

AMENDMENT APPLICATION FOR LICENCE TO IMPORT CHINESE PROPRIETARY MEDICINES

Please note that companies must register with Client 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 amend@prism. For more information on CRIS, please refer to https://www.hsa.gov.sg/e-services/cris

The following amendments do not require submitting amendment application via this module:

- Amendment to change company's particulars such as company name and address has to be made via the "Amend Company Information" module.
- Amendment to change applicant's particulars such as name and contact details has to be made via the "Amend Applicant's Details for Licences and Applications" module.
- Both "Amend Company Information" and "Amend Applicant's Details for Licences and Applications" modules can be accessed at

https://www.hsa.gov.sg/e-services/prism/chinese-proprietary-medicines

1. The online form may take an average of 10 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 the time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

- 2. The following information/item(s) are required to complete the form:
 - (A) **Current layout plan for the premises**, specifying the storage area(s) (Mandatory) The layout floor plan will need to have the following information:
 - (i) The full address of the warehouse
 - (ii) The dimensions (length and width) of the warehouse
 - (iii) Indication of various storage areas, e.g. receiving bay, quarantined product area, released product area, rejected product area, returned product area, recalled product area, outgoing staging area, etc.
 - (B) Good Distribution Practice (GDP) Standard Operating Procedures
 - (C) Good Distribution Practice (GDP) Records or Recording Templates
- 3. The applicant will require a Corppass* or Singpass 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* / Singpass or HSA PIN login is necessary for authentication and authorisation 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 Corppass, please refer to http://www.corppass.gov.sg/

4. Mode of payment

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

The mode of payment available is as follows:

Non-GIRO: eNETS (Credit/Debit Card)

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- GIRO (Preferred mode of payment)

Payment by GIRO requires pre-registration. The <u>GIRO application form</u> 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.

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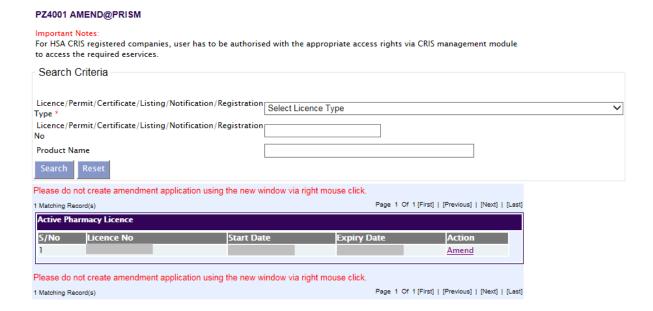


Application Form

Fields marked with an asterisk * are mandatory.

This section allows the search for the licence to be amended.

- (1) Select the **Licence Type** (Chinese Proprietary Medicine Import Licence).
- (2) Enter the **Licence Number** and click **'Search'** button. When the search result is displayed, click **Amend**.



Part 1. Licence/Permit/Certificate/Listing Summary

The applicable Licence No., the effective and expiry dates of the existing licence will be pre-populated.

This section requires the applicant to verify and fill in the following information.

(1) Amendment Details

Please provide the reason for the amendment in this entry.

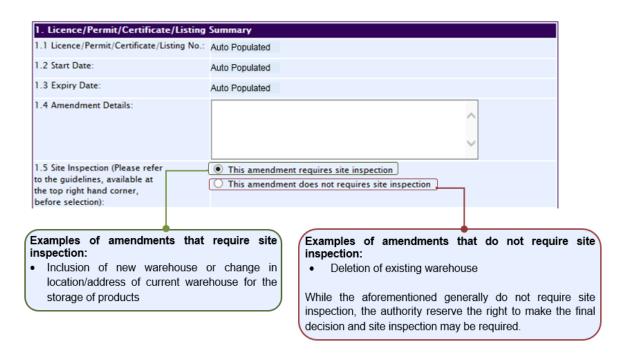
(2) Site Inspection

Applicant is required to indicate if the amendment requires site inspection.

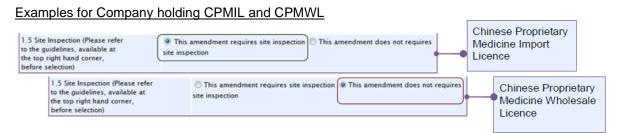
Please find below some examples of amendments that require site inspection and examples of amendments that do not require site inspection.

(3) Click 'Next' button to go to Part 2. Company Particulars section.





Note: For companies submitting amendment applications that require site inspection for both Chinese Proprietary Medicine – Import Licence (CPMIL) and Chinese Proprietary Medicine – Wholesale Licence (CPMWL), choose the option "This amendment requires site inspection" for one licence and "This amendment does not require site inspection" for the other licence.



If you are in doubt or encounter a situation which is not found in the above lists of examples, please contact us before submission.

Part 2. Company's particulars

The company name and address will be pre-populated based on the registered CRIS records. If you need to make changes to this information, please submit the change via the 'Amend Company Information' module.

Part 3. Applicant Particulars

The applicant particulars will be pre-populated based on the previous records. If you need to make changes to this information, please submit the change via the 'Amend Applicant's Details for Licences and Applications' module.

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Part 4. Warehouse Particulars

This section requires the applicant to fill in the following information if there is an amendment to the warehouse particulars.

Add new warehouse(s)

- (1) Fill in **Postal Code** and click 'Retrieve Address' button. The **Block/House No, Street Name** and **Building Name** will be populated on the screen.
- (2) Fill in **Level-Unit** information and any additional detail relating to the warehouse store in the **Other Address Detail** field (if applicable).
- (3) Fill in the Storage Condition of Warehouse.
- (4) Fill in **Approved By** information.
- (5) Click 'Add Warehouse' button.

The screen will be automatically refreshed, and the refreshed page will display the warehouse particulars that were added.

- (6) Repeat Step (1) to (5) to add other warehouse(s) information.
 Addresses of all warehouses where the products will be stored should be provided.
- (7) Click 'Next' button to go to Part 5. Supporting Documents section.

Update warehouse(s)

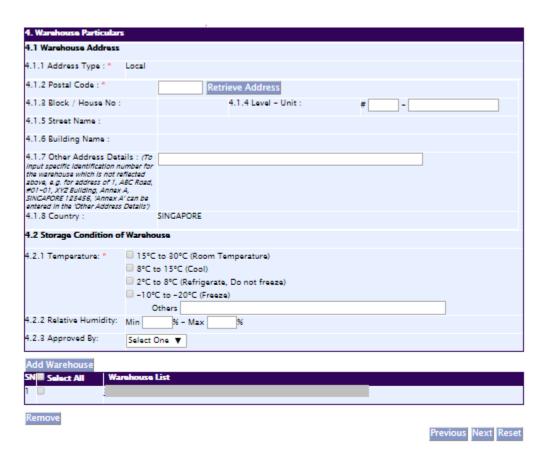
- (1) Click on the warehouse required amendment from the Warehouse List table.
- (2) Make the required update.
- (3) Click 'Update Warehouse' button.

Remove warehouse(s)

- (1) Click on the checkbox adjacent to the warehouse(s) from the Warehouse List table.
- (2) Click 'Remove' button to delete the warehouse(s).

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Part 5. Supporting Documents

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

Add Attachment

- (1) Click 'Choose File' button to select the required file for attachment.
- (2) Select the required file.
- (3) Click 'Open' button in the pop-up window.
- (4) Click 'Attach File' button for the file to be attached to this application.
- (5) Fill in the remarks in the 'Remark' field with regards to the file attached (if required).
- (6) Repeat Step (1) to (5) to add other documents. All supporting documents should be provided.
- (7) Click 'Next' button to proceed to Part 6. Confirmation and Declaration section.

Remove Attachment

- (1) Click on the checkbox beside the attachment or attachments from the **List of Attachments** table.
- (2) Click 'Remove' button to delete the document.



| 5. Supporting Documents | | | | | |
|---|--------------------------------|----------------------------|------------------------------------|--|--|
| To add an attachment, type in the the list below. Please click <u>here</u> for guideline on | | . Then hit the Attach File | s button to save the attachment to | | |
| Documents | | | | | |
| 5.1 Store Layout Plan : | Choose File No file chose | n | | | |
| 5.2 Good Distribution Standard Operating Procedures : | Choose File No file chose | n | | | |
| 5.3 Good Distribution Practice Records : | Choose File No file chose | n | | | |
| 5.4 Other Supporting Documents : | Choose File No file chose | n | | | |
| Attach Files | | | | | |
| Select All to delete all attachment | records | | | | |
| Sn Attachment Name At | tachment Type Size (Kb) | | | | |
| 1 🗆 | | | | | |
| To remove an attachment, click o Remove | n the checkbox. Then hit the R | emove button to remove | the attachment from the list. | | |
| | | | Previous Next Reset | | |

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 big (estimate about 2MB and above), the uploading time may be longer.

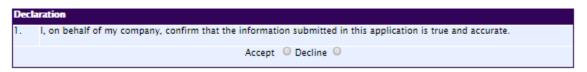
Part 6. Confirmation and Declaration

This section shows the information provided in all sections of the Application Form.

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

(Note: Applicant may click '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, applicant is advised to read through the declaration carefully before accepting to undertake the conditions.
- (3) Click 'Submit' button to submit the Application Form.





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Payment Advice

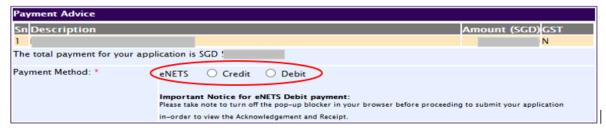
This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO (deducted from the relevant bank account)
- eNETS (Credit Card or Debit Card)



or



If the eNETS option is selected and then 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 eNETS option is selected and then 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.



mber should be 13 or 16 digits. out space or dash. [What is CVV/CVV2/CID]

(eg: 2017) I have read, understood and accepted the following: The return & refund policy for the purchase of

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

SUBMIT X CANCEL

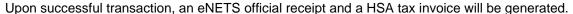
relevant products / services.

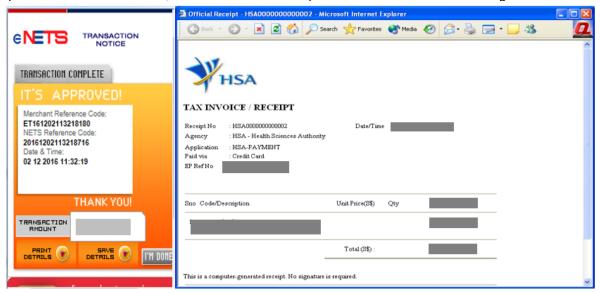
Month

Policy.

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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.

<u>Acknowledgment</u>

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

Applicant may wish to print a copy of this acknowledgement page or take note of the application number for ease of reference. Applicant may provide the application number if he/she wishes to communicate with HSA.



| Acknowledgement | | |
|---------------------|-----------------------------------|--|
| Your application h | ave been successfully submitted | |
| Please note that yo | ur application number is 1600797N | |
| Client Code | ‡ | |
| Licensee | | |
| Name | | |
| Amount | 4 | |

Note: Applicant can click 'Show Printer-Friendly version' to print or view the application.

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Input Request

This section illustrates how applicant can respond to the Input Request raised to the application.

Input Request arises when the reviewing HSA officer requires further clarification from the applicant regarding the Application Form.

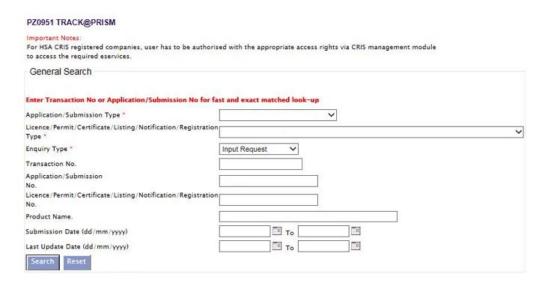
A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

Input request can be classified as Primary or Secondary.

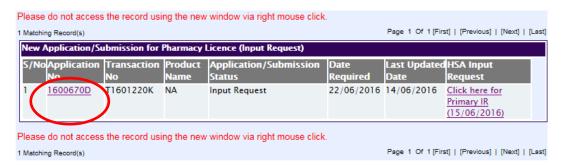
- Primary Input Request requires changes to be made directly in the application form.
- <u>Secondary Input Request</u> requires applicant's explanation to certain matters pertaining to the application form submitted.

Responding to Primary Input Request

(1) <u>Log on to track@prism</u> -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click '**Search**' button.



(2) When the search result is displayed, click the 'Application No.'



- (3) The webpage will display the application form as per previously submitted.
- (4) Proceed to make the necessary changes for the section(s) that required amendment, click 'Save' button and submit the revised application form.

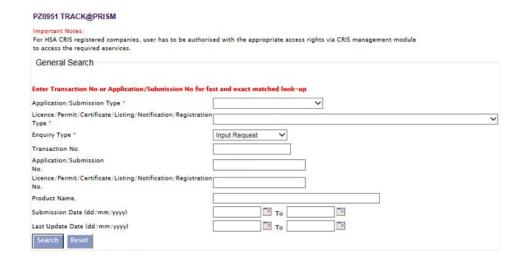
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Responding to Secondary Input Request

(1) <u>Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click 'Search' button.</u>



(2) When the search result is displayed, click under 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.



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





Other useful information

- 1. Applicant may check on the status of your application upon submission at track@prism.
- 2. Kindly contact the HSA Helpdesk if any technical issues (IT problems) during the application submission are encountered.

HSA HelpDesk

Hotline: (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.

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