose File No file chosen	
8.6 Good Distribution Practice Records or Recording Templates :	Choose File No file chosen	
8.7 Store Approval Letter :	Choose File No file chosen	
8.8 Other Supporting Documents	Choose File No file chosen	
Attach Files		
Select All to delete all attachment		
	ttachment Type Size Remarks (Kb)	
1 0 !		
To remove an attachment, click o Remove	n the checkbox. Then hit the Remove button to remove the attachment from the list.	

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)

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• 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	Application for Importer's Licence (IL)	Application for Wholesaler's Licence (WL)
Current Store layout plan for premise(s) specifying storage area(s)	Yes *	Yes *
Pharmacist Practising Certificate	Yes, for Responsible Person who is a pharmacist	Yes, for Responsible Person who is a pharmacist
Authorisation Letter from Product Registrant	Yes *, for products not registered under your company	No
List of products to sell by wholesale	No	Yes
GDP Operating Procedures	Yes	Yes
GDP Records or Recording Templates	Yes	Yes
Store Approval Letter	Yes	Yes

^{*} denotes mandatory items

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Part 9. Confirmation

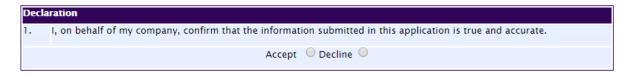
Once all the relevant sections are completed the confirmation page would display all the information from the sections earlier. Click 'Validate' to check if all fields are filled up correctly.

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 10. Declaration

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



Payment Advice

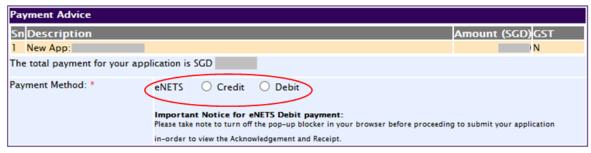
This section shows the application fee for the licence applied.

There are 2 modes of payment available:

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



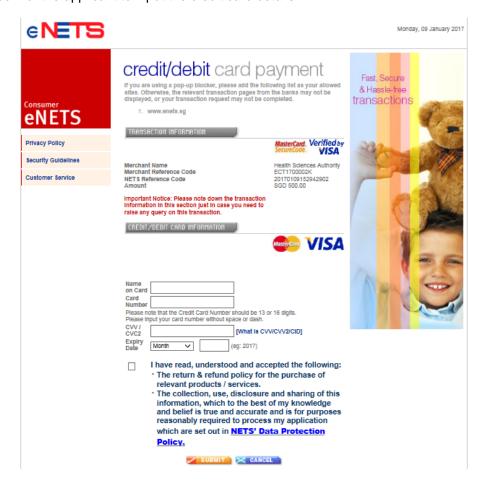
or



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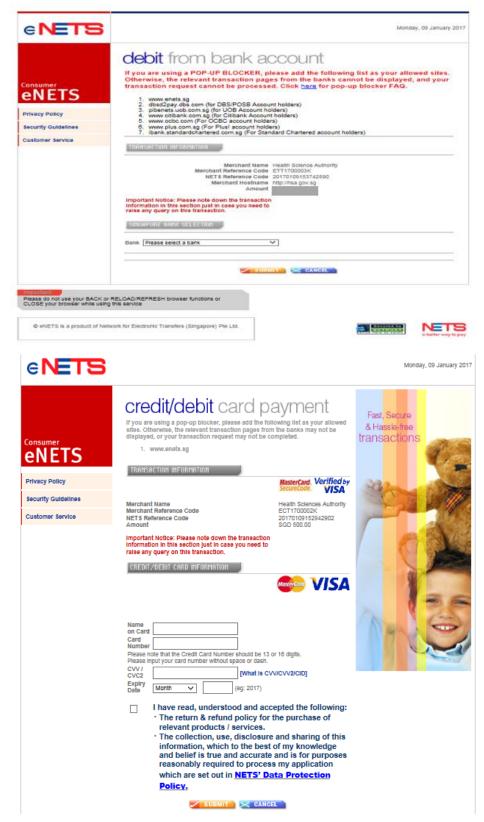
If the eNETS option is selected and then Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.



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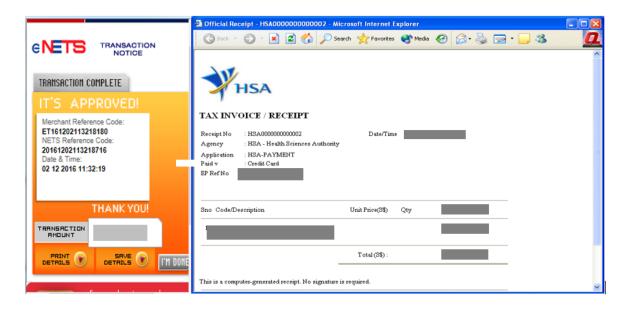
If the eNETS option is selected and then the Debit option is selected, the page will be re-directed to the relevant screen for the applicant to select the bank first before being re-directed to input the debit card details.



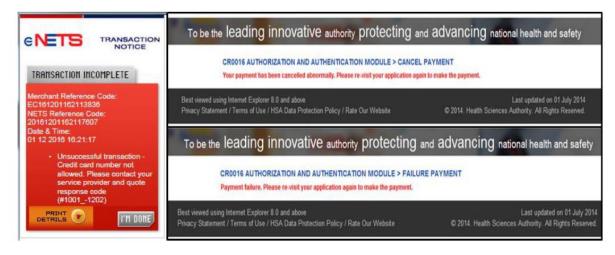
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Upon successful transaction, an eNETS official receipt and a HSA tax invoice will be generated.



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 '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.



PR1001 APPLICATION FOR THERAPEUTIC PRODUCTS - COMBINED LICENCE

icknowledgement	\Box
our application have been successfully submitted	
Please note that your licence applied is	
Please note that your application numb (is 1600375M	
nease note that your application number is 1000013M	
Client Code :	
icensee	
Amount : BISIS	
Show Printer–Friendly versi	on

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

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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 TP Licence Application Form.

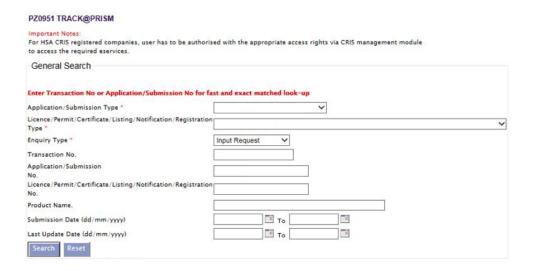
A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

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.'



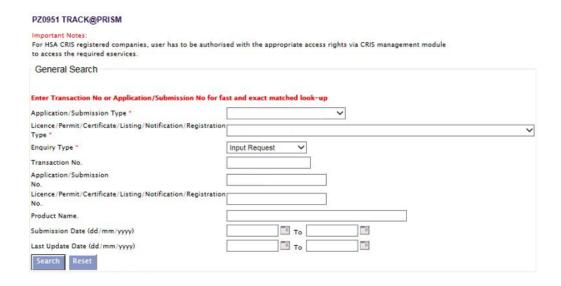
- (3) The webpage will display the application form as per previously submitted.
- (4) Proceed to make the necessary changes for the section(s) that required amendment, click 'Save' button and submit the revised application form.

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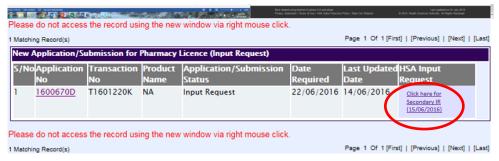


Responding to Secondary Input Request

(1) <u>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.</u>



(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.



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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.

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