NEW APPLICATION FOR GOOD MANUFACTURING PRACTICE CERTIFICATE

Companies and its applicants must register with Client, Registration, and Identification Service (CRIS) with valid CRIS user rights in order to be able to submit applications on behalf of the company via apply@prism.

The applicant will also 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.

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 CRIS, please refer to

https://www.hsa.gov.sg/e-services/cris

For more information on Corppass, please refer to

http://www.corppass.gov.sg/

For more information on HSA PIN, please refer to

https://www.hsa.gov.sg/e-services/hsa-pin

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).

2 . 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:

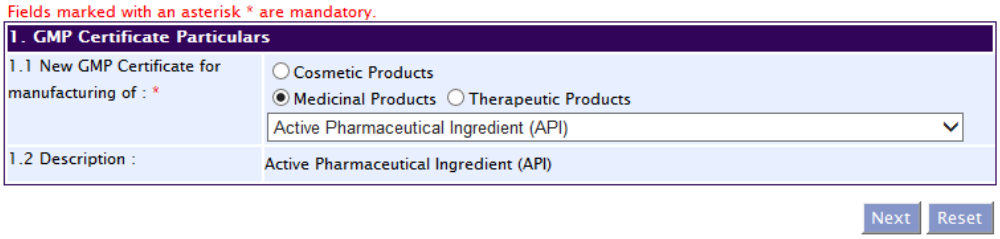
- GIRO
- Non-GIRO: eNETS (Credit/Debit Card)

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. GMP Certificate Particulars

This section requires the applicant to select the class of products to be covered by the GMP Certificate. If "Medicinal Products" or "Therapeutic Products" are selected, a drop-down list will appear for further selection of product types.



Click **'Next'** button to proceed to **Part 2. Company Particulars** section

Part 2. 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.

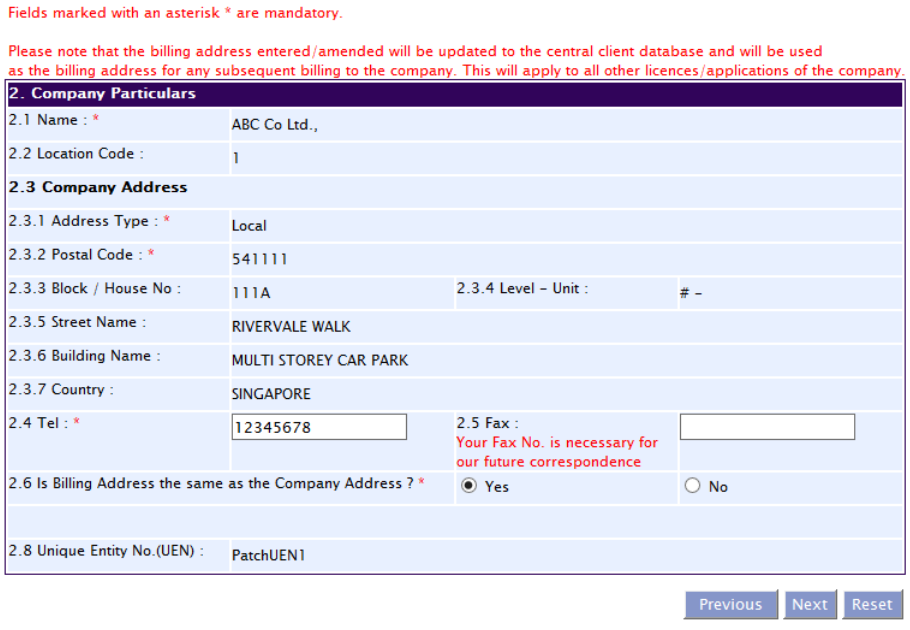
If you need to makes changes to this information, please submit the changes via the **"Amend Company Information"** module under the amend@prism on PRISM e-Service webpage.

(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 3. Applicant Particulars** section.



Part 3. 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.

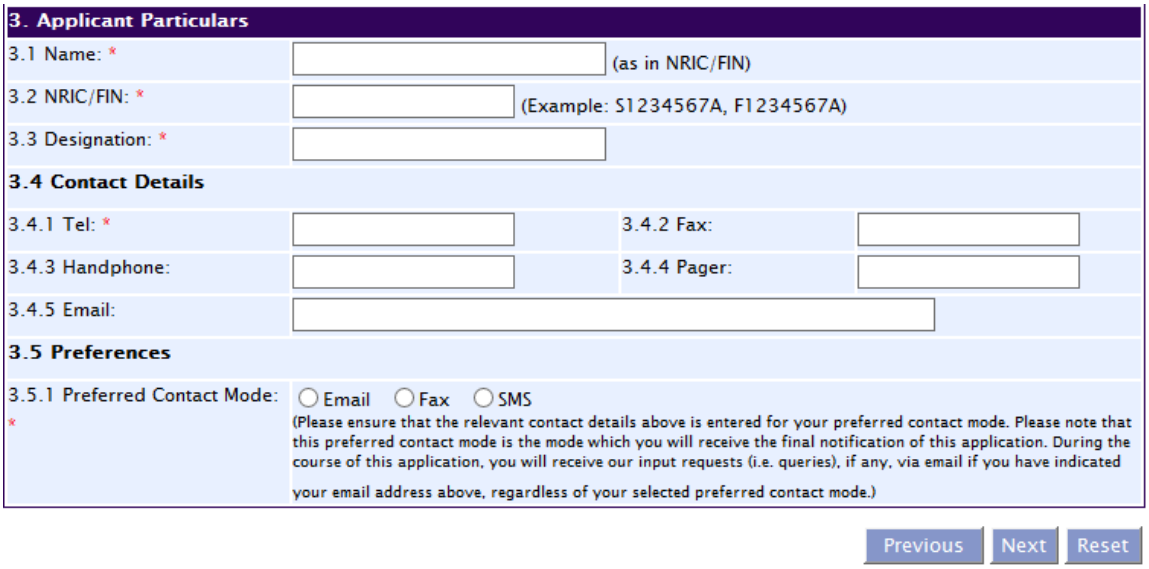
If you need to makes changes to this information, please submit the changes via the **"Amend Applicant's Details For Licences and Applications"** module under the amend@prism on PRISM e-Service webpage.

(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 4. Manufacturing Facility Particulars** section.



Part 4. Manufacturing Facility Particulars

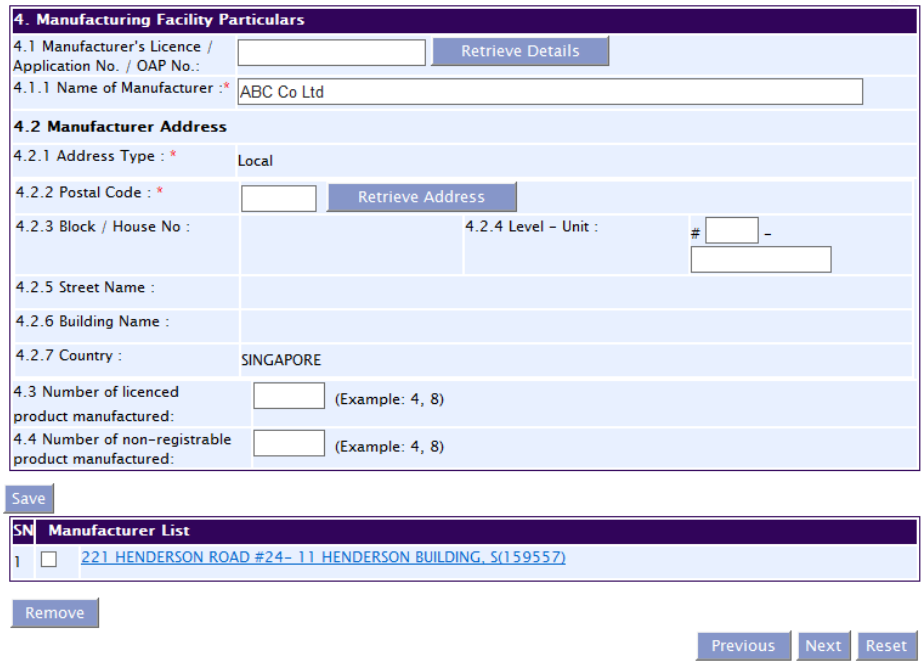
This section requires the applicant to enter name and address of the manufacturing facility.

(1) If the company has a Manufacturer's Licence / Application No / OAP Number, the applicant can key in the Manufacturer's Licence (ML) no. or ML application no. (if ML application is still pending approval) or Overseas Audit Programme (OAP) application no. (if applicable). By keying in the above information, when the applicant clicked the 'retrieve details' button, the manufacturer address will be automatically displayed.

(2) If the above licence numbers are not available or applicable, the applicant would need to provide the name of manufacturer and address of manufacturing site through Postal Code retrieval function. Fill in the **'Level-Unit'** field and any additional detail relating to the company in the **'Other Address Details'** field. *(If applicable)*

(3) Number of licenced products and number of non-registrable products manufactured may also be entered in sections 4.3 and 4.4.

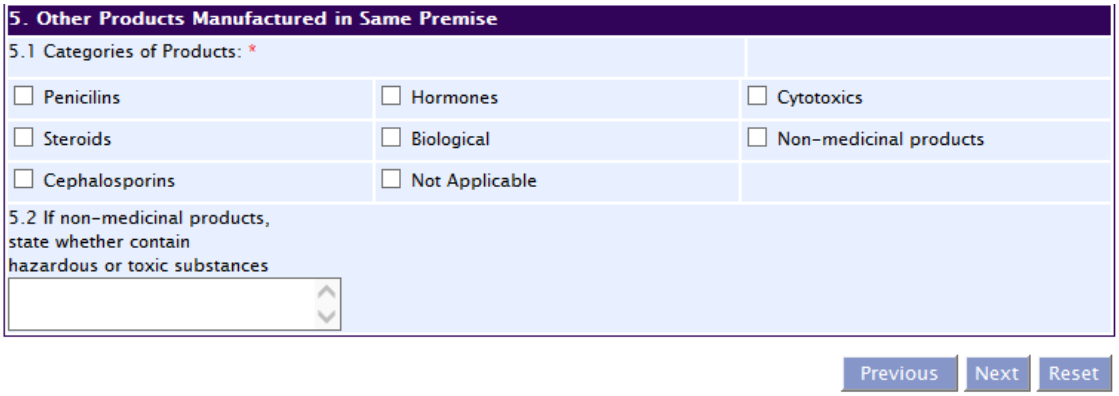
(4) Click "Save" to save the record. Additional manufacturing sites (if any) may be added after each facility is saved.



Click 'Next' button to proceed to **Part 5. Other Products Manufactured in Same Premise** section.

Part 5. Other Products Manufactured in Same Premise

If any of the listed categories of products are manufactured in the same premise, select as appropriate. If the company does not manufacture any of the listed categories, select "Not Applicable".



To proceed to the next section, **Part 6. Warehouse Particulars,** click **'Next'.**

Part 6. Warehouse Particulars

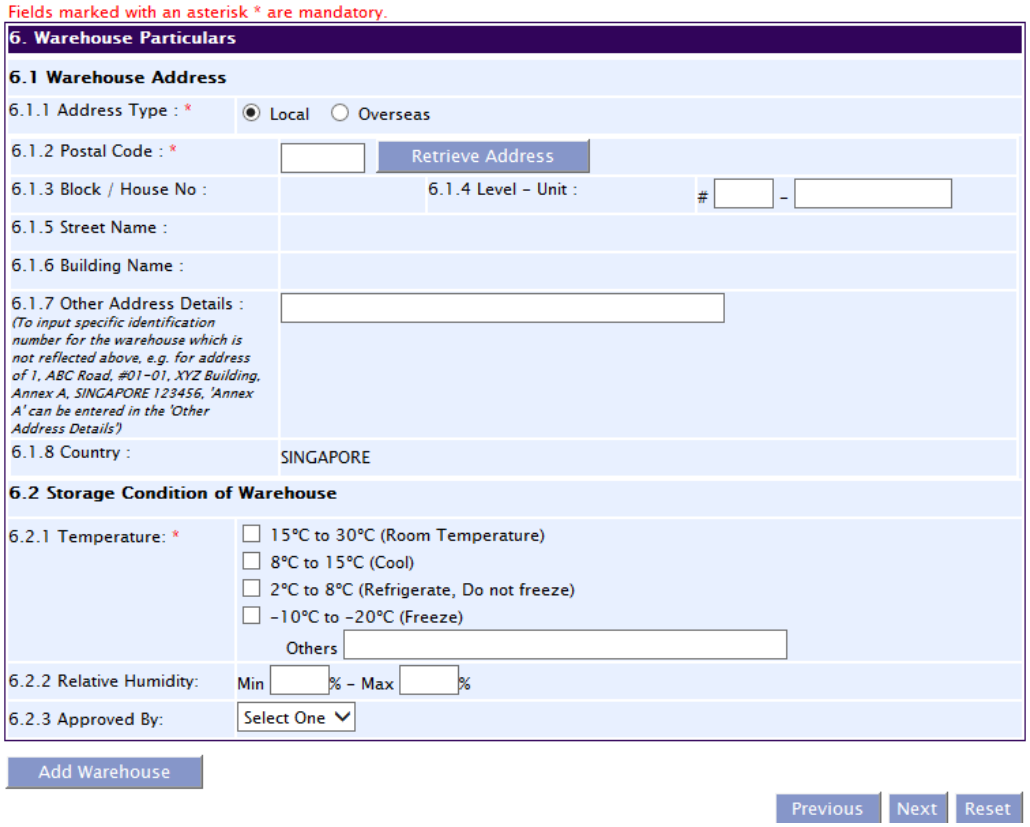
This section requires the applicant to enter the address of the warehouse facility. To enter address,

(1) Fill in the **'Postal Code'** field and click the **'Retrieve Address'** button. The **Block/House No**, **Street Name** and **Building Name** will be populated.

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

Section 6.2 requires the applicant to furnish the storage conditions such as temperature and relative humidity of the warehouse. More than one option for the warehouse temperature can be selected. The details of the agency/institution that approves the use of the warehouse for the storage of health products should also be provided.

After completing sections 6.1 and 6.2, click “Add Warehouse” to save the warehouse details. If there is more than one warehouse to be entered, repeat the above steps to add further warehouses after adding the first warehouse.
Addresses of all warehouses where the products would be stored should be provided.



Click ‘Next’ button to proceed to **Part 7. Contract Testing Laboratory Particulars** section.

Part 7. Contract Testing Laboratory Particulars

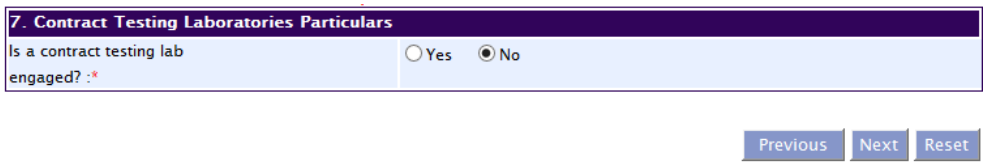
(1) Indicate if your company engages a contract testing lab. If your answer to the question is “No”, you can proceed to the next Part. If your answer is “Yes”, you will be required to give details of the contract testing laboratory in the following sections:

(2) Name and address of the contract testing laboratory

(3) Type of analytical test performed by the laboratory based on your contract. You will only need to give a brief description of the test(s) performed

(4) If the contract testing laboratory is accredited to any international quality system standards, and the scope of accreditation. You will only need to give a brief description of the scope of accreditation

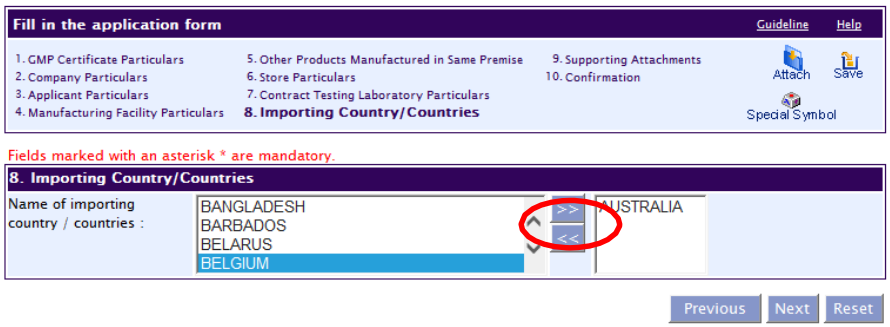
(5) Add the contract testing laboratory by clicking on the “Save” button. You will see the page refreshes, and the refreshed page will display the details of the contract testing laboratory you have added



Click 'Next' button to proceed to **Part 8. Importing Countries** section.

Part 8. Importing Countries

Select the countries that your company exports its products to. After selecting a country, click the double arrows to the right to add the country to the column on the right.



To remove a country added incorrectly, select the country and click the double arrows to the left.

Click 'Next' button to proceed to **Part 9. Supporting Documents** section.

Part 9. Supporting documents

This section allows the attachment of any supporting documents for the application. For applications for GMP certificate, please attach the following:

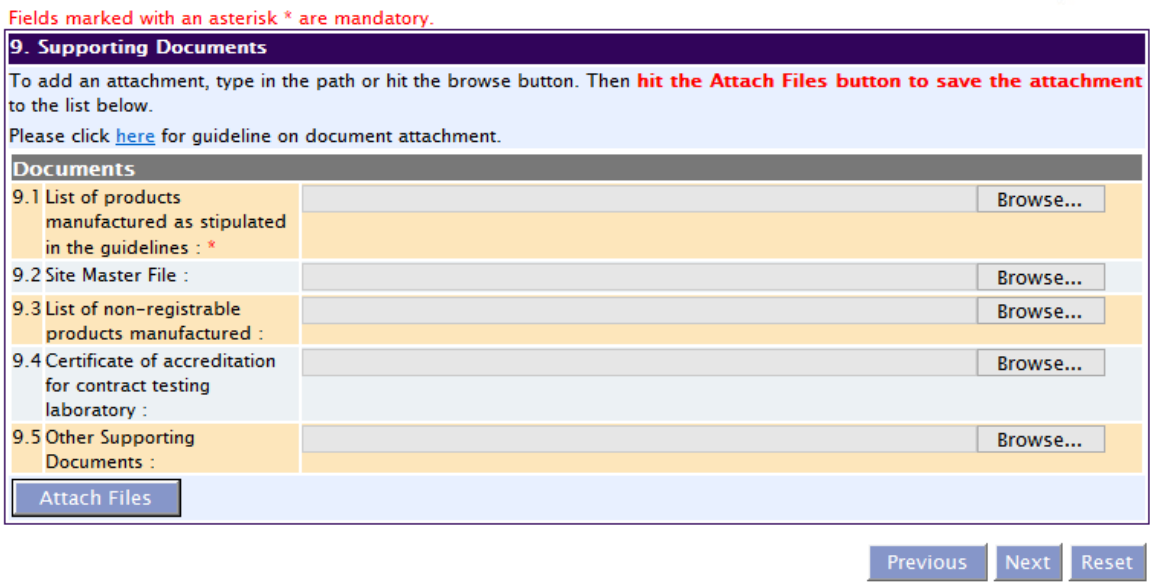
- Site Master File
- List of dosage forms manufactured

To 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** section.

To 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 10. Confirmation

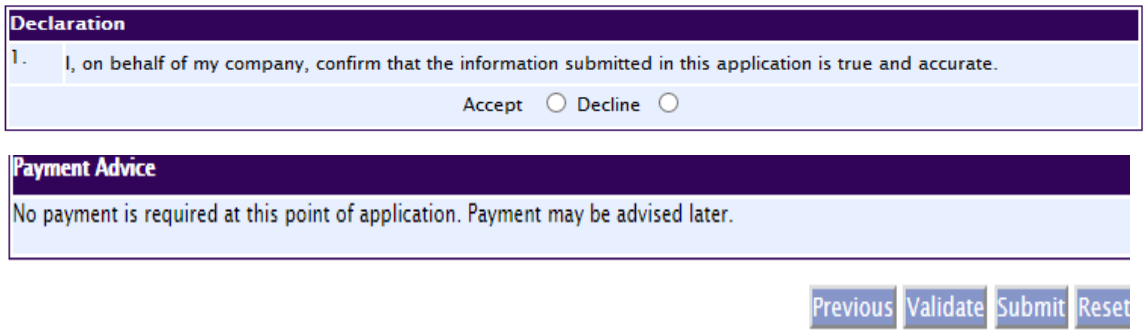
This section shows the information provided in all sections of the Application Form for a Good Manufacturing Practice Certificate.

(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. (No payment is made at this point. Payment may be advised later.)

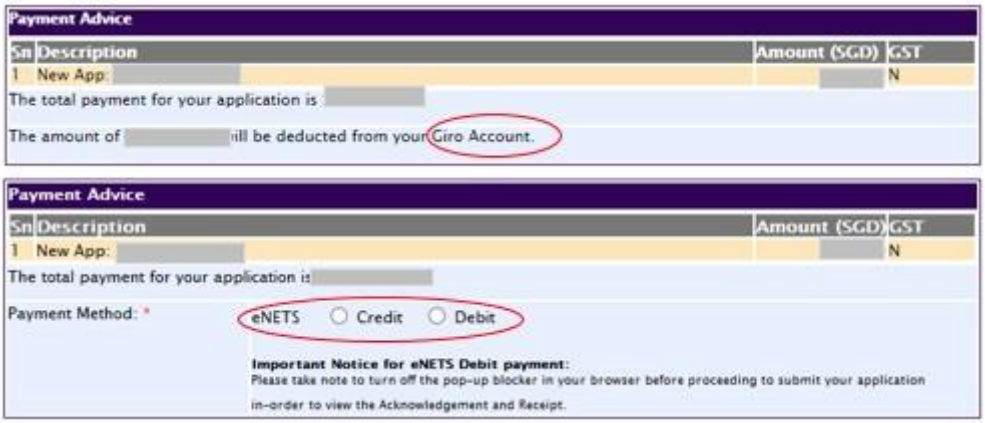


Payment Advice

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.

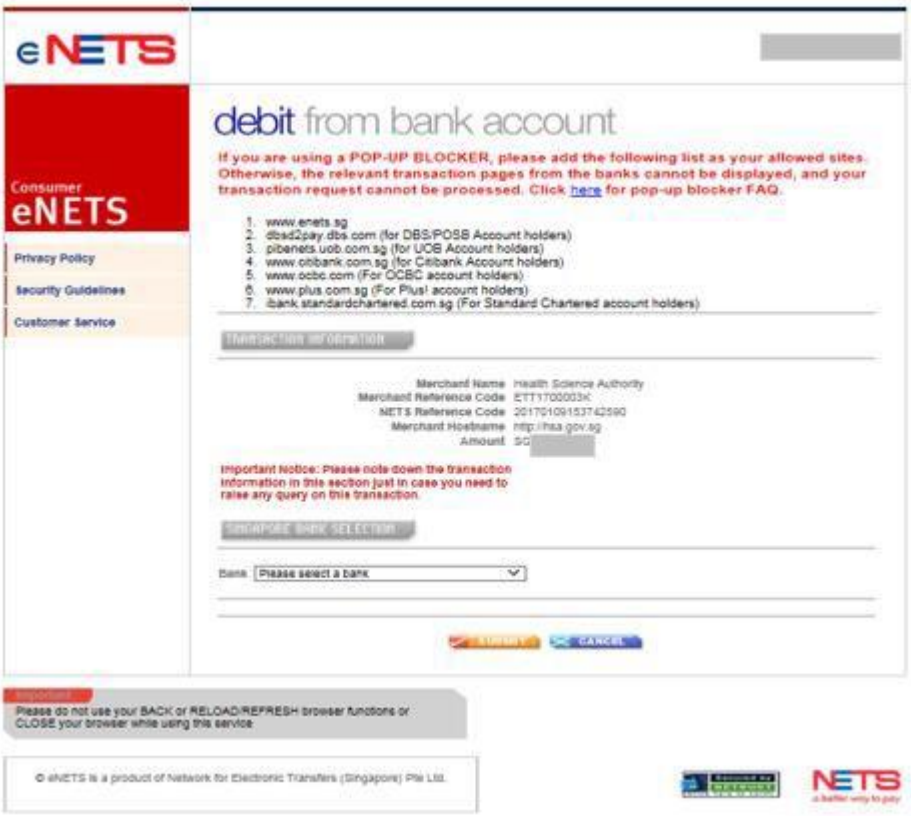
For eNETS, the payment choice is either Credit Card or Debit Card.

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

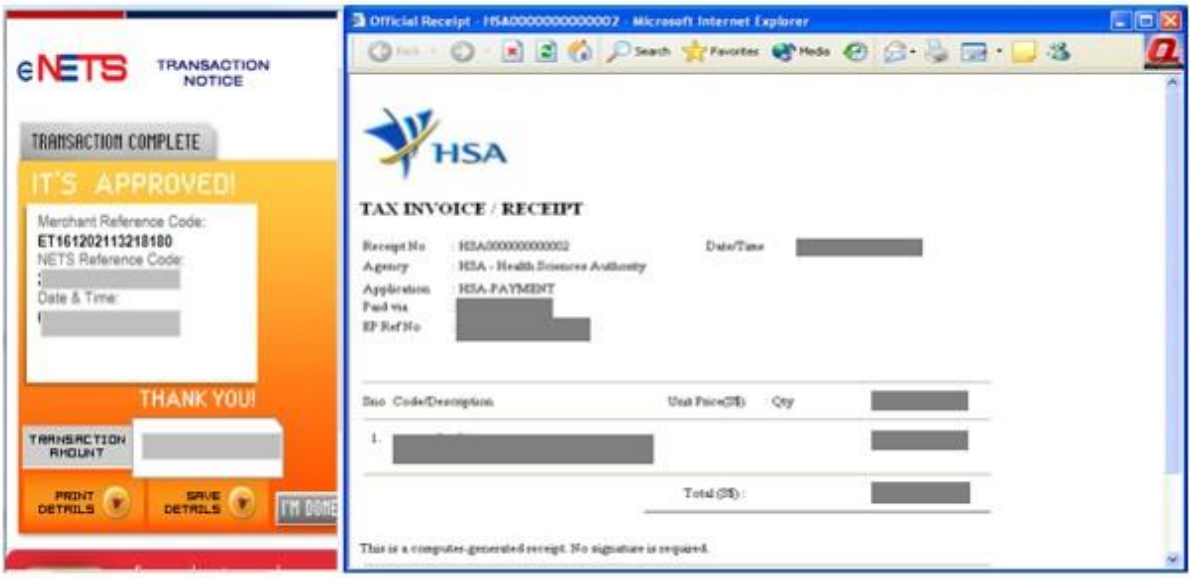
If the Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.



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.

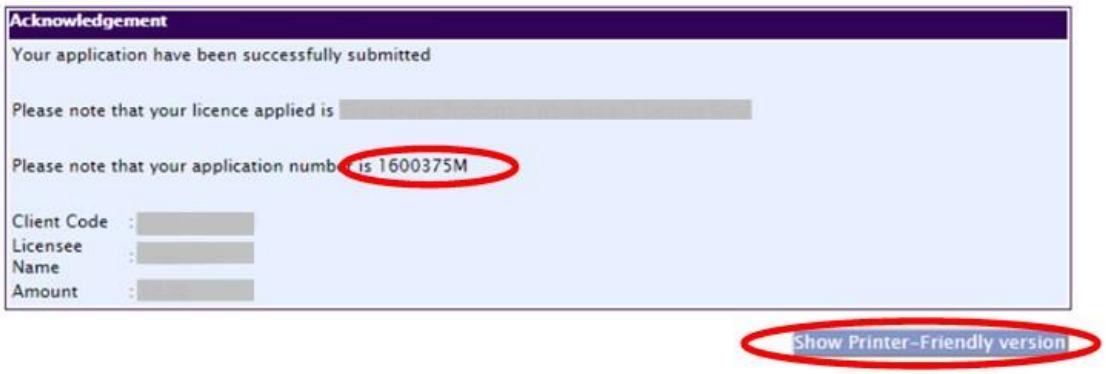


To submit the completed application, click the **'Submit'** button. Applicant will be prompt to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

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.

Input Request

Input Requests arise when the reviewing HSA officer requires further clarification from the applicant regarding the application. This section illustrates how applicants can respond to the Input Request.

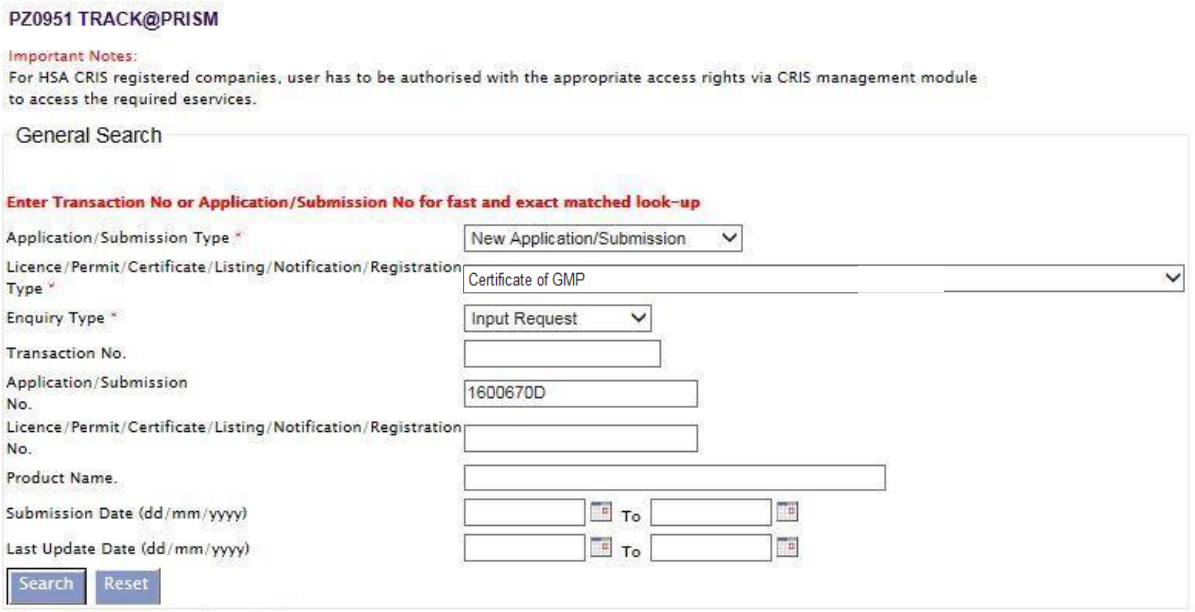
A notification will be sent to the applicant to inform the applicant to log in to track@prism to make the necessary changes.

Input requests can be classified as Primary or Secondary.

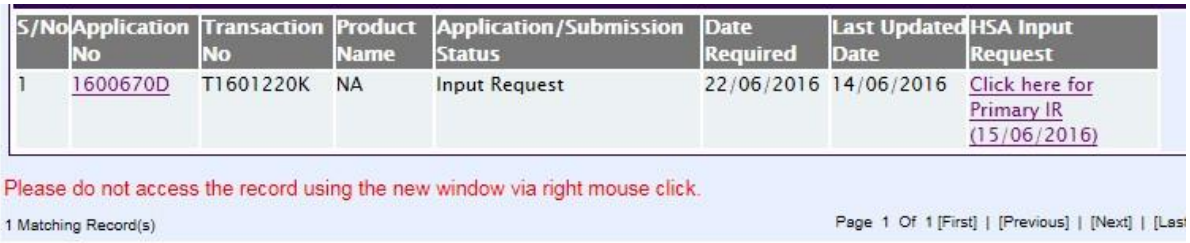
- Primary Input Request requires changes to be made directly on the application form.
- Secondary Input Request requires applicant's explanation to certain matters pertaining to the application form submitted.

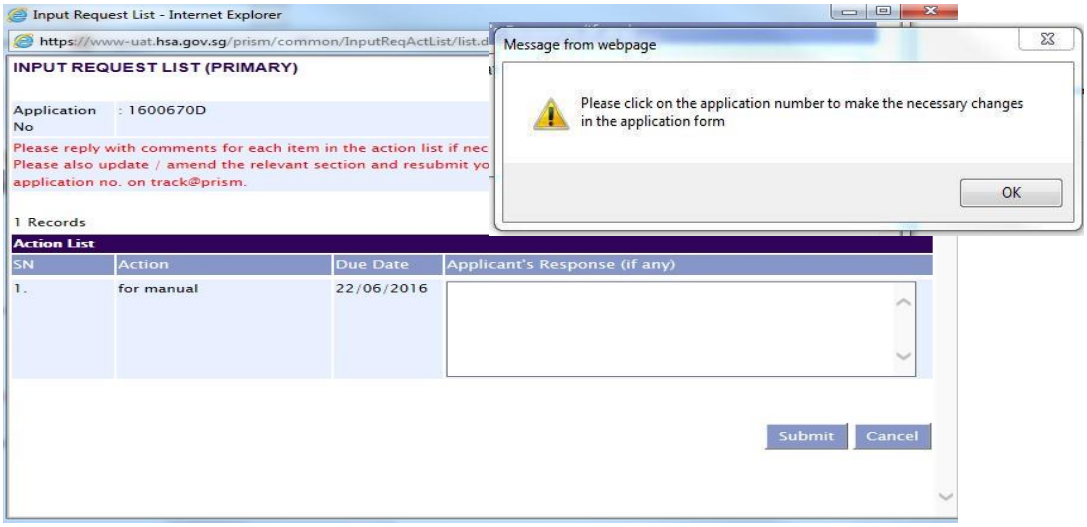
Responding to Primary Input Request

(1) In track@prism enter the Application Number to retrieve the application that requires clarification.

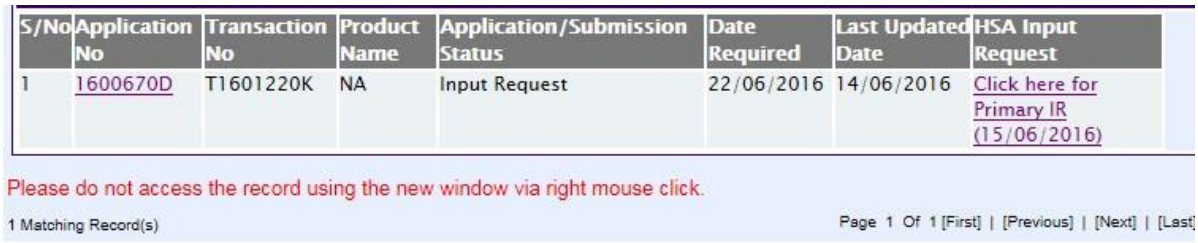


(2) Click on the **'HSA Input Request'** to view if any reply is required from the applicant. Click the **'Submit'** button and an alert message will pop up to prompt you to make the necessary changes in the application form.





(3) Click on the **'Application No.'** to open the application.

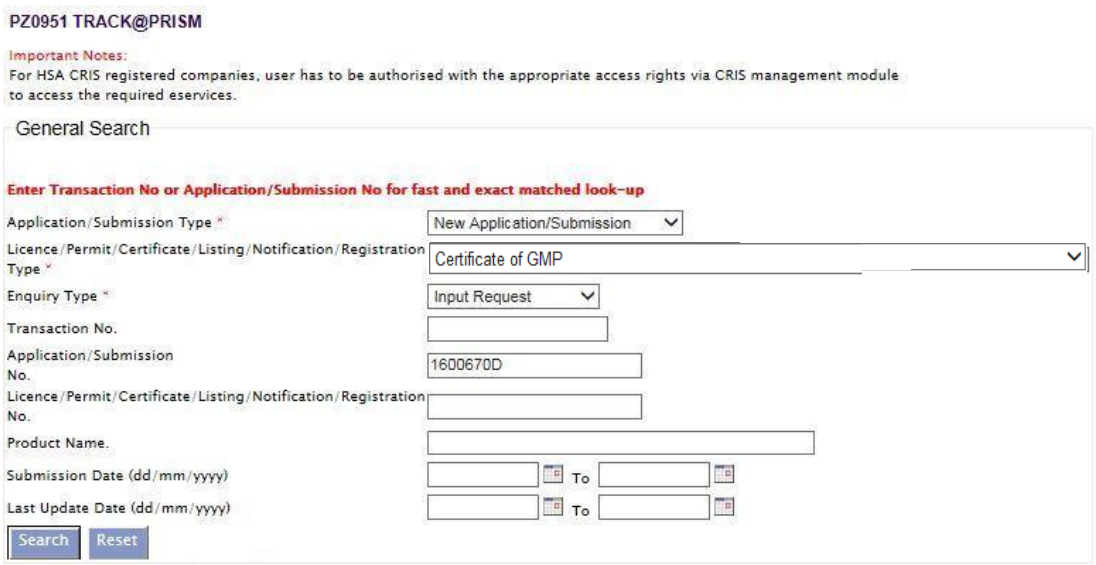


(4) The webpage will display the application form as per previously submitted.

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

Responding to Secondary Input Request

(1) In track@prism enter the **Application Number** to retrieve the application that requires clarification.



(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 application.



S/No	Application No	Transaction No	Licence/Registration No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1600783J	T1601374K		NA	Input Request	11/07/2016	04/07/2016	Click here for Secondary IR (04/07/2016)

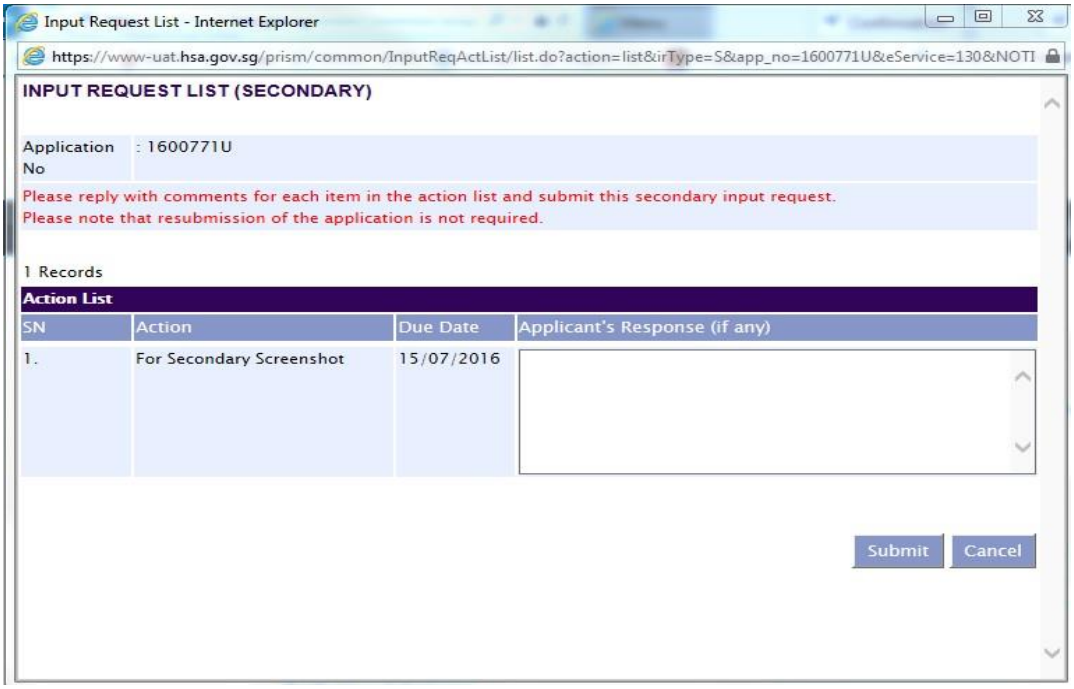
Please do not access the record using the new window via right mouse click.

1 Matching Record(s)

Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Note:
Application resubmission is required for Primary IR but not for Secondary IR.
For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

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



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)
   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