NEW APPLICATION FOR LICENCE TO IMPORT CONTROLLED DRUGS

Please note that companies must register with Client and 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 http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html

1. The online form may take an average of 15 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).

   The recommended computer and network configurations can be found at

   http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/system- requirements-for-prism.html

2. With effect from 1 September 2018, the applicant will require a CorpPass 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 or HSA PIN is necessary for authentication and authorization purposes.

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

   For more information on HSA PIN, please refer to

   http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/HSA_PIN.html

3. Mode of payment

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

   The modes of payment available are as follow:

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

   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

Part 1. Company Particulars

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

(1) Company details such as **Name**, **Address**, **Telephone** and/or **Fax** will be pre-populated based on the registered CRIS records.

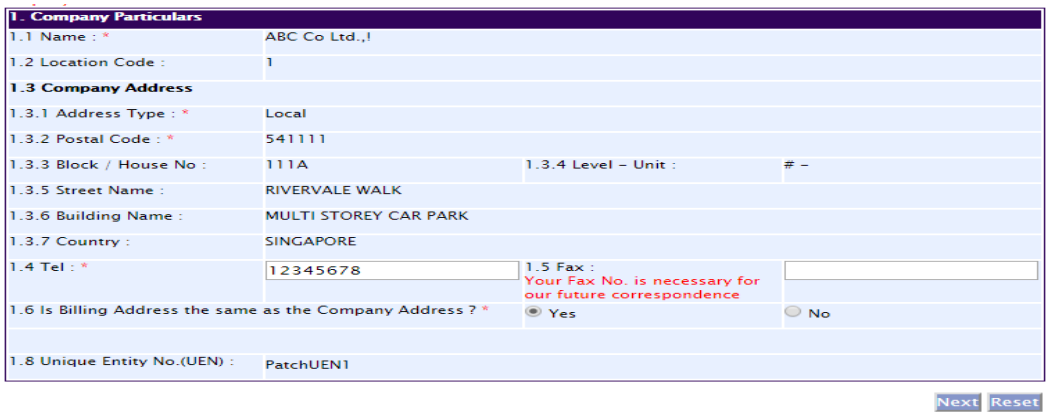
If you need to makes changes to this information, please submit the changes via the **"Amend Company Information"** module under the amend@prism on PRISM e-Service webpage.

(2) Indicate if the Billing Address is the same as the Company Address.

(3) If the Billing Address is not the same as **Company Address**, please fill in the **'Postal Code'** field and click the **'Retrieve Address'** button. The **Block/House No**, **Street Name** and **Building Name** will be populated.

(4) Fill in the **'Level-Unit'** field and any additional detail relating to the company in the **'Other Address Details'** field. *(If applicable)*

(5) Click **'Next'** button to proceed to **Part 2. Applicant Particulars** section.



1. Company Particulars			
1.1 Name : *	ABC Co Ltd.,I		
1.2 Location Code :	1		
1.3 Company Address			
1.3.1 Address Type : *	Local		
1.3.2 Postal Code : *	541111		
1.3.3 Block / House No :	111A	1.3.4 Level – Unit :	# –
1.3.5 Street Name :	RIVERVALE WALK		
1.3.6 Building Name :	MULTI STOREY CAR PARK		
1.3.7 Country :	SINGAPORE		
1.4 Tel : *	12345678	1.5 Fax : Your Fax No. is necessary for our future correspondence	
1.6 Is Billing Address the same as the Company Address ? *		(•) Yes	( ) No
1.8 Unique Entity No.(UEN) :	PatchUEN1		

Next Reset

Part 2. Applicant Particulars

This section requires the applicant to verify and enter 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.

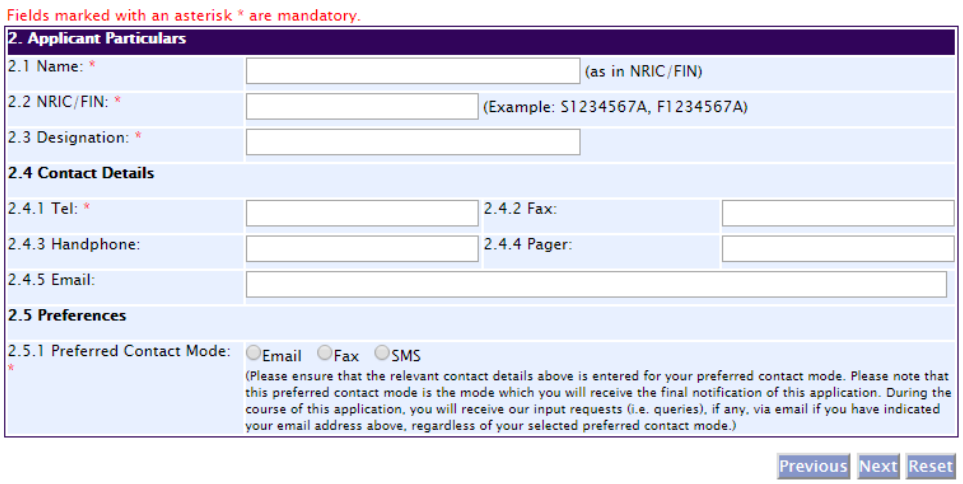
If you need to makes changes to this information, please submit the changes via the **"Amend Applicant's Details For Licences and Applications"** module under the amend@prism on PRISM e-Service webpage.

(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.

During the course of this application, you will receive our Input Request (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

(3) Click **'Next'** button to proceed to **Part 3. Licence Information** section.



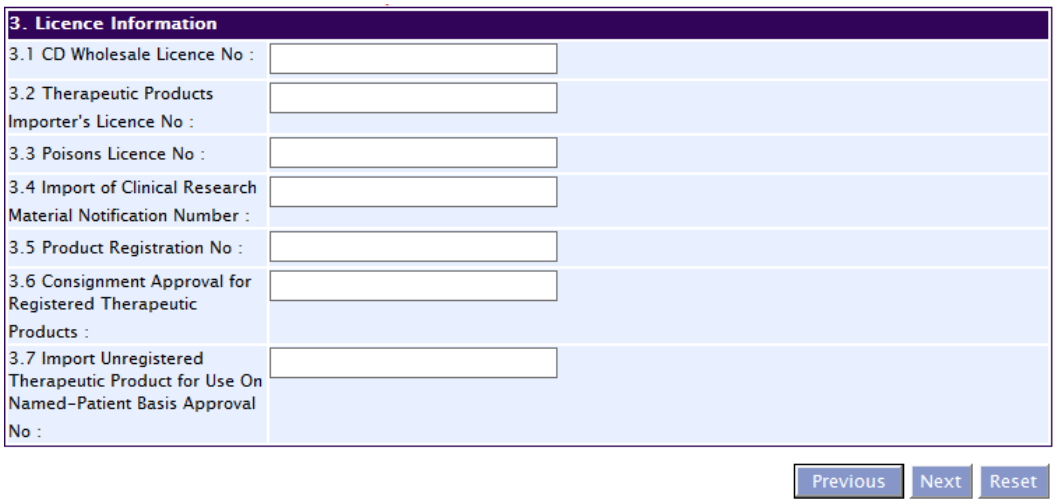
Part 3. Licence Information

This section requires the applicant to enter the following information as applicable:

- 3.1 CD Wholesale Licence Number
- 3.2 Therapeutic Products Importer's Licence Number
- 3.3 Poisons Licence Number
- 3.4 Import of Clinical Research Material Notification Number
- 3.5 Product Registration Number
- 3.6 Consignment Approval for Registered Therapeutic Products
- 3.7 Import Unregistered Therapeutic Product for Use On Named-Patient Basis Approval Number

At least one of items 3.2, 3.3 or 3.4 should be entered.

Click **'Next'** button to proceed to **Part 4. Name of Person to Appear on Licence** section.



Part 4. Name of Person to Appear on Licence

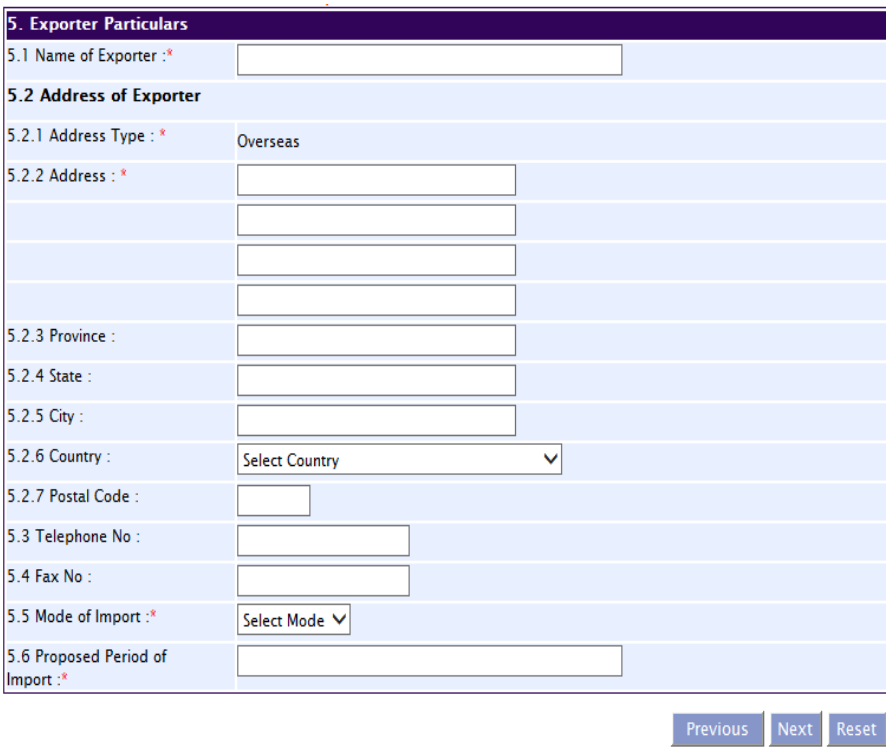
Enter the name of the person responsible for the import. The person indicated should be of sufficient authority to take responsibility for the import.

To proceed to the next section, **Part 5. Exporter Particulars,** click **'Next'.**

Part 5. Exporter Particulars

This section requires the applicant to fill in the name and address of the exporter, mode of import (Air, Land or Sea) and proposed period of import.

Click **'Next'** button to proceed to **Part 6. Substances to be Imported** section.



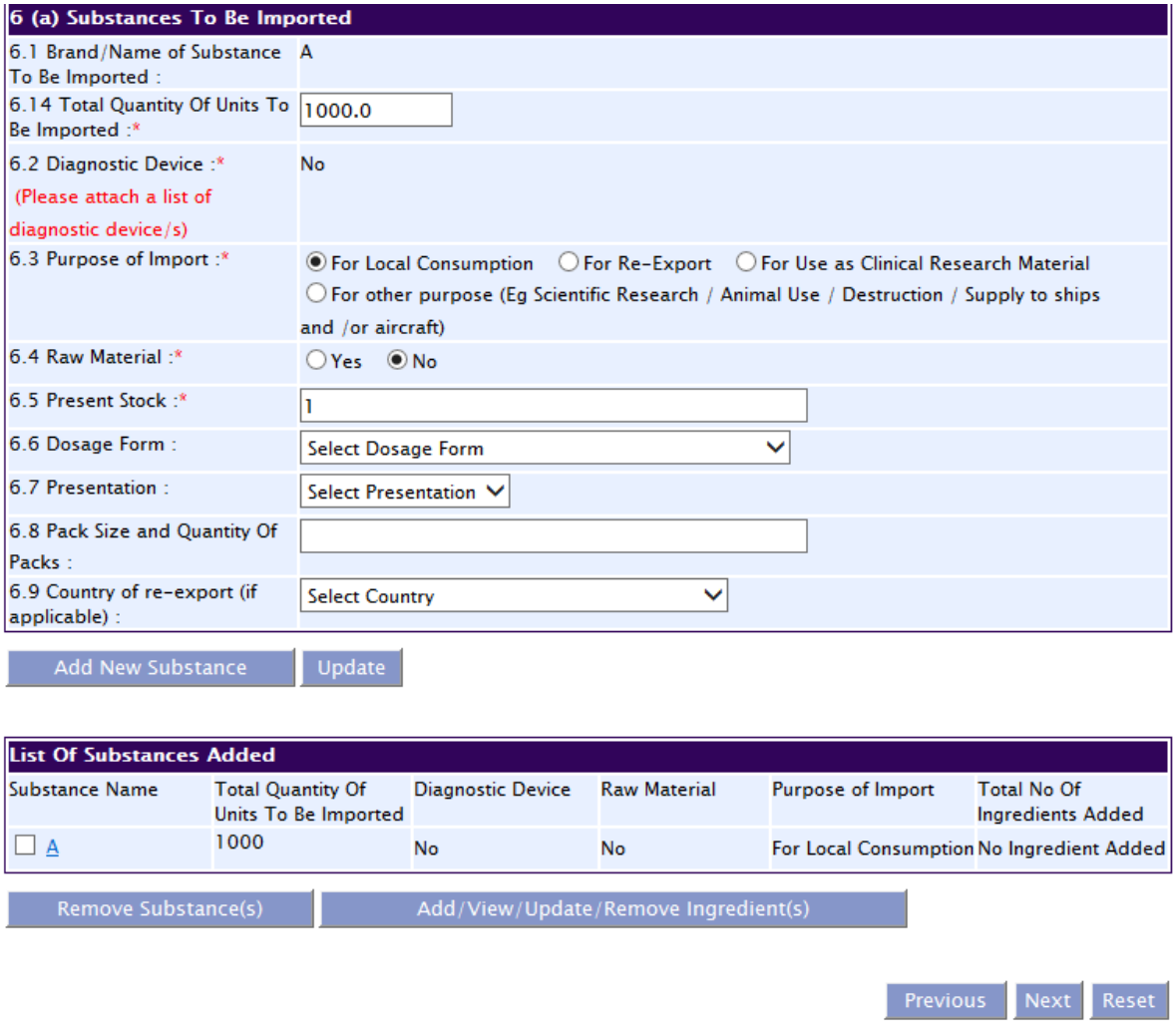
Part 6. Substances to be Imported

(1) In section 6(a), the applicant is required to fill in the following information:

1) Brand/name of substance to be imported
2) Total quantity of units to be imported
3) Indicate "Yes" or "No" for diagnostic device or raw material
4) Purpose of import. If "For other purpose" is selected, a text box will appear for the applicant to enter further details
5) Present stock
6) Country of re-export (if importing for re-export)

(2) Click on the "Add Substance" button. The page will refresh showing the Substance Name in the "List of Substances Added". To remove any substance name that has been wrongly added to the "List of Substances Added", tick the box beside the Substance Name and click the "Remove Substance(s)" button.

(3) Tick the box beside the substance name and click on the "Add/View/Update/Remove Ingredient(s)" button which will bring you to section 6(b) Ingredient Details.



6 (a) Substances To Be Imported

6.1 Brand/Name of Substance To Be Imported :	A
6.14 Total Quantity Of Units To Be Imported :*	1000.0
6.2 Diagnostic Device :* (Please attach a list of diagnostic device/s)	No
6.3 Purpose of Import :*	◉ For Local Consumption ○ For Re-Export ○ For Use as Clinical Research Material ○ For other purpose (Eg Scientific Research / Animal Use / Destruction / Supply to ships and /or aircraft)
6.4 Raw Material :*	○ Yes ◉ No
6.5 Present Stock :*	1
6.6 Dosage Form :	Select Dosage Form
6.7 Presentation :	Select Presentation
6.8 Pack Size and Quantity Of Packs :	
6.9 Country of re-export (if applicable) :	Select Country

Add New Substance | Update

List Of Substances Added

Substance Name	Total Quantity Of Units To Be Imported	Diagnostic Device	Raw Material	Purpose of Import	Total No Of Ingredients Added
☐ A	1000	No	No	For Local Consumption	No Ingredient Added

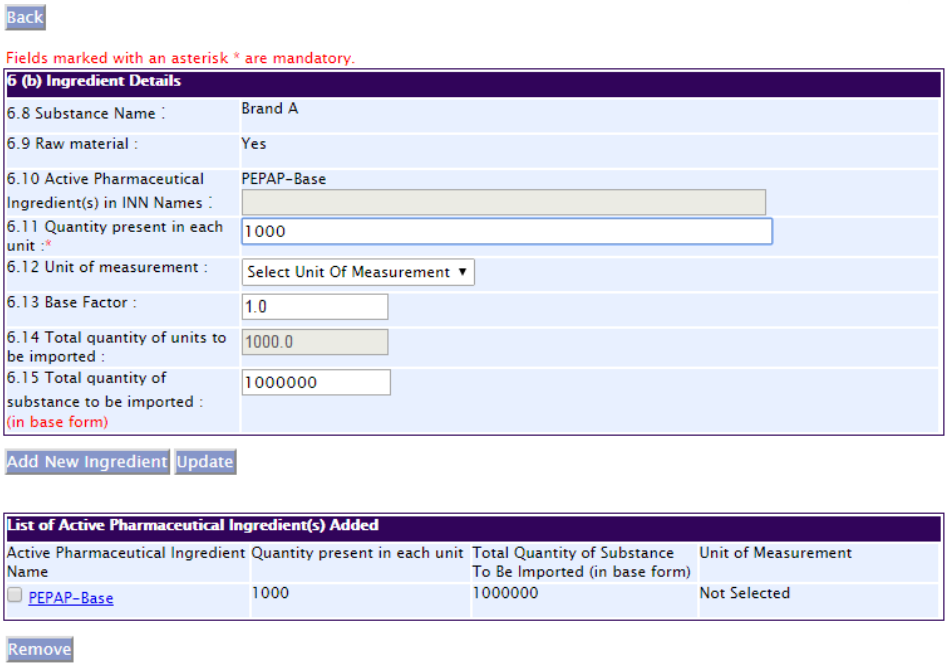
Remove Substance(s) | Add/View/Update/Remove Ingredient(s)

Previous | Next | Reset

(4) In section 6(b), the applicant is required to fill in the following information:

1) Type the Active pharmaceutical ingredient name and click "Search Ingredient" button to select ingredient. If the ingredient is not available from the list, select "Others", then type in the Ingredient Name in section 6.11 and the Base Factor in section 6.14 (The Base Factors or approximate percentage of pure anhydrous drug/base contents are available in the "Yellow list" and "Green list" from the INCB website)
2) Quantity present in each unit (before conversion to base quantity)
3) Unit of measurement

(5) Once all the information for the Ingredient Details has been entered, click on the "Add Ingredient" button. The page will refresh showing the Active Pharmaceutical Ingredient in the "List of Active Pharmaceutical Ingredient(s) Added". Check that the information on the list is correct. Click the "Back" button to return to section 6(a).



Additional instructions:
i. If the information displayed on the "List of Active Pharmaceutical Ingredient(s) Added" requires correction, click onto the name of the Active Pharmaceutical Ingredient on the list. The information on the Active Pharmaceutical Ingredient that has been selected will appear in section 6(b). Make the necessary correction and click the "Update" button when done. The updated information will now appear in the "List of Active Pharmaceutical Ingredient(s) Added".
ii. To remove any Active Pharmaceutical Ingredient that has been wrongly added to the "List of Active Pharmaceutical Ingredient(s) Added", tick the box beside the Active Pharmaceutical Ingredient Name and click the "Remove Substance(s)" button.

Click 'Next' button to proceed to **Part 7. Supporting Attachments** section.

Part 7. Supporting Attachments

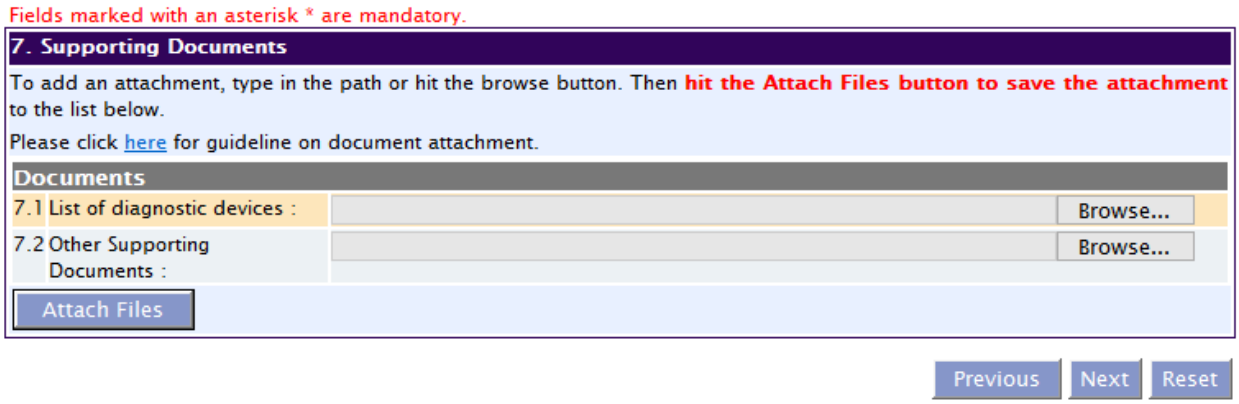
This section allows the attachment of any supporting documents for the application.

Add Supporting Attachments:

(1) Click on the **Browse** button to select the required file for attachment.
(2) Select the required file.
(3) Click on the **Ok** button.
(4) Click on the **Attach File** button for the file to be attached to this application.
(5) Fill up remarks with regards to the attachment if required.
(6) Click **'Next'** button to proceed to **Part 8. Confirmation and Declaration** section.

Remove Supporting Attachments:

(1) Click on the checkbox next to the attachment(s) from the **List of Attachments Table**.
(2) To delete the attachment, click on the checkbox beside the attachment.
(3) Click the **'Remove'** button.



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 too big (estimate about 2MB and above), the attachment time may take a longer time to upload.)

Part 8. Confirmation and Declaration

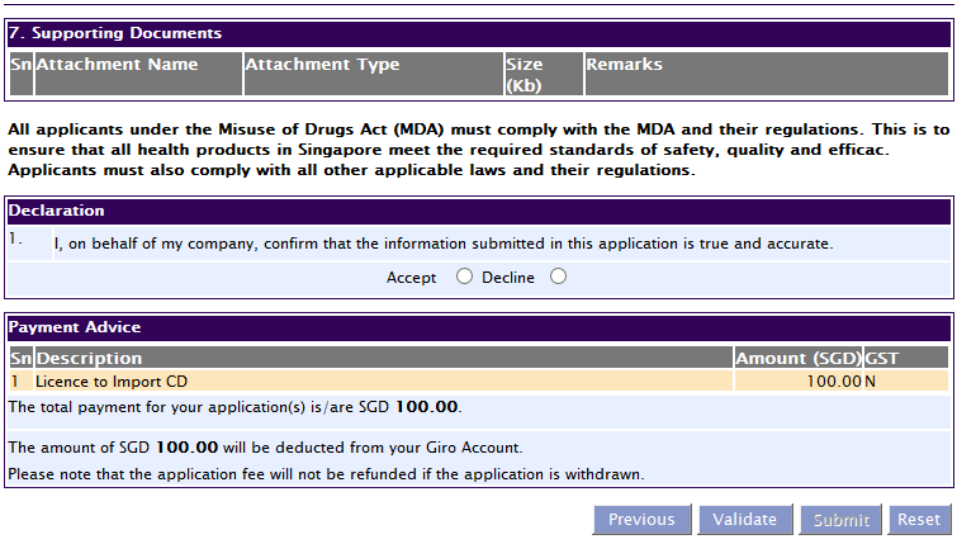
This section shows the information provided in all sections of the Application Form for Licence to Import Controlled Drugs.

(1) The applicant is required to confirm that the information provided in all sections are correct and click the **'Validate'** button.

*(Note: Applicant may click the **'Save'** button to save a copy of the draft application if he/she wishes to complete the application at a later time.)*

(2) Once validation is successful, the applicant is advised to read through the declaration carefully before accepting to undertake the conditions.

(3) Click the **'Submit'** button to submit the application.

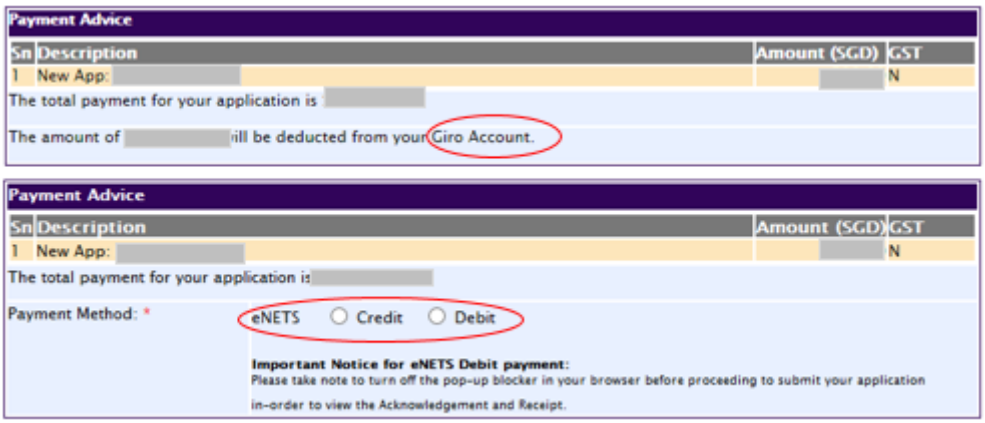


Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO
- eNETS



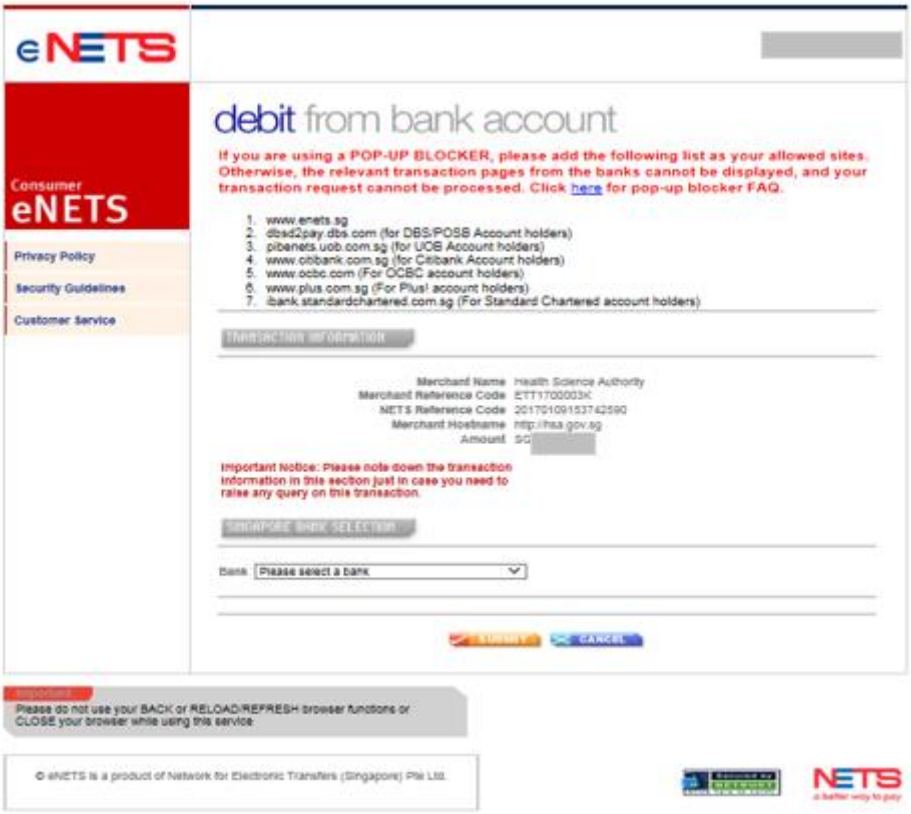
For GIRO, the amount payable will be deducted from the relevant bank account. This mode of payment is a recurring deduction.

For eNETS, the payment choice is either Credit Card or Debit Card.

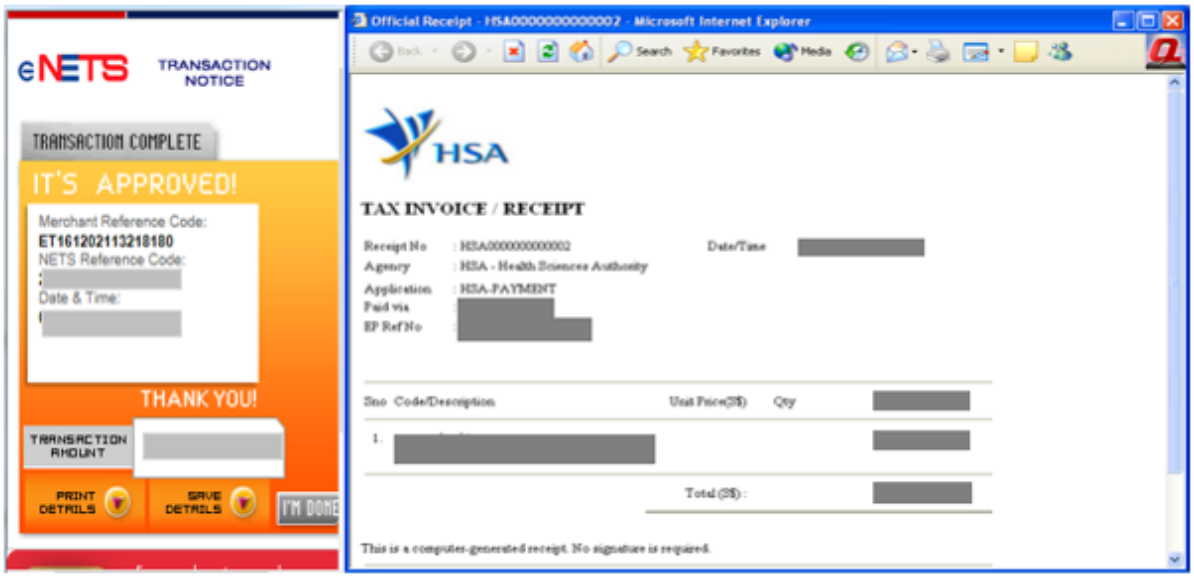
This is applicable for applicants with Non-GIRO Payment Method.

If 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 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. This mode of payment is a one-time deduction only.



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



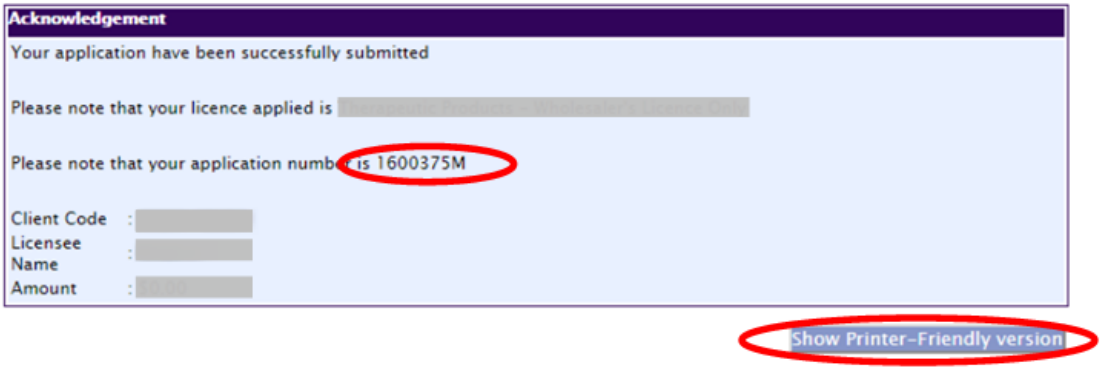
If the payment was made via eNETS and was not completed successfully, the system will prevent retrieval of the draft application and the applicant will need to contact HSA HelpDesk for assistance.

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

Acknowledgement

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

Applicants may wish to print a copy of this acknowledgement page or take note of the **Application Number** for ease of reference. Applicants may provide the application number if they wish to communicate with HSA.



Note: The show Printer Friendly version allows applicant to print or view the application.

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.

   HSA HelpDesk
   Tel : 6776 0168 (from 7:00 am to midnight daily)
   Fax : 6872 3054
   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 or write to https://crm.hsa.gov.sg/event/feedback.aspx