

NEW APPLICATION FOR CERTIFICATE OF A PHARMACEUTICAL PRODUCT

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 make 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.

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.

2. Company Particulars			
2.1 Name : *	ABC Co Ltd.,		
2.2 Location Code :	1		
2.3 Company Address			
2.3.1 Address Type : *	Local		
2.3.2 Postal Code : *	541111		
2.3.3 Block / House No :	111A	2.3.4 Level - Unit :	# -
2.3.5 Street Name :	RIVERVALE WALK		
2.3.6 Building Name :	MULTI STOREY CAR PARK		
2.3.7 Country :	SINGAPORE		
2.4 Tel : *	12345678	2.5 Fax :	<input type="text"/>
		Your Fax No. is necessary for our future correspondence	
2.6 Is Billing Address the same as the Company Address ? *	<input checked="" type="radio"/> Yes <input type="radio"/> No		
2.8 Unique Entity No.(UEN) :	PatchUEN1		

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 make 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. Product Particulars** section.

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>	

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Part 3. Product Particulars

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

- (1) Select 'Yes' or 'No' as to whether the product is licensed in Singapore
- (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).

- (5) Select 'Yes' or 'No' as to whether the product is on the market in Singapore.
- (6) Select the importing country from the 'Drop down' list of import countries.
- (7) 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
- (8) Click the Next button to go to **Part 4. Manufacturer Particulars** section.

PR1001 APPLICATION FOR CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Fill in the application form Guideline Help

1. Company Particulars **3. Product Particulars** 5. Supporting Attachments
 2. Applicant Particulars 4. Manufacturer Particulars 6. Confirmation

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Fields marked with an asterisk * are mandatory.

3. Product Particulars

3.1 Is the product licensed to be placed on the market in Singapore? : * Yes No

3.2 Product Licence Number : * [Retrieve Details](#)

3.3 Name of the product (in English) : * Name

3.4 Is this product actually on the market in Singapore? : * Yes No

3.5 Name of the Importing Country : *

3.6 Remarks :

3.7 Dosage Form : * CREAM

3.7.1 Route of Administration INTRACAUDAL

3.8 Complete Composition Of the Product

Name of the Substance	Strength
Substance	Strength

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Part 4. Manufacturer Particulars

This section allows the input of manufacturer particulars.

- (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 medicinal product, 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 (the New and Save buttons will be disabled).
- (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.

Remove Manufacturer(s)

- (1) Click on the checkbox adjacent to the manufacturer(s) from the Manufacturer List table.
- (2) Click on the Remove button to delete the manufacturer(s).
- (5) Click the Next button to go to **Part 5. Supporting Attachments** section.

Fields marked with an asterisk * are mandatory.

4. Manufacturer Particulars

4.1 Is the manufacturer licenced? : Yes No

4.2 Manufacturer Licence Number [Retrieve Details](#)

Manufacturer Licence	Manufacturer Name
	TestMfc
	TestMfcActive

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Part 5. Supporting Attachments

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

Listing of supporting documents	For registered product	For non-registered product
Recent local sales invoice	If applicable	If applicable
Scanned / digital photograph of the product sample	NA	Yes
Label and printed packaging materials of product	NA	Yes
Master Formula and manufacturing procedure of product	NA	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
The schedule	If applicable	Yes

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.

PR1001 APPLICATION FOR CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Fill in the application form
Guideline Help

1. Company Particulars

2. Applicant Particulars

3. Product Particulars

4. Manufacturer Particulars

5. Supporting Attachments

6. Confirmation

Attach Save

Special Symbol

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Click here to encrypt documents

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 : *	Choose File	No file chosen
5.2 Other Supporting Documents :	Choose File	No file chosen

Attach Files

Select All to delete all attachment records

Sn	Attachment Name	Attachment Type	Size (Kb)	Remarks
1	test1.txt	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.

Remove

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The file extensions, which are acceptable and supported for attachments, are:

- tif (Black & White)
- jpg (graphics files)
- pdf (Adobe Acrobat files)
- doc (Microsoft Word files)
- xls (Microsoft Excel files)
- ppt (Microsoft PowerPoint files)
- avi (audio visual, if required)
- 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. (No payment is made at this point. Payment may be advised later.)

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

Accept Decline

Payment Advice

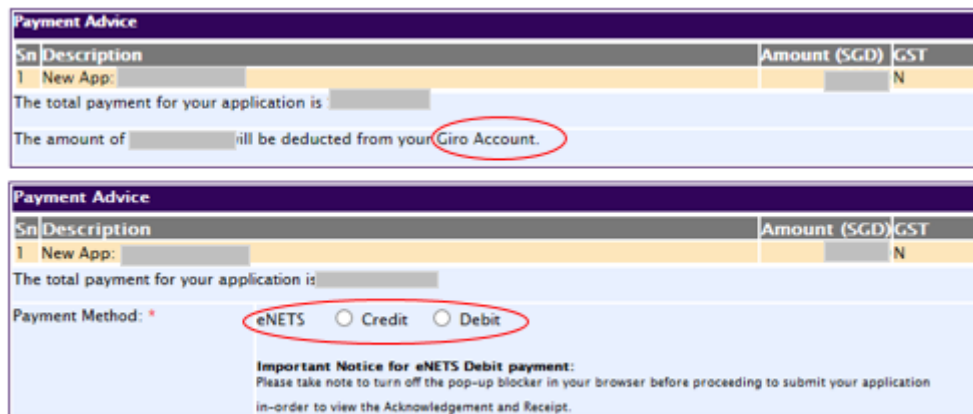
No payment is required at this point of application. Payment may be advised later.

Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO
- eNETS



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.

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.

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 relevant transaction pages from the banks may not be displayed, or your transaction request may not be completed.

- www.enets.sg

TRANSACTION INFORMATION

Merchant Name	Health Sciences Authority
Merchant Reference Code	ECT170003K
NETS Reference Code	20170109153742590
Amount	S\$0 500.00

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

Card Number

Please note that the Credit Card number should be 13 or 16 digits. Please input your card number without space or dash.

CVV2 (What is CVV/CVV2/CID)

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.

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.

- www.enets.sg
- dbad2pay.dbs.com (for DBS/POSS Account holders)
- piবেনেস.লুব.কম.সগ (for UCB Account holders)
- www.cibank.com.sg (for Citibank Account holders)
- www.ocbc.com (For OCBC account holders)
- www.plus.com.sg (For Plus! account holders)
- bank.standardchartered.com.sg (For Standard Chartered account holders)

TRANSACTION INFORMATION

Merchant Name	Health Science Authority
Merchant Reference Code	ETT170003K
NETS Reference Code	20170109153742590
Merchant Hostname	netp.hsa.gov.sg
Amount	S\$

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

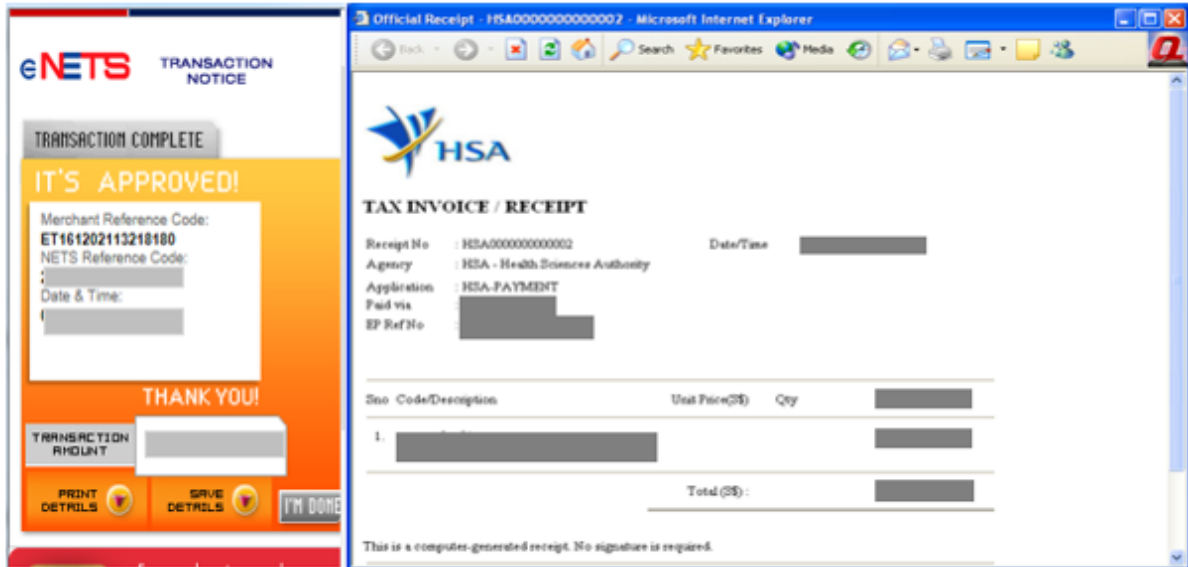
SINGAPORE BANK SELECTION

Bank Please select a 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.

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.

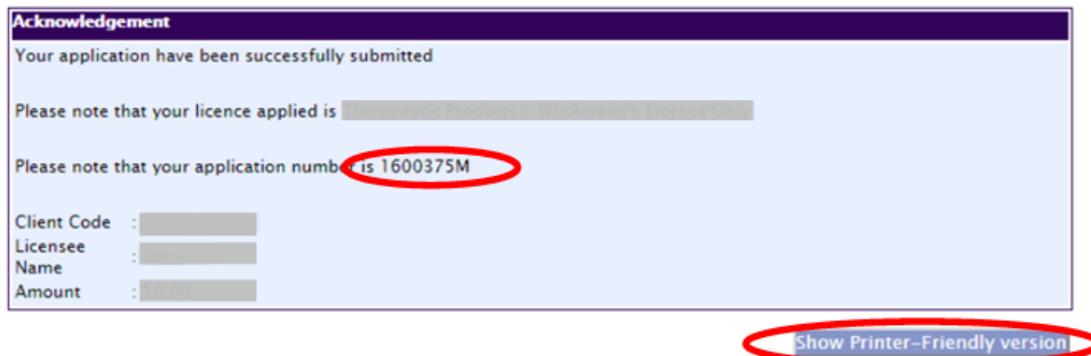


To submit the completed application, click the **'Submit'** button. Applicant will be prompted to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

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.

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 eservices.

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

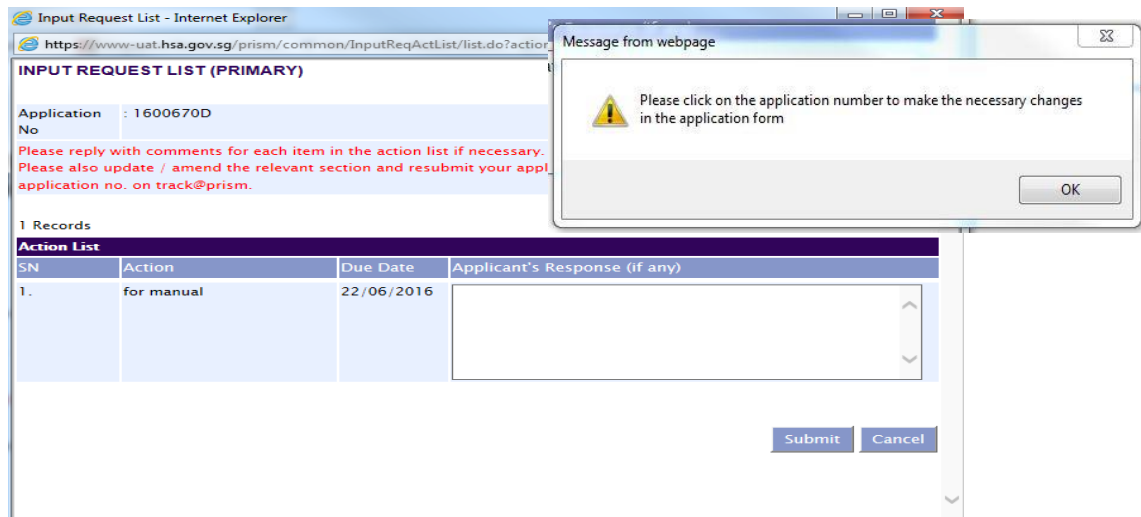
- (2) Click on the **'HSA Input Request'** to view if any reply is required from the applicant. Click the **'Submit'** button and an alert message will pop up to prompt you to make the necessary changes in the application form.

S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	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)

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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	

- (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)

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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 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	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)

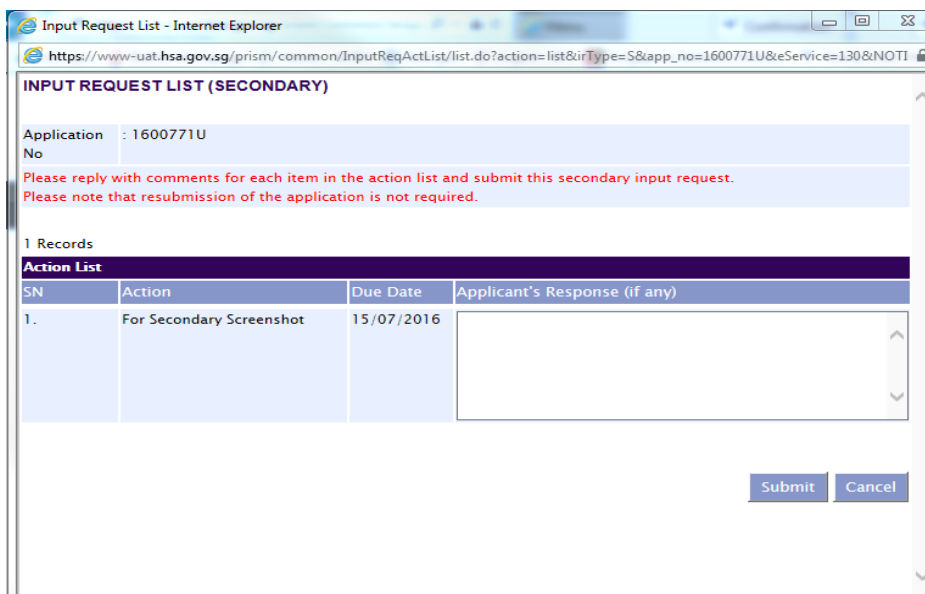
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Note:

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.



Input Request List - Internet Explorer

https://www-uat.hsa.gov.sg/prism/common/InputReqActList/list.do?action=list&irType=S&app_no=1600771U&eService=130&NOTI

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	

Submit Cancel

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>