NEW APPLICATION FOR AUTHORISATION / APPROVAL TO IMPORT PSYCHOTROPIC SUBSTANCES,THERAPEUTIC PRODUCTS CONTAINING PSYCHOTROPIC SUBSTANCE OR ACTIVE INGREDIENTS THAT ARE PSYCHOTROPIC SUBTANCES

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: *The login process for Corppass will require verification of the user's identity via Singpass first before 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:

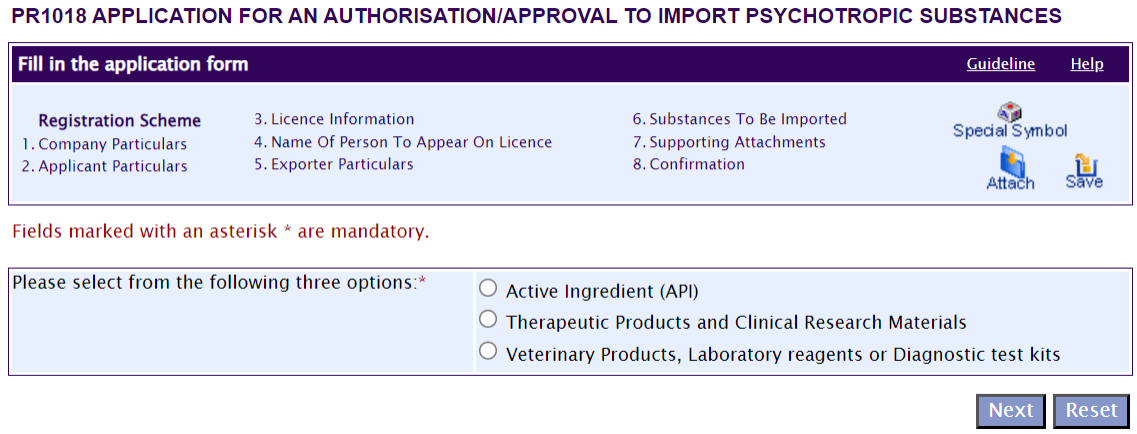
   - GIRO
   - Non-GIRO: eNETS (Credit/Debit Card)

   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

Registration Scheme

This section requires the applicant to select the relevant registration scheme based on the product type.



(1) If you are applying for an approval to import an Active Ingredient that is a Psychotropic Substance, select "**Active Ingredient (API)**" button. This includes import of Active Ingredients :

- for local manufacturing use
- for use to manufacture Clinical Research Material
- for laboratory use such as reference standards.
- for re-export

(2) If you are applying for an approval/ authorization to import Therapeutic Products or Clinical Research Materials that contains Psychotropic Substance, select "**Therapeutic Products and Clinical Research Materials**" button.

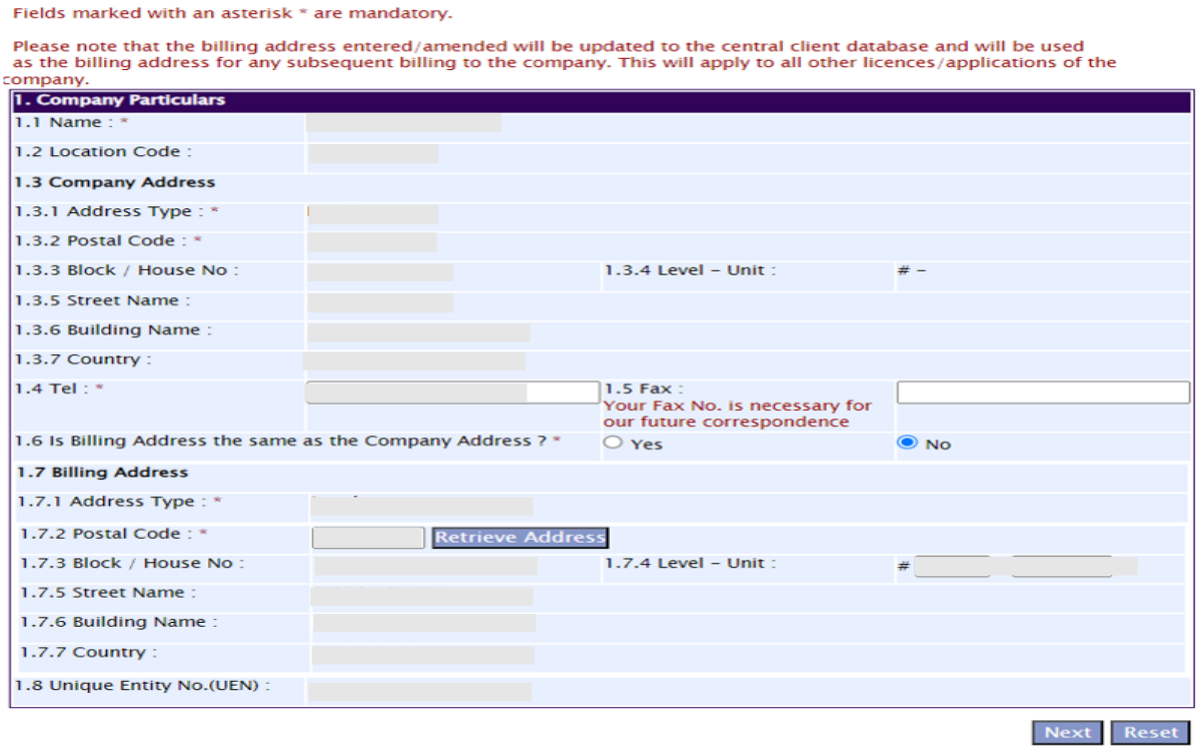
(3) If you are applying for an approval/ authorization to import Veterinary Products, Laboratory Reagents or Diagnostic test kits that contains Psychotropic Substance, select "**Veterinary Products, Laboratory reagents or Diagnostic test kits**" button.

(4) Click 'Next' button to proceed to **Part 1. Company Particulars section**.

***This section cannot be amended after you have submitted the application*.**

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.

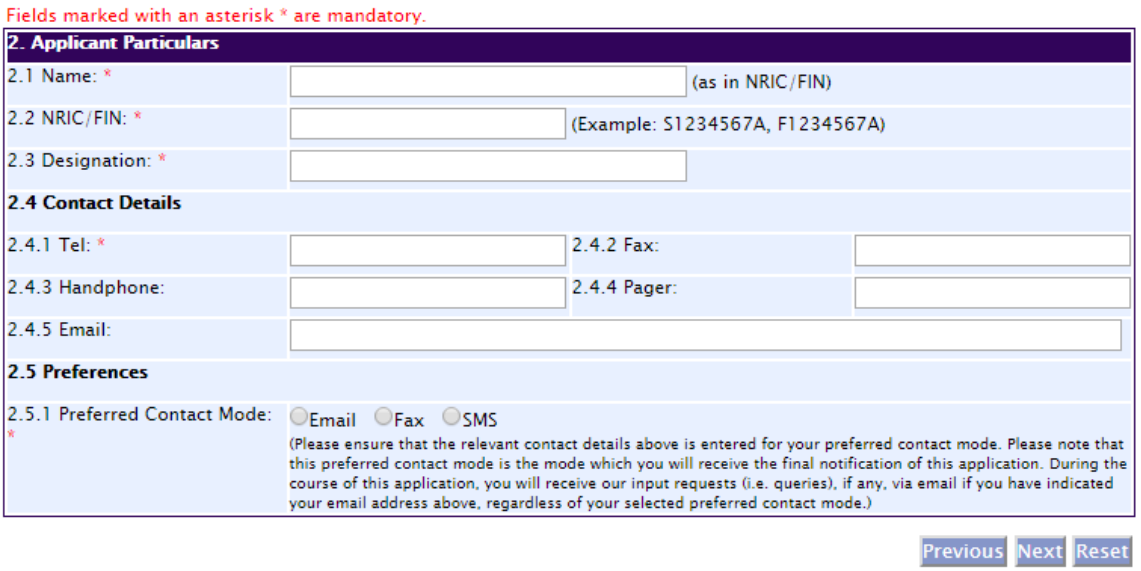
(3) If the Billing Address is not the same as **Company Address**, please fill in the **'Postal Code'** field and click the **'Retrieve Address'** button. The **Block/House No**, **Street Name** and **Building Name** will be populated.

(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.

Part 2. Applicant Particulars

This section requires the applicant to enter relevant information relating to the applicant particulars.


Fields marked with an asterisk * are mandatory.

2. Applicant Particulars

2.1 Name: *	(as in NRIC/FIN)		
2.2 NRIC/FIN: *	(Example: S1234567A, F1234567A)		
2.3 Designation: *			
2.4 Contact Details			
2.4.1 Tel: *		2.4.2 Fax:	
2.4.3 Handphone:		2.4.4 Pager:	
2.4.5 Email:			
2.5 Preferences			
2.5.1 Preferred Contact Mode: *	Email Fax SMS (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.)		

Previous Next Reset

(1) Applicant details such as name, NRIC / FIN, designation, Telephone/Fax/Handphone number and e-mail address.

(2) Select the type of **Preferred Contact Mode**.

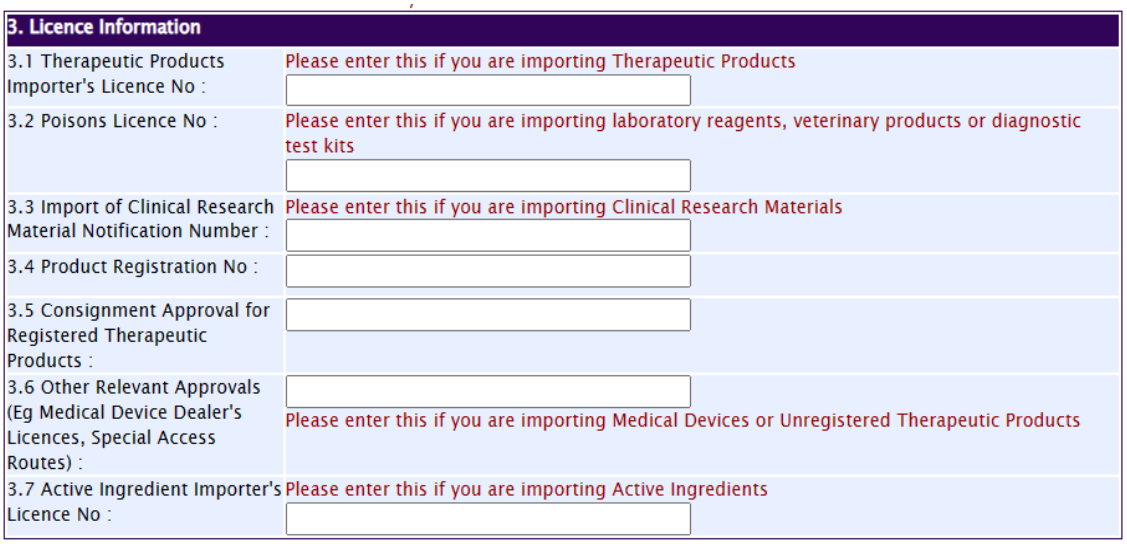
(Note: Please ensure that the relevant contact details above are entered for your preferred contact mode. Please note that the preferred contact mode is the mode which you will receive the final notification of this application.

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 relevant licence information. Refer to table below for the list of licence required to be entered for different types of product.



3. Licence Information

3.1 Therapeutic Products Importer's Licence No :	Please enter this if you are importing Therapeutic Products
3.2 Poisons Licence No :	Please enter this if you are importing laboratory reagents, veterinary products or diagnostic test kits
3.3 Import of Clinical Research Material Notification Number :	Please enter this if you are importing Clinical Research Materials
3.4 Product Registration No :	
3.5 Consignment Approval for Registered Therapeutic Products :	
3.6 Other Relevant Approvals (Eg Medical Device Dealer's Licences, Special Access Routes) :	Please enter this if you are importing Medical Devices or Unregistered Therapeutic Products
3.7 Active Ingredient Importer's Licence No :	Please enter this if you are importing Active Ingredients

Previous Next Reset

Type of product:	Licence information required to be entered in section 3:
Registered Therapeutic Product	3.1 Therapeutic Products Importer's Licence No. 3.4 Product Registration No. 3.5 Consignment Approval for Registered Therapeutic Product (Where applicable)
Unregistered Therapeutic Product	3.1 Therapeutic Products Importer's Licence No. 3.6 Other Relevant Approvals (enter Special Access Route reference)
Clinical Research Materials	3.3 Import of Clinical Research Material Notification Number
Laboratory Reagents, Veterinary Products or Diagnostic Test Kits	3.2 Poisons Licence No. 3.6 Other Relevant Approvals (enter Medical Device Dealer's Licence reference) where applicable.
Active ingredient	3.7 Active Ingredient Importer's Licence No.

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

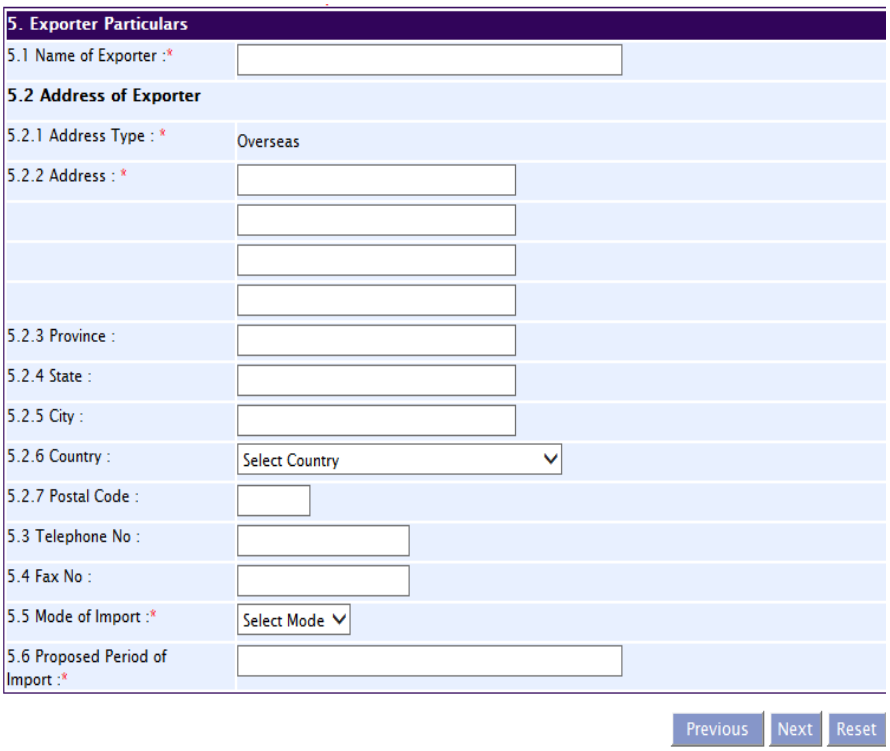
Part 4. Name of Person to Appear on Licence

This section is optional. It is completed if the company wishes to have a person responsible for the import to be named in the authorisation / approval. The person indicated should be of sufficient authority to take responsibility for the import.

Click **'Next'** button to proceed to **Part 5. Exporter Particulars** section.

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.

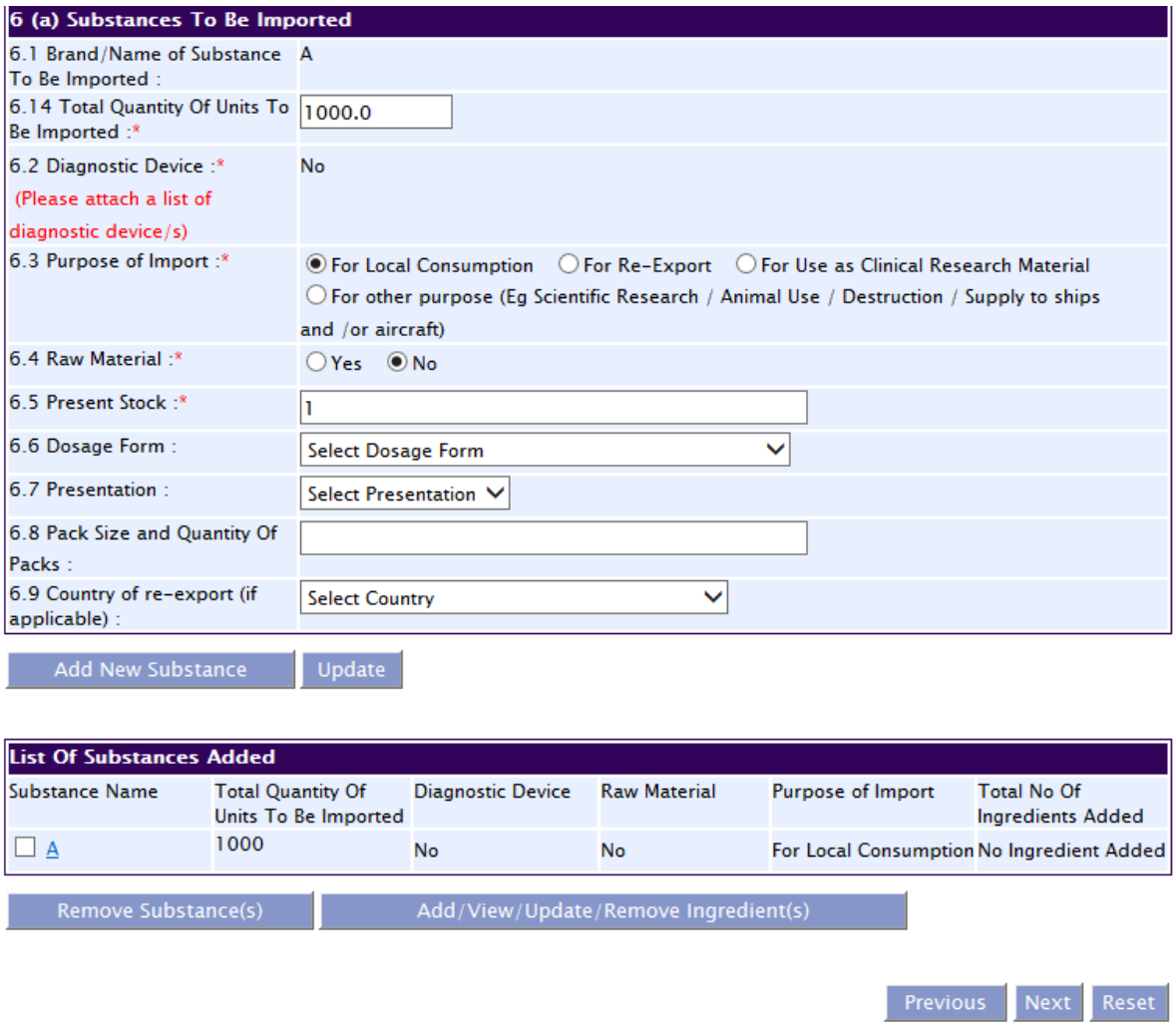
Part 6. Substances to be Imported

(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.

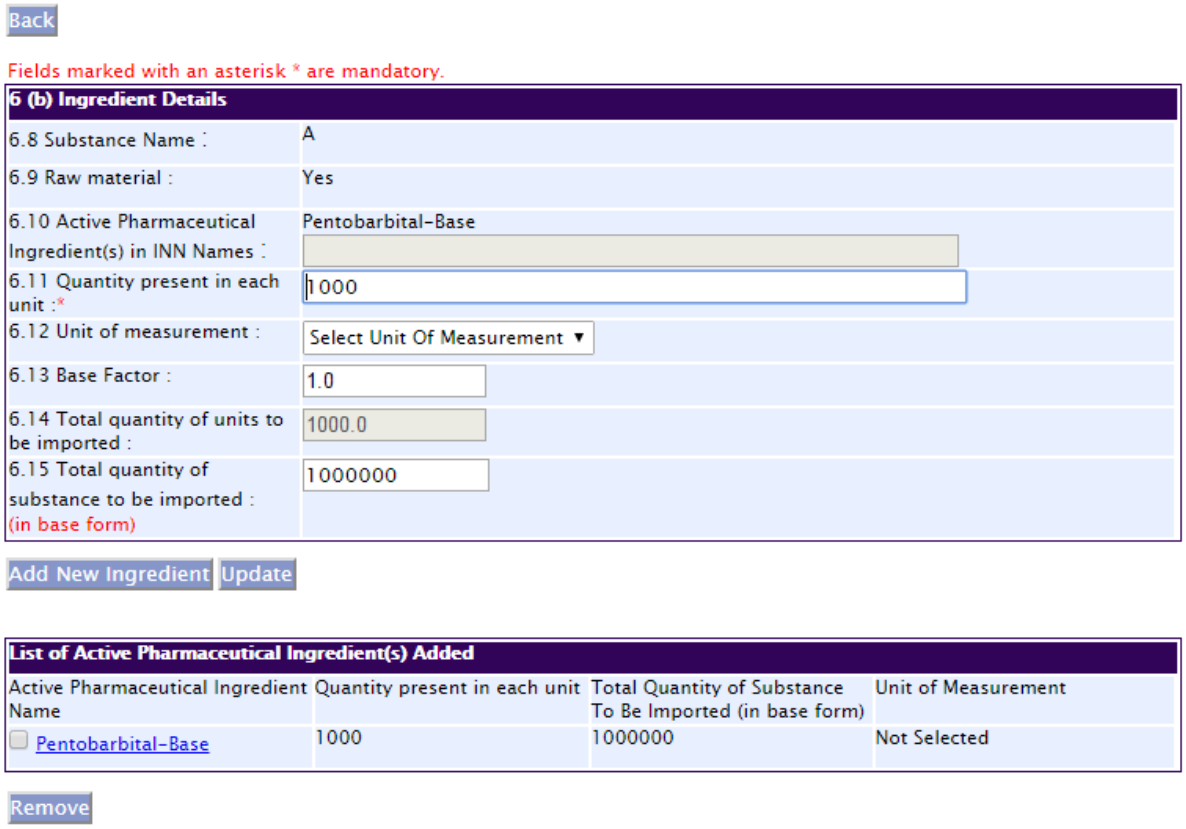
(3) Tick the box beside the substance name and click on the "**Add/View/Update/Remove Ingredient(s)**" button which will bring you to section 6(b) Ingredient Details.



(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" to proceed to **Part 7. Supporting Attachments** section.

Part 7. Supporting Attachments

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

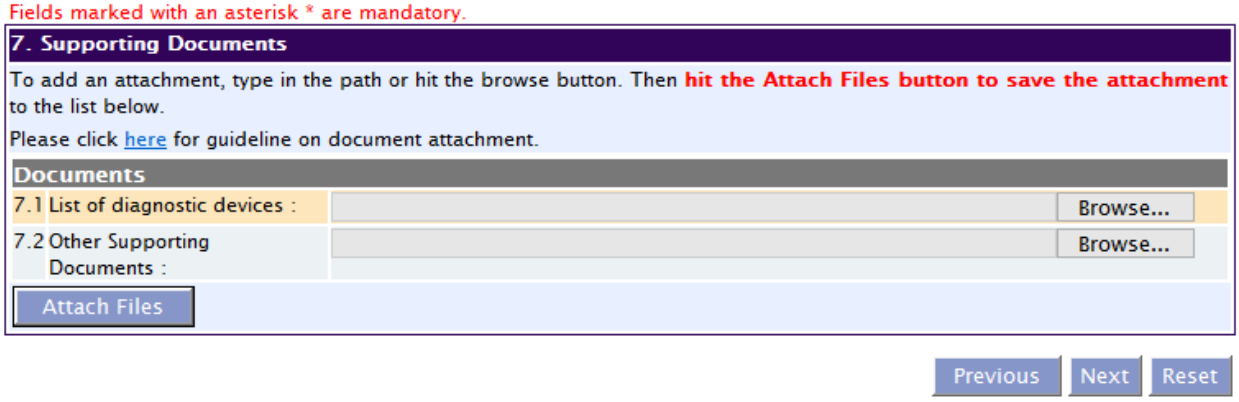
Add Supporting Attachments:

(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.

Purpose of Import	Documents required for import
Import of an Unregistered Therapeutic Product for patient's use.	Consignment approval of an Unregistered Therapeutic Product for patient's use
An Unregistered Therapeutic Product or Active Ingredient (API) imported solely for re-export.	Purchase order from overseas customer.
Import of diagnostic test kits.	List of psychotropic substances. The list should contain the following information: 1) The name of the diagnostic test kit 2) The quantity of diagnostic test kit to be imported. 3) The concentration and volume of each psychotropic substance contained within each diagnostic test kit.



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

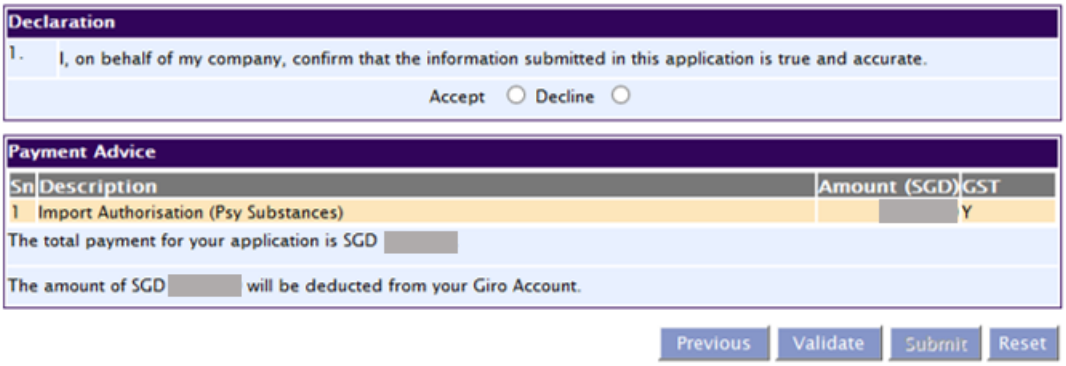
This section shows the information provided in all sections of the Application Form for Authorisation / Approval to Import Psychotropic Substances.

(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.

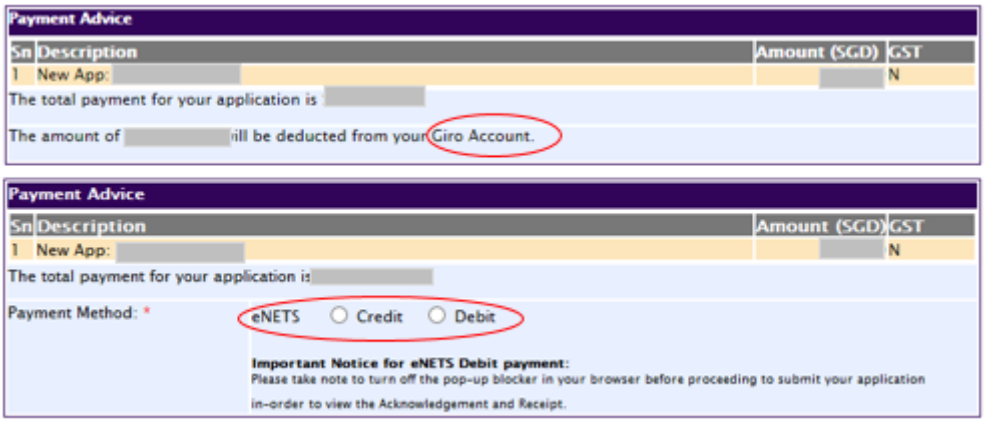


Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO
- eNETS



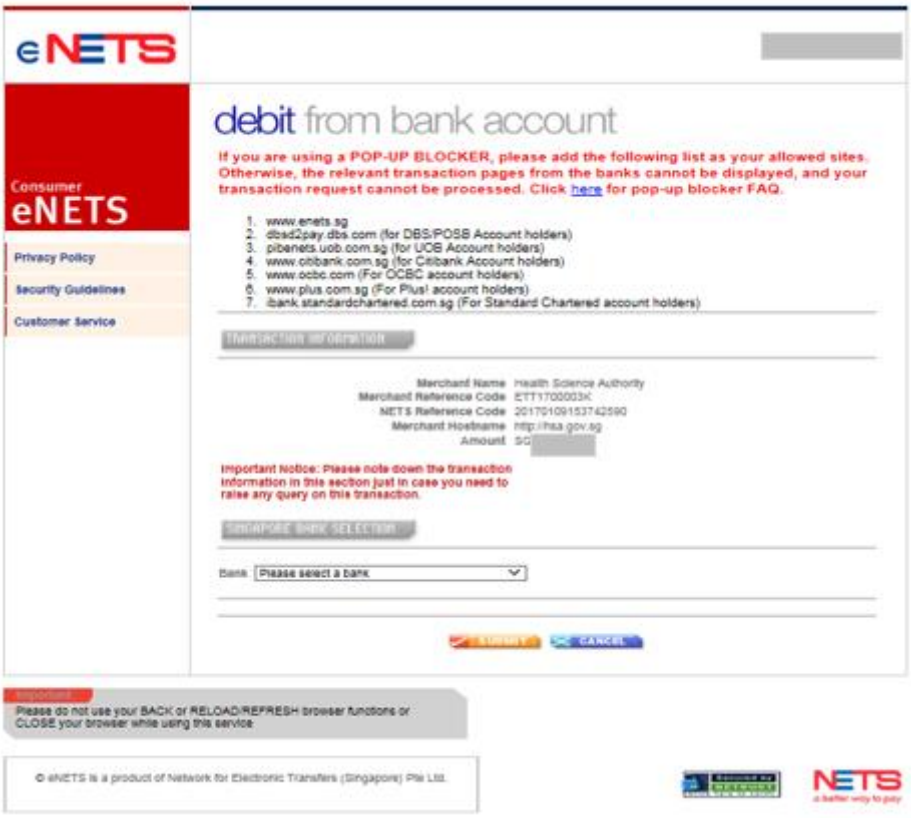
For GIRO, the amount payable will be deducted from the relevant bank account. This mode of payment is a recurring deduction.

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

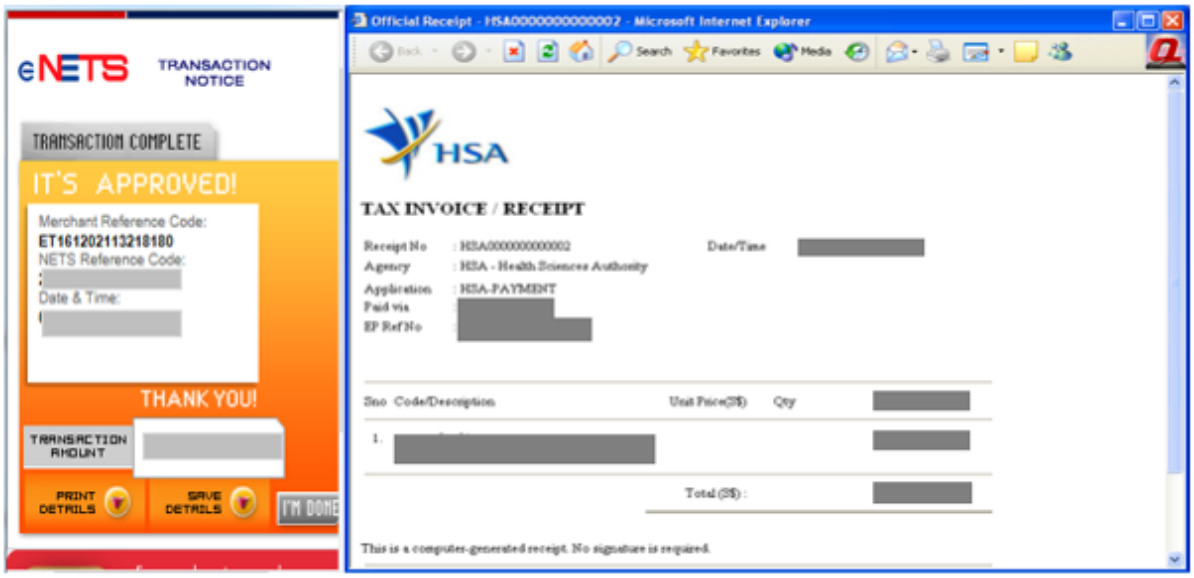
This is applicable for applicants with Non-GIRO Payment Method.

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.



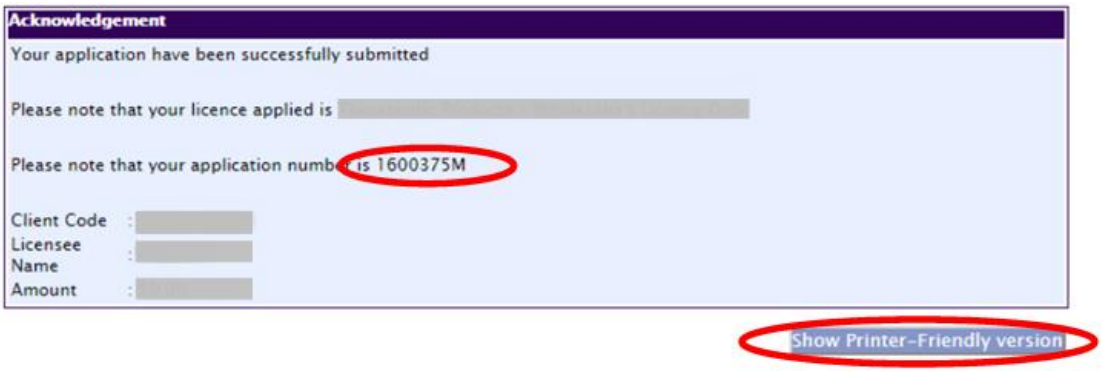
If the payment was made via eNETS and was not completed successfully, the system will prevent retrieval of the draft application and the applicant will need to contact HSA HelpDesk for assistance.

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.

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.

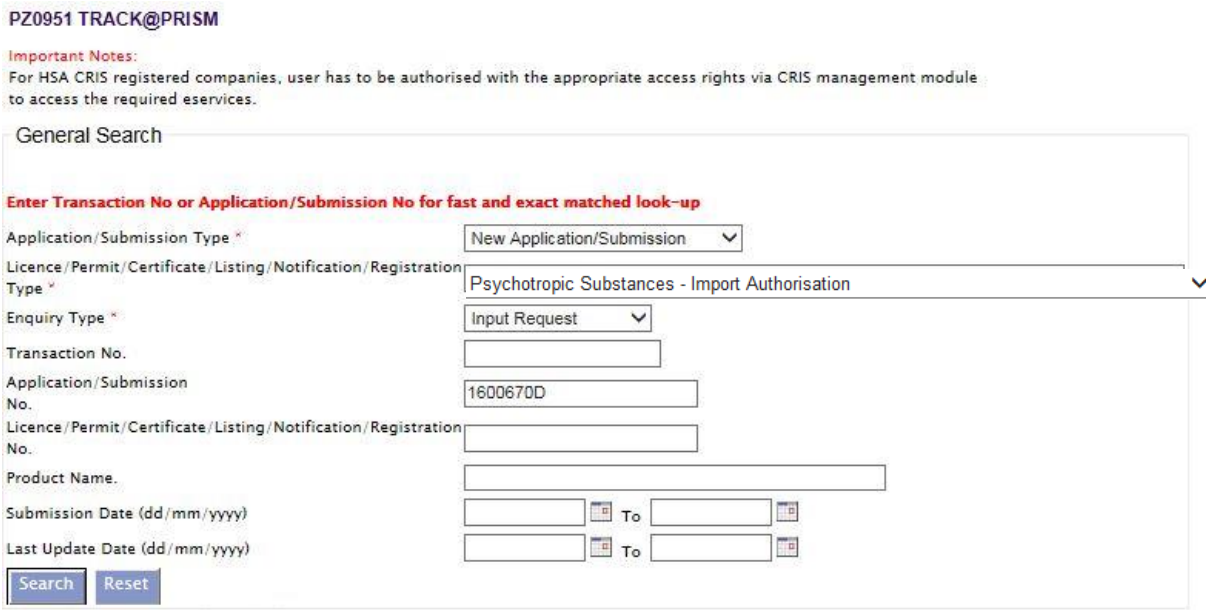
A notification will be sent to the applicant to inform the applicant to log in to track@prism to make the necessary changes.

Input requests can be classified as Primary or Secondary.

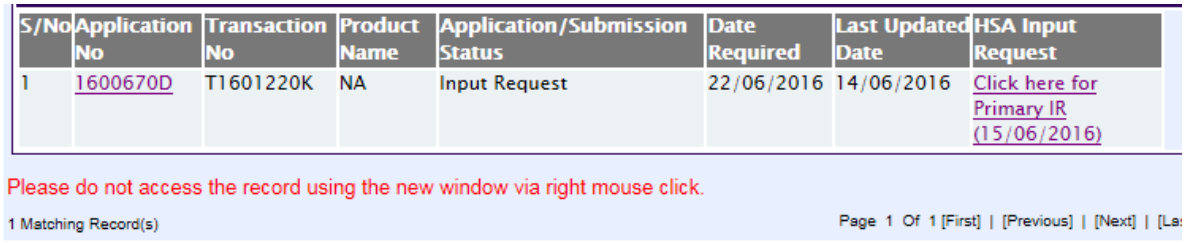
- Primary Input Request requires changes to be made directly on the application form.
- Secondary Input Request requires applicant's explanation to certain matters pertaining to the application form submitted.

Responding to Primary Input Request

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



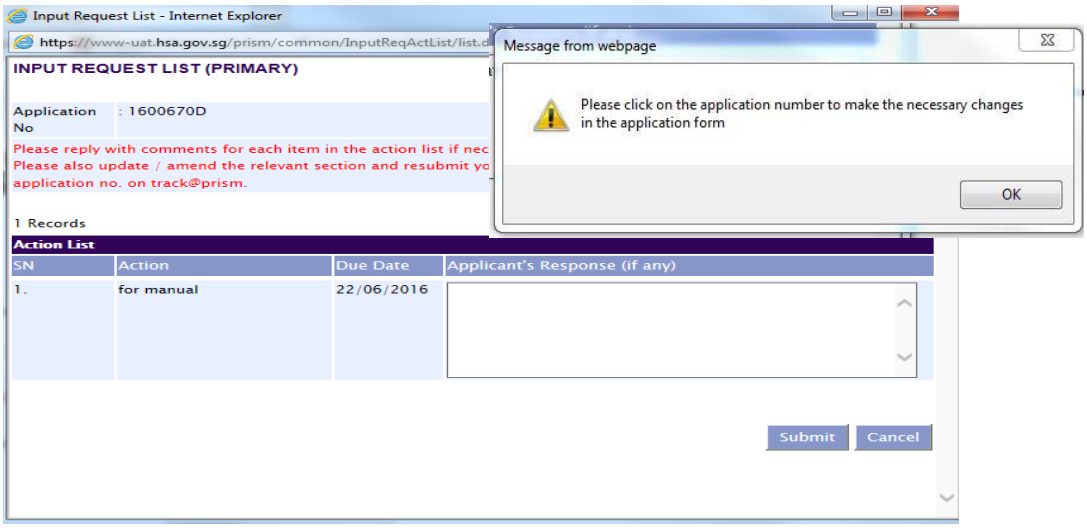
(2) Click on the **'HSA Input Request'** to view if any reply is required from the applicant. Click the **'Submit'** button and an alert message will pop up to prompt you to make the necessary changes in the application form.



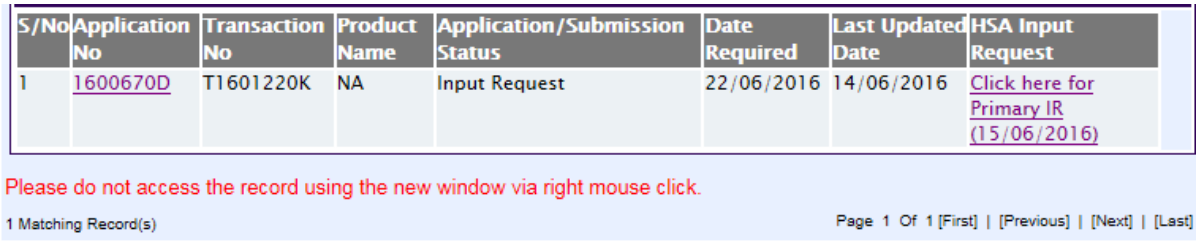
S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1600670D	T1601220K	NA	Input Request	22/06/2016	14/06/2016	Click here for Primary IR (15/06/2016)

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] | [La



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



S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1600670D	T1601220K	NA	Input Request	22/06/2016	14/06/2016	Click here for Primary IR (15/06/2016)

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

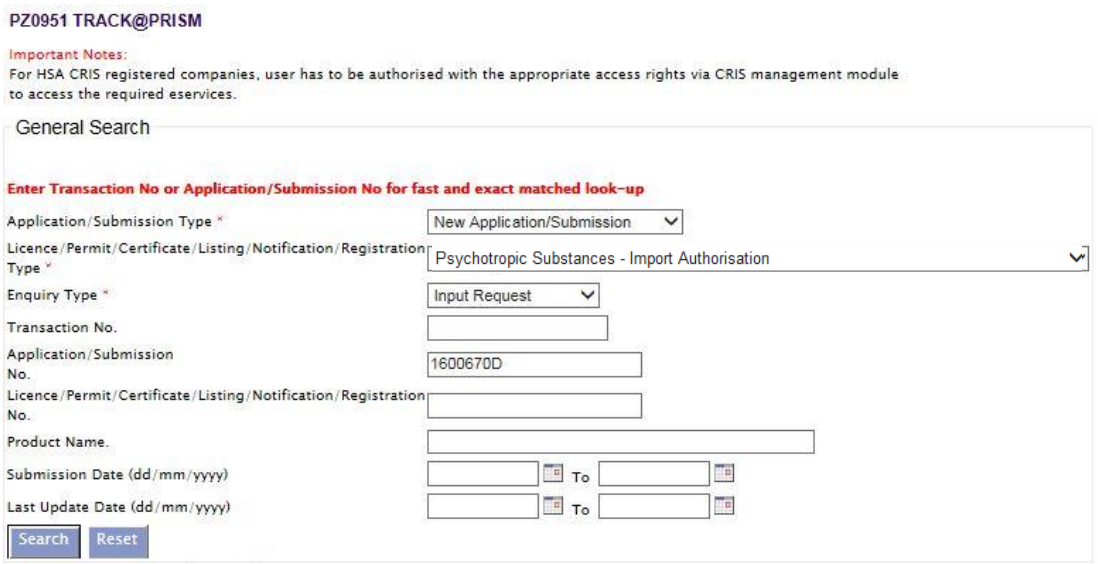
1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

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

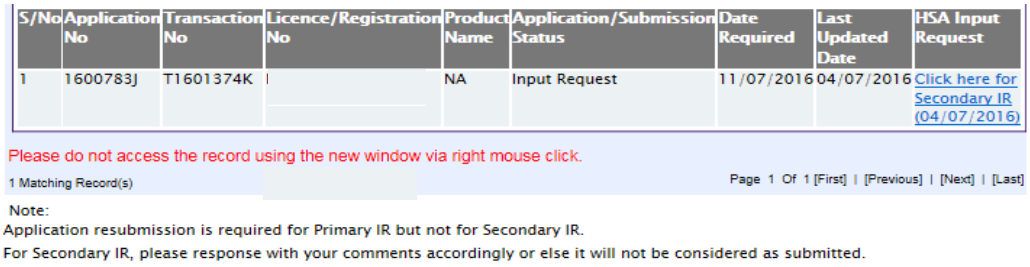
(5) Proceed to make the necessary changes for the section(s) that require clarification and submit the revised application form.

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)

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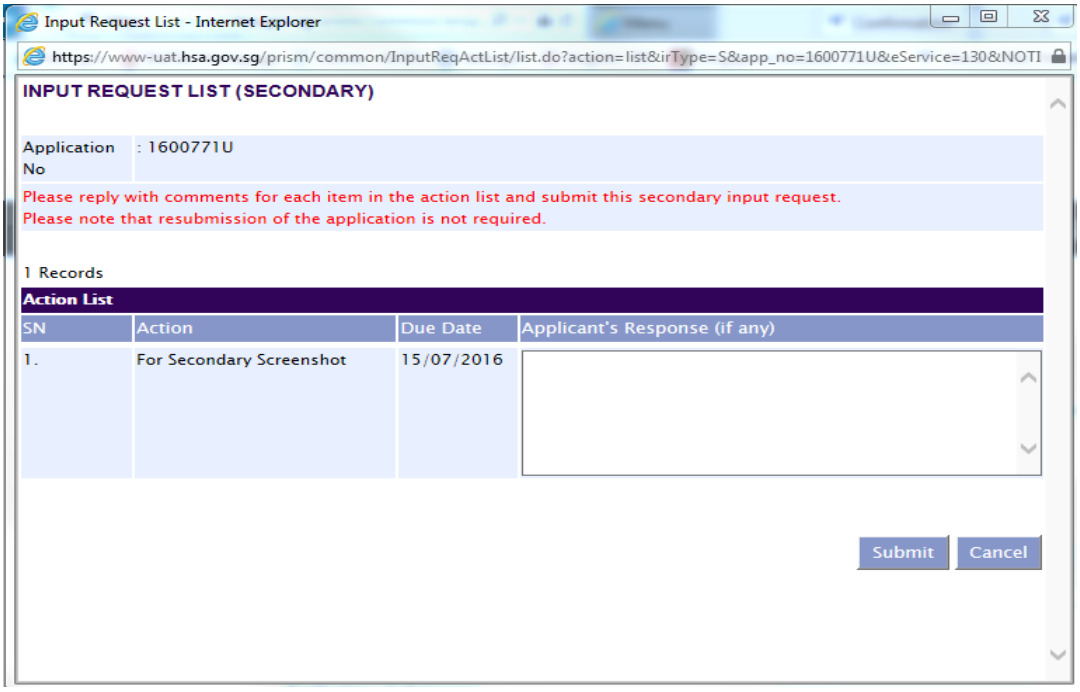
Note:
Application resubmission is required for Primary IR but not for Secondary IR.
For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

(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. For enquiries related to PSIA applications, please contact the Audit and Licensing Division at Tel: 6866 1111 or email to hsa_certification@hsa.gov.sg .

3. For IT issues encountered during the application submission, kindly contact the HSA Helpdesk at Tel: 6776 0168 (from 7:00 am to midnight daily) or email to helpdesk@hsahelp.gov.sg.