

## **NEW APPLICATION FOR CERTIFICATE OF A PHARMACEUTICAL PRODUCT**

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](mailto: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.

#### PR1001 APPLICATION FOR CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Fill in the application form				Guideline	Help
<b>Registration Scheme</b>	2. Applicant Particulars	4. Manufacturer Particulars	6. Confirmation		
1. Company Particulars	3. Product Particulars	5. Supporting Attachments			

Fields marked with an asterisk \* are mandatory.

Please select from the following two options:\*

Active Ingredient (API)  
 Pharmaceutical Product

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- (1) If you are applying for a CPP for Registered/Non-registered Therapeutic Product or Medicated Oil and Balm, select “**Pharmaceutical Product**” button.
- (2) If you are applying for a CPP for Active Ingredient (API), select “**Active Ingredient (API)**” button.
- (3) 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.

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.

1. Company Particulars			
1.1 Name : *	<input type="text"/>		
1.2 Location Code :	<input type="text"/>		
<b>1.3 Company Address</b>			
1.3.1 Address Type : *	<input type="text"/>		
1.3.2 Postal Code : *	<input type="text"/>		
1.3.3 Block / House No :	<input type="text"/>	1.3.4 Level – Unit :	# - <input type="text"/>
1.3.5 Street Name :	<input type="text"/>		
1.3.6 Building Name :	<input type="text"/>		
1.3.7 Country :	<input type="text"/>		
1.4 Tel : *	<input type="text"/>	1.5 Fax :	<input type="text"/>
		Your Fax No. is necessary for our future correspondence	
1.6 Is Billing Address the same as the Company Address ? *	<input type="radio"/> Yes <input checked="" type="radio"/> No		
<b>1.7 Billing Address</b>			
1.7.1 Address Type : *	<input type="text"/>		
1.7.2 Postal Code : *	<input type="text"/>	<a href="#">Retrieve Address</a>	
1.7.3 Block / House No :	<input type="text"/>	1.7.4 Level – Unit :	# <input type="text"/>
1.7.5 Street Name :	<input type="text"/>		
1.7.6 Building Name :	<input type="text"/>		
1.7.7 Country :	<input type="text"/>		
1.8 Unique Entity No.(UEN) :	<input type="text"/>		

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- (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 make changes to this information, please submit the changes via the “**Amend Company Information**” module under the [amend@prism](mailto: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: *	<input type="text"/>	(as in NRIC/FIN)	
2.2 NRIC/FIN: *	<input type="text"/>	(Example: S1234567A, F1234567A)	
2.3 Designation: *	<input type="text"/>		
2.4 Contact Details			
2.4.1 Tel: *	<input type="text"/>	2.4.2 Fax:	<input type="text"/>
2.4.3 Handphone:	<input type="text"/>	2.4.4 Pager:	<input type="text"/>
2.4.5 Email:	<input type="text"/>		
2.5 Preferences			
2.5.1 Preferred Contact Mode: *	<input type="radio"/> Email <input type="radio"/> Fax <input type="radio"/> SMS		
	<small>(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.)</small>		

- (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. Product Particulars** section.

### Part 3. Product Particulars

This section requires the applicant to verify and enter any other relevant information relating to the product particulars.

Fields marked with an asterisk \* are mandatory.

3. Product Particulars	
3.1 Is the product licensed to be placed on the market in Singapore? *	<input type="radio"/> Yes <input checked="" type="radio"/> No
3.2 Product Licence Number : *	<input type="text"/> <input type="button" value="Retrieve Details"/>
3.3 Name of the product (in English) : *	<input type="text"/>
3.4 Is this product actually on the market in Singapore? *	<input type="radio"/> Yes <input checked="" type="radio"/> No
3.5 Name of the Importing Country : *	<input type="text"/>
3.6 Remarks :	<input type="text"/>
3.7 Dosage Form : *	<input type="text"/>
3.8 Complete Composition Of the Product	
3.8.1 Name of the Substance : *	<input type="text"/>
3.8.2 Strength : *	<input type="text"/>
<input type="button" value="Add Substance and Strength"/>	

**Default printing of the Schedule includes both the active pharmaceutical ingredients and excipients, unless otherwise stated under remarks in your application.**

- (1) Select '**Yes**' or '**No**' as to whether the product is licensed in Singapore. For Active Ingredients (API), please select "No".
- (2) If you select '**Yes**', enter the Product Registration Number (must be registered under the same company as the applicant) and click on Retrieve Details button. The following details will be populated on the screen:
  - Name of the product (in English)
  - Dosage form
  - Complete composition of the product (the Add Substance and Strength button is disabled)
  - Route of administration
- (3) If you select '**No**',
  - (1) Provide the **name of product (in English)** under section 3.3
  - (2) Select the **dosage form** of the product from the 'drop down list' under section 3.7
  - (3) Provide the complete composition of the product, using the '**Add Substance and Strength**' button.
 

Add Substance(s)

    - (1) Fill in Name of the Substance and Strength.
    - (2) Click on the Add Substance and Strength button.
    - (3) Repeat steps (1) to (2) to add another substance in the product.

Remove Substance(s)

    - (1) Click on the checkbox adjacent to the substance(s) from the table.
    - (2) Click on the Remove button to delete the substance(s).
- (4) Select '**Yes**' or '**No**' as to whether the product is on the market in Singapore. For Active Ingredients (API), please select "No".

- (5) Select the **importing country** from the 'Drop down" list of import countries.
- (6) Under the "**Remarks**" field you can provide information such as
  - (1) whether products would be marketed under different trade name in the importing country
  - (2) whether complete composition or active ingredients is required in the default schedule
  - (3) which manufacturing sites are required in the certificate
- (7) Click the Next button to go to **Part 4. Manufacturer Particulars** section.

#### **Part 4. Manufacturer Particulars**

This section allows the input of manufacturer particulars.

Fields marked with an asterisk \* are mandatory.

4. Manufacturer Particulars	
4.1 Is the manufacturer licenced ? :	<input checked="" type="radio"/> Yes <input type="radio"/> No
4.2 Manufacturer Licence Number	<input type="text"/> <a href="#">Retrieve Details</a>

Manufacturer Licence	Manufacturer Name
	TestMfc
	TestMfcActive

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***Default printing on the certificate includes all sites related to bulk manufacturing, labelling and packing activities for the product, unless otherwise stated under remarks in your application.***

- (1) Based on the information provided Part 3 - Product Particulars, the manufacturer's licence and name will be automatically displayed if the product is registered to be placed on the market in Singapore.
- (2) For Non-Registered Therapeutic Product, Medicated oil and Balm and Active Ingredient (API), select '**Yes**' or '**No**' as to whether the manufacturer is licensed.
- (3) If the manufacturer is licensed, provide the **Manufacturer Licence Number** and click on **Retrieve Details** button. The Manufacturer Name and the Manufacturer Address will be populated on the screen.
- (4) If the manufacturer is not licensed, provide the **GMP Certificate Number** and click '**Retrieve Details**' button. The information regarding the manufacturer will be retrieved and displayed.
- (5) Click the Next button to go to **Part 5. Supporting Attachments** section.

### Part 5. Supporting Attachments

This section requires the applicant to attach the following supporting documents:

Listing of supporting documents	For Registered Therapeutic Product	For Non-Registered Therapeutic Product and Medicated Oil and Balm	For Active Ingredient (API)
Recent local sales invoice	If applicable	If applicable	NA
Scanned / digital photograph of the product sample	NA	Yes	Yes
Label and printed packaging materials of product	NA	Yes	Yes
Master Formula and manufacturing procedure of product	NA	Yes	Yes
Package Insert and other additional product details (e.g. patient information leaflet or composition) Company's declaration letter for the above	If applicable	NA	NA
The schedule (in Microsoft Word format)	If applicable	Yes	Yes

Fields marked with an asterisk \* are mandatory.

**5. 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**

5.1 Recent local sales invoice : \*  No file chosen

5.2 Other Supporting Documents :  No file chosen

Select All to delete all attachment records

Sn	Attachment Name	Attachment Type	Size (Kb)	Remarks
1	<a href="#">test1.txt</a>	Recent local sales invoice	1	

To remove an attachment, click on the checkbox. Then hit the Remove button to remove the attachment from the list.

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 6. 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 6. Confirmation**

This section shows the information provided in all sections of the Application Form for a Certificate of a Pharmaceutical Product.

- (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.

Declaration	
1.	I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
<input type="radio"/> Accept <input type="radio"/> Decline	

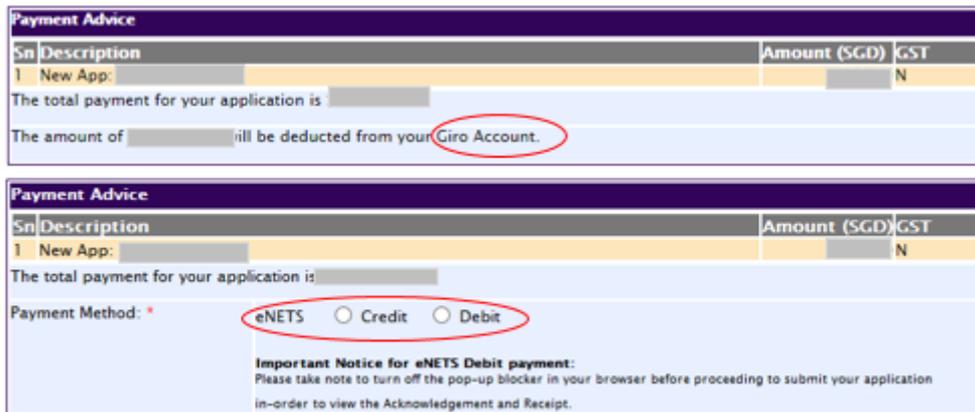
Payment Advice			
Sn	Description	Amount (SGD)	GST
1	Certificate of Pharmaceutical Product		Y
The total payment for your application is SGD [ ]			
The amount of SGD [ ] will be deducted from your Giro Account.			

## Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO
- eNETS



**Payment Advice**

Sn	Description	Amount (SGD)	GST
1	New App: [redacted]	[redacted]	N

The total payment for your application is [redacted]

The amount of [redacted] will be deducted from your **Giro Account**.

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**Payment Advice**

Sn	Description	Amount (SGD)	GST
1	New App: [redacted]	[redacted]	N

The total payment for your application is [redacted]

Payment Method: \* **eNETS**  Credit  Debit

**Important Notice for eNETS Debit payment:**  
Please take note to turn off the pop-up blocker in your browser before proceeding to submit your application in-order to view the Acknowledgement and Receipt.

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.



**eNETS**

Consumer eNETS

Privacy Policy  
Security Guidelines  
Customer Service

### credit/debit card payment

If you are using a pop-up blocker, please add the following list as your allowed sites. Otherwise, the required transaction pages from the banks may not be displayed, or your transaction request may not be completed.

1. www.enets.sg

**TRANSACTION INFORMATION**

Merchant Name: Health Sciences Authority  
Merchant Reference Code: ECT1700002K  
NETS Reference Code: 2017010R152942902  
Amount: SGD 500.00

**Important Notice:** Please note down the transaction information in this section just in case you need to raise any query on this transaction.

**CREDIT/DEBIT CARD INFORMATION**

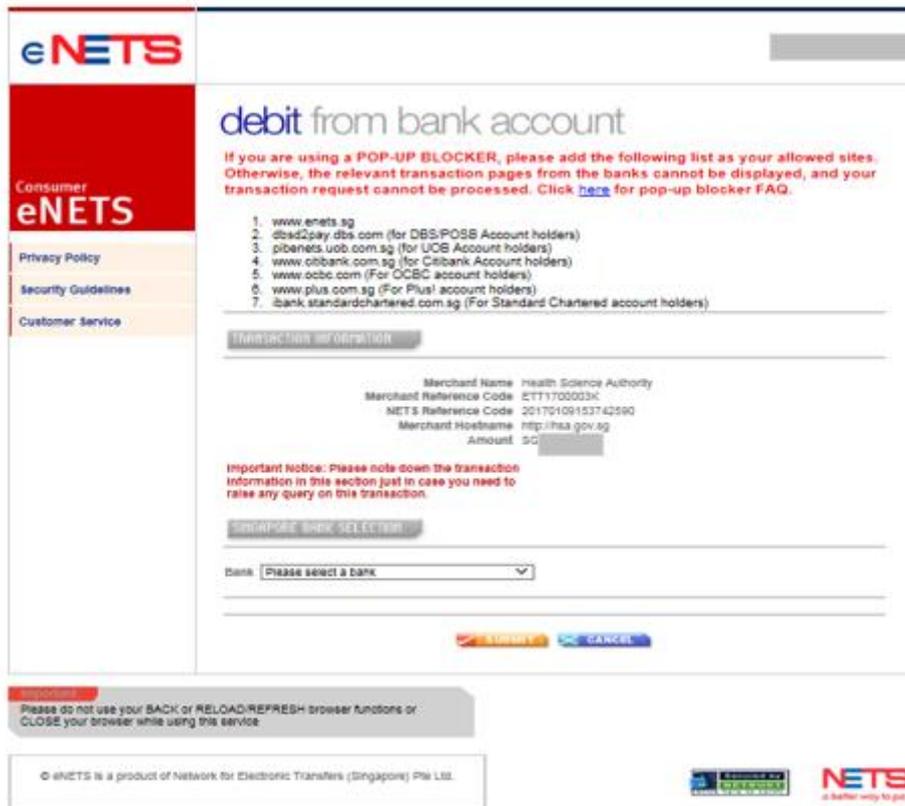
Name on Card: [input]  
Card Number: [input]  
CVV / CVC2: [input] (What is CVV/CVC2)  
Expiry Date: [Month] [Year] (eg. 2017)

I have read, understood and accepted the following:

- The return & refund policy for the purchase of relevant products / services.
- The collection, use, disclosure and sharing of this information, which to the best of my knowledge and belief is true and accurate and is for purposes reasonably required to process my application which are set out in **NETS' Data Protection Policy**.

Fast, Secure & Hassle-free transactions

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.



**eNETS**

Consumer eNETS

Privacy Policy  
Security Guidelines  
Customer Service

### debit from bank account

If you are using a POP-UP BLOCKER, please add the following list as your allowed sites. Otherwise, the relevant transaction pages from the banks cannot be displayed, and your transaction request cannot be processed. Click [here](#) for pop-up blocker FAQ.

1. www.enets.sg
2. dbad2pay.dbs.com (for DBS/POSB Account holders)
3. pibanets.uob.com.sg (for UOB Account holders)
4. www.ccbank.com.sg (for Citibank Account holders)
5. www.ocbc.com (For OCBC account holders)
6. www.plus.com.sg (For Plus+ account holders)
7. /bank.standardchartered.com.sg (For Standard Chartered account holders)

**Transaction Information**

Merchant Name: Health Science Authority  
 Merchant Reference Code: ETT1700003K  
 NETS Reference Code: 20170109153742590  
 Merchant Hostname: http://hsa.gov.sg  
 Amount: SG [REDACTED]

**Important Notice:** Please note down the transaction information in this section just in case you need to raise any query on this transaction.

**SINGAPORE BANK SELECTOR**

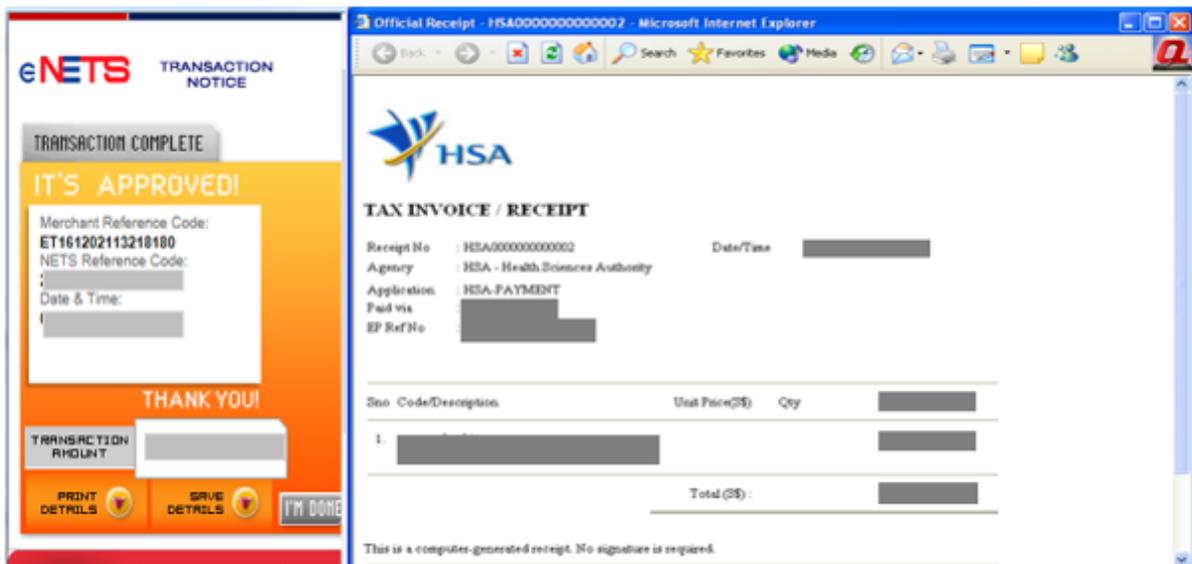
Bank:

Please do not use your BACK or RELOAD/REFRESH browser functions or CLOSE your browser while using this service.

© eNETS is a product of Network for Electronic Transfers (Singapore) Pte Ltd.

NETS a better way to pay

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



**eNETS TRANSACTION NOTICE**

TRANSACTION COMPLETE

**IT'S APPROVED!**

Merchant Reference Code: ET161202113218100  
 NETS Reference Code: [REDACTED]  
 Date & Time: [REDACTED]

**THANK YOU!**

TRANSACTION AMOUNT: [REDACTED]

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Official Receipt - HSA0000000000007 - Microsoft Internet Explorer

**HSA**

**TAX INVOICE / RECEIPT**

Receipt No : HSA0000000000002      Date/Time : [REDACTED]  
 Agency : HSA - Health Sciences Authority  
 Application : HSA-PAYMENT  
 Paid via : [REDACTED]  
 EP RefNo : [REDACTED]

Slno	Code/Description	Unit Price(S\$)	Qty
1.	[REDACTED]	[REDACTED]	[REDACTED]
Total (S\$):			[REDACTED]

This is a computer-generated receipt. No signature is required.

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.

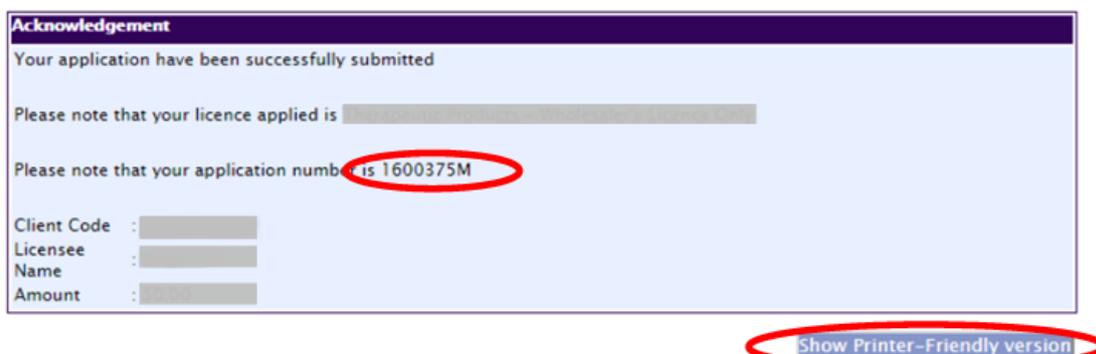


To submit the completed application, click the **'Submit'** button. Applicant will be prompt to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

### **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](mailto: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](mailto:track@prism) enter the Application Number to retrieve the application that requires clarification.

PZ0951 TRACK@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 services.

**General Search**

**Enter Transaction No or Application/Submission No for fast and exact matched look-up**

Application/Submission Type \*

Licence/Permit/Certificate/Listing/Notification/Registration Type \*

Enquiry Type \*

Transaction No.

Application/Submission No.

Licence/Permit/Certificate/Listing/Notification/Registration No.

Product Name.

Submission Date (dd/mm/yyyy)  To

Last Update Date (dd/mm/yyyy)  To

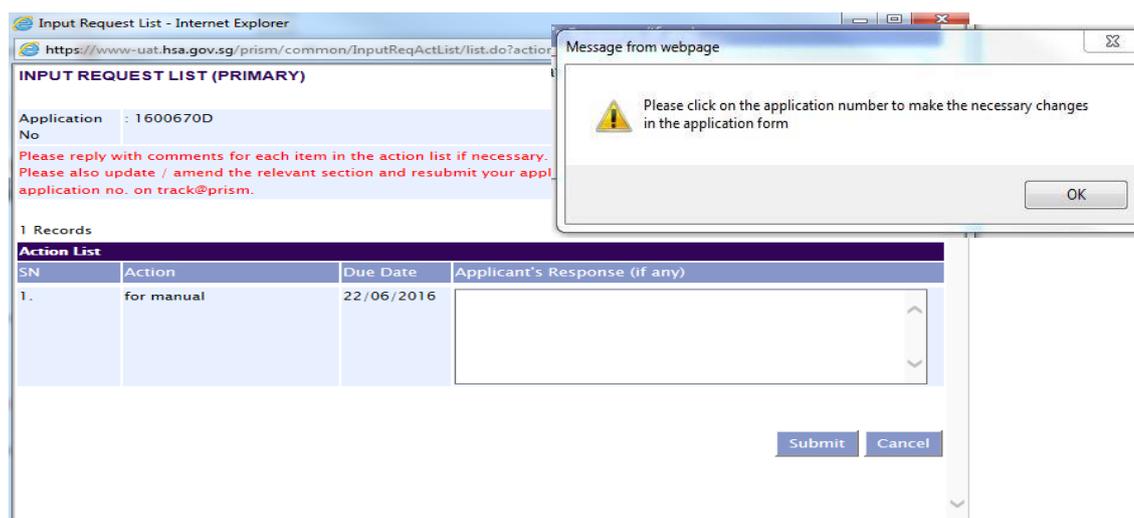
- (2) Click on the 'HSA Input Request' to view if any reply is required from the applicant. Click the 'Submit' button and an alert message will pop up to prompt you to make the necessary changes in the application form.

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

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

1 Matching Record(s)

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Input Request List - Internet Explorer

https://www-uat.hsa.gov.sg/prism/common/InputReqActList/list.do?action=...

**INPUT REQUEST LIST (PRIMARY)**

Application No : 1600670D

Please reply with comments for each item in the action list if necessary. Please also update / amend the relevant section and resubmit your application no. on track@prism.

1 Records

SN	Action	Due Date	Applicant's Response (if any)
1.	for manual	22/06/2016	

Message from webpage

Please click on the application number to make the necessary changes in the application form

- (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	<a href="#">1600670D</a>	T1601220K	NA	Input Request	22/06/2016	14/06/2016	<a href="#">Click here for Primary IR (15/06/2016)</a>

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

1 Matching Record(s)

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- (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](mailto:track@prism) enter the **Application Number** to retrieve the application that requires clarification.

PZ0951 TRACK@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 services.

**General Search**

**Enter Transaction No or Application/Submission No for fast and exact matched look-up**

Application/Submission Type \*

Licence/Permit/Certificate/Listing/Notification/Registration Type \*

Enquiry Type \*

Transaction No.

Application/Submission No.

Licence/Permit/Certificate/Listing/Notification/Registration No.

Product Name.

Submission Date (dd/mm/yyyy)  To

Last Update Date (dd/mm/yyyy)  To

- (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	<a href="#">Click here for Secondary IR (04/07/2016)</a>

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

1 Matching Record(s)

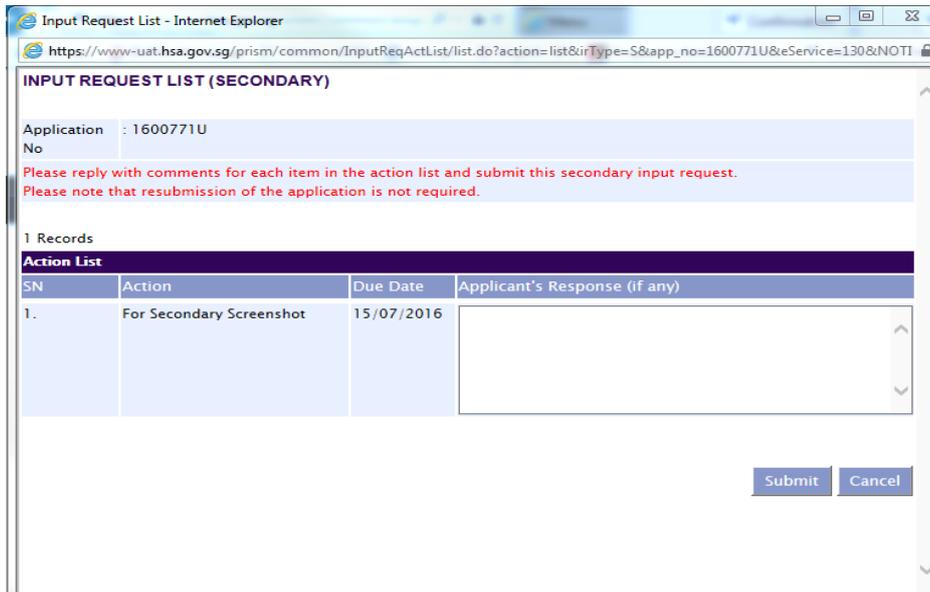
Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

**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.



**INPUT REQUEST LIST (SECONDARY)**

Application No : 1600771U

Please reply with comments for each item in the action list and submit this secondary input request.  
Please note that resubmission of the application is not required.

1 Records

Action List			
SN	Action	Due Date	Applicant's Response (if any)
1.	For Secondary Screenshot	15/07/2016	

### **Other Useful Information**

1. You may check on the status of your application upon submission at [track@prism](mailto:track@prism).
2. For enquiries related to CPP applications, please contact the Audit and Licensing Division at Tel: 6866 1111 or email to [hsa\\_certification@hsa.gov.sg](mailto: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](mailto:helpdesk@hsahelp.gov.sg).