

AMENDMENT APPLICATION FOR PHARMACY LICENCE

Pharmacy licence holders must not, without the prior approval of the Authority -

- (a) make any change to any matter the particulars of which are contained in the pharmacy licence or the holder's application for the pharmacy licence (e.g. change in the pharmacist-in-charge or change in name of pharmacy)
- (b) make or cause any change to the layout or infrastructure of the retail pharmacy (e.g. change in the pharmacy dispensing counter from one corner of the shop unit to another corner without changing the address of the retail pharmacy); or
- (c) make or cause any change in the conduct of the holder's retail pharmacy business that the holder is approved to conduct at or from the retail pharmacy (e.g. addition / cessation of additional activities such as Telepharmacy services, special mode of supply of therapeutic products change in warehouse addresses for storing of TP, other than the retail pharmacy, including the addition of a new warehouse, etc.)

Pharmacy licence holder must submit amendment application for the existing pharmacy licence before implementing any changes to the pharmacy. Changes should be made known to HSA and in-principal approval should be obtained prior implementing the changes.

Applicants must have valid Client Registration and Identification Service (CRIS) user rights in order to be able to submit applications on behalf of the company via <u>amend@prism.</u> For more information on CRIS, please refer to https://www.hsa.gov.sg/e-services/cris

- (1) This 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 system, 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) The following document(s) are required to provide to support the amendment application for Pharmacy Licence.
 - a) Revised Pharmacy Store Layout Plan, specifying the dispensing counter, general sales area(s), area for storing Pharmacy Only medicines (P) and Prescription-Only medicines (POM) and other ancillary area(s). The layout should clearly indicate the full address of the pharmacy outlet. This is a mandatory document for amendment application submitted for change in the layout or infrastructure of the pharmacy.
 - b) **Pharmacist Practising Certificate** with a valid and active practising certificate for the appointed Pharmacist-in-charge (PIC). This is a mandatory document for amendment application submitted for change in PIC for the pharmacy.
 - c) Signed **Telepharmacy Declaration Form** from the PIC for the provision of Telepharmacy. (*If applicable*). This is a mandatory document for pharmacy providing telepharmacy service for P medicines.
 - d) **Company's Standard Operating Procedures** for additional activities/services.(*If applicable*) Additional activities or services can include compounding of non-sterile preparations in accordance with a patient's valid prescription, telepharmacy service, medication delivery service and provision of e-pharmacy service etc.
- (3) 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 login is necessary for authentication and authorisation purposes.

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*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 https://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:

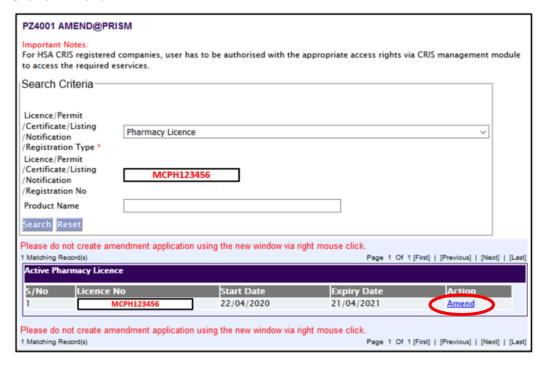
- Non-GIRO: eNETS (Credit/Debit Card)
- GIRO (Preferred mode of payment)

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.

Amendment Application Form for Pharmacy Licence

This section allows the search for the Pharmacy Licence to be amended.

- (1) Select the **Licence Type** (Pharmacy Licence).
- (2) Enter the Licence Number to be amended.
- (3) Click on 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.

a) Amendment Details

Select from the list of pre-defined amendments or specify the amendments under 'Others'.

If the option 'Others, please specify:' is selected, please keyed the exact amendment detail in the field provided.

b) Site Inspection

The applicant is required to indicate if the amendment requires site inspection.

The changes may be categorized into 2 types: namely administrative change that do not require on-site inspection and change that requires on-site inspection.

- 1) Examples of administrative changes which do not require on-site inspection:
 - Change of Pharmacist-in-charge.
 - Deletion of existing warehouse.
 - Cessation of provision of additional services/activities such as Telepharmacy Services, Home Delivery Service Medication Pick-up Service, e-pharmacy Service, Compounding of non-sterile therapeutic products, Pharmacy Automation Service, etc.

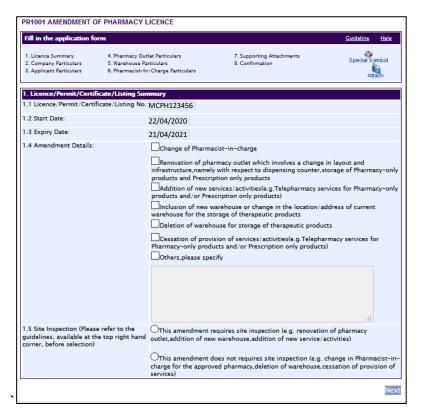
While the aforementioned generally do not require site inspection, the authority reserves the right to make the final decision and site inspection may be required.

- 2) Examples of changes which <u>requires on-site inspection</u>:
 - Inclusion of new warehouse or change in location/address of current warehouse for the storage of therapeutic products.
 - Addition of new Activities/Services, e.g. Telepharmacy Services, Home Delivery Service, Medication Pick-up Service*, e-pharmacy Service, Compounding of nonsterile therapeutic products, Pharmacy Automation Service etc.
 - * Medication Pick-up Service included and not limited to secured box, pilbox box for self-collection.
 - (For Secured Box for self-collection and home delivery service, no on site audit will be conducted during the amendment application. However, pharmacy should submit approved Standard Operating Procedures (SOPs) describing the scope, responsibility, process, controls and quality system to ensure that quality, safety and security of the products are ensured through the supply chain. This service will be checked against the approved SOPs during the next routine audit.)
 - Renovation of pharmacy outlet which involves a change in layout and infrastructure namely with respect to dispensing counter, storage areas of P and/or POM within the approved pharmacy premises.

Please note that a NEW Pharmacy Licence application would be required for all relocation of pharmacies to another unit, level or building.

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

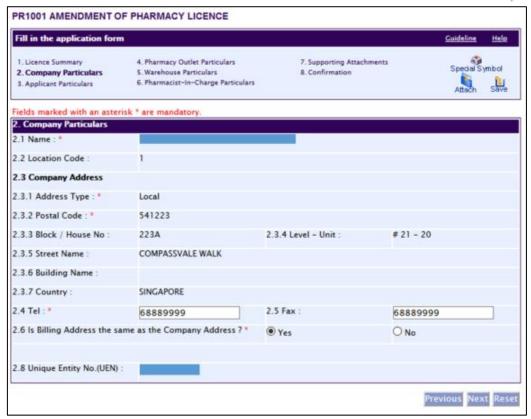
Part 2. Company Particulars

This section requires the applicant to verify and fill in any other relevant information relating to the company.

- (1) Company details such as **Name**, **Address**, **Telephone** and/or **Fax** will be pre-populated based on the registered CRIS records.
 - If you need to makes changes to this information, please submit the changes via the "Amend Company Information" module under the amend@prism on PRISM e-Service webpage.
- (2) Indicate if the Billing Address is the same as the Company Address.
- (3) If the Billing Address is not the same as **Company Address**, please fill in the '**Postal Code**' field and click the '**Retrieve Address**' button. The **Block/House No**, **Street Name** and **Building Name** will be populated.
- (4) Fill in the 'Level-Unit' field and any additional details relating to the company in the 'Other Address Details' field. (If applicable)
- (5) Click 'Next' button to proceed to Part 3. Applicant Particulars section.

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Part 3. Applicant Particulars

This section requires the applicant to verify and fill in 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

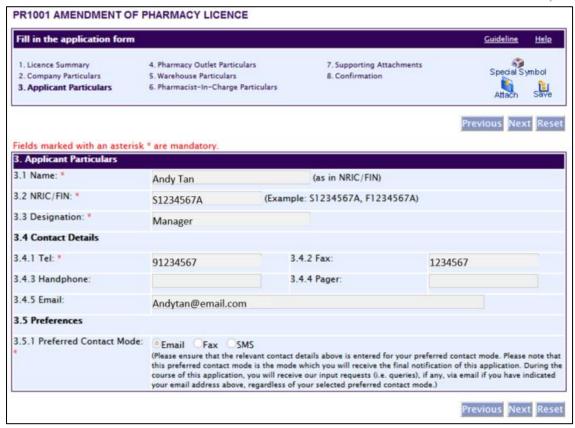
(Note: Please ensure that the relevant contact details above are entered for your preferred contact mode. Please note that the preferred contact mode is the mode which you will receive the final notification of this application.

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 4. Pharmacy Outlet Particulars section.

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Part 4. Pharmacy Outlet Particulars

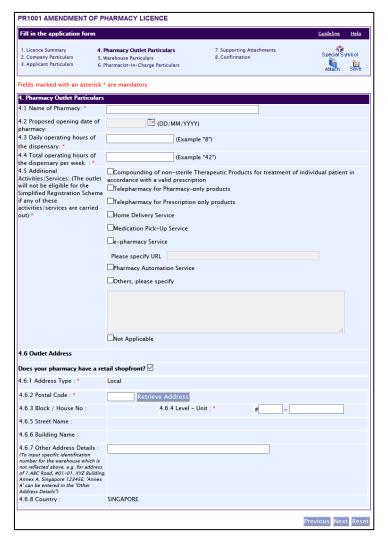
This section requires the applicant to fill in the following information if there is any amendment to the existing pharmacy outlet particulars.

- (1) Fill in the Pharmacy outlet name in the 'Name of Pharmacy' field.
- (2) Fill in the 'Proposed Opening Date of Pharmacy' field.
 - (Note: The proposed opening date <u>must</u> be at least <u>1 month</u> in advance of the submission date for amendment application submitted for change in layout or infrastructure of the pharmacy.)
- (3) Fill in the 'Daily operating hours of dispensary' field.
- (4) Fill in the 'Total dispensary hours provided by the attending pharmacist per week' field.
 - (Note: Provide only the operating duration in hours per day and per week of these entries, e.g. '42' for 42 operating hours per week.
 - Please be reminded that the pharmacy must meet the minimum total dispensing hours, i.e. 35 hours provided by the attending pharmacist(s) per week.)
- (5) Select the 'Additional Activities/Services' from the pre-defined list given in the application form or specify the activity/service under 'Others' field.
 - Pharmacy providing the additional activities/services must ensure that proper records are kept for the retail supply of products. Additionally, pharmacy is required to submit approved Standard Operating Procedure (SOP) describe the scope, responsibility, process and quality system to ensure that the service is safe, appropriate and the supply of the products reaches the intended customer.
- (6) If e-pharmacy service under the pre-defined list is selected, please specify the Uniform Resource Location (URL) in the field provided. This service must be hosted on a valid URL with a Singapore registered domain name.
- (7) Click 'Next' button to proceed to Part 5. Warehouse Particulars section.

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Please note that a NEW Pharmacy Licence application would be required for all relocation of pharmacies.



Part 5. Warehouse Particulars

This section requires the applicant to fill in the warehouse particulars. Please fill in this section **only** if there is an additional warehouse other than the pharmacy outlet used to store P and/or POM for the retail pharmacy operation. Do not fill in this section if there is no additional warehouse.

Add warehouse:

- (1) If the warehouse is owned by your company, select 'Yes' otherwise select 'No' and fill in the 'Name Of The Company Owning The Warehouse'
- (2) Fill in the 'Postal Code' and click the 'Retrieve Address' button for warehouse Particulars. Warehouse details such as Block/House No, Street Name and Building Name will be populated.
- (3) Fill in the 'Level-Unit' field and any additional detail relating to the pharmacy warehouse in the in the 'Other Address Detail' field. (If applicable)
- (4) Click the 'Add Warehouse' button and 'Save' button to save the warehouse particulars. The webpage will be automatically refreshed, and the refreshed page will display the details of the warehouse particulars that were added.
- (5) Repeat Step (1) to (4) to add other additional warehouse(s). Addresses of all warehouses where the therapeutic products, i.e. Pharmacy-only medicines (P) and Prescription- only medicines (POM), would be stored should be provided.

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(6) Click 'Next' button to proceed to Part 6. Pharmacist-In-Charge Particulars section.

Update warehouse:

- (1) Click on the warehouse to be updated from the 'Warehouse List' table.
- (2) Make the required update.
- (3) Click the 'Update Warehouse' button (next to the 'Cancel' button).

Remove warehouse:

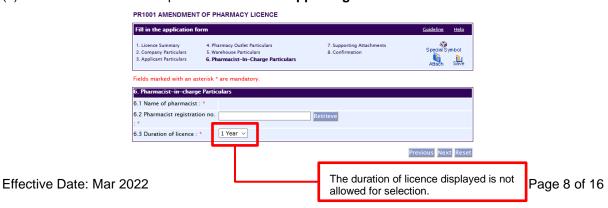
- (1) Click on the checkbox adjacent to the warehouse(s) from the 'Warehouse List' table.
- (2) Click the 'Remove' button to delete the warehouse(s).



Part 6. Pharmacist-In-Charge Particulars

This section requires the applicant to fill in the following information if there is any amendment to the pharmacist-in-charge (PIC) particular.

- (1) Fill in the 'Pharmacist Registration Number (PRN)' for the appointed Pharmacist-In-Charge (PIC) of the premises and click the 'Retrieve' button. The name of pharmacist will be reflected automatically in the refreshed webpage.
 - (Note: The appointed pharmacist **MUST NOT** be already a named PIC of an approved pharmacy or Responsible Person (RP) named in the Therapeutic Product Importer's and/or Wholesaler's Licences.)
- (2) Click 'Next' button to proceed to Part 7. Supporting Attachments section.





Part 7. Supporting Attachments

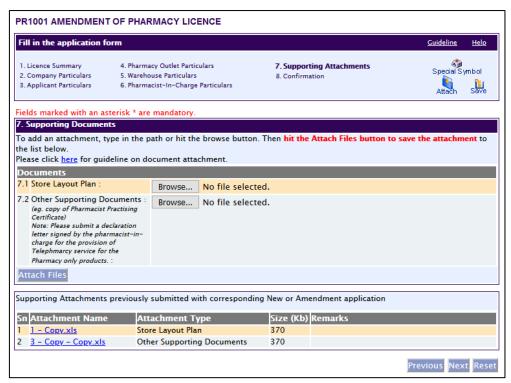
This section requires the applicant to attach the supporting documents to the application made.

Add Supporting Attachments:

- (1) Click the 'Choose File' button and 'Browse' button to select the documents to be attached into the application.
- (2) Click the 'OK' button.
- (3) Click the 'Attach File' button to attach the selected file into this application.
- (4) Fill in the remarks in the 'Remark' field with regards to the file attached (if required).
- (5) 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.



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.)

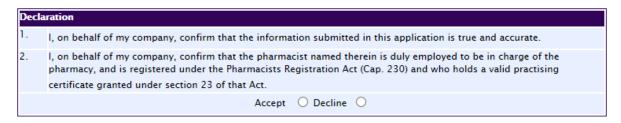
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Part 8. Confirmation and Declaration

This section shows the information provided in all sections of the Amendment Application to Pharmacy Licence.

- (1) Applicant is required to confirm 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, applicant is advised to read through the declaration carefully before accepting to undertake the conditions.
- (3) Click the 'Submit' button to submit the Amendment Application.



Payment Advice

This section shows the total amount of money for the pharmacy application.

There are 2 modes of payment available:

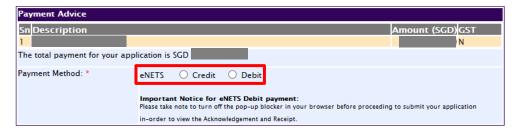
- GIRO
- eNETS

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



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

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



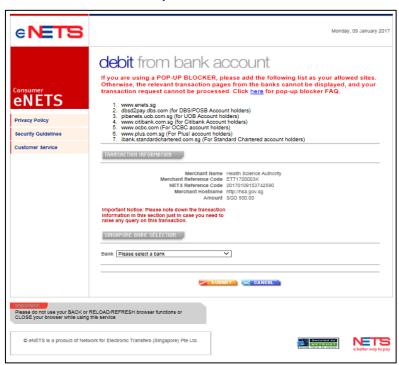
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(2) If the Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.



(3) 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.

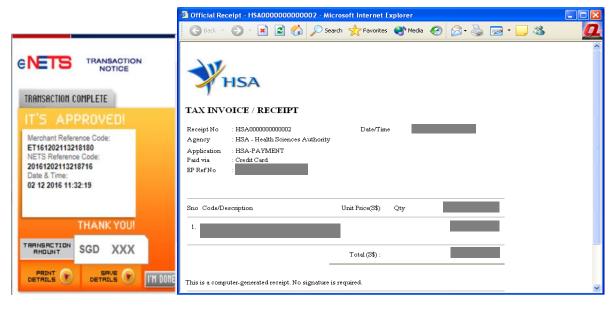


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(4) Upon successful transaction, an eNETS official receipt and a HSA tax invoice will be generated.



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(5) 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.

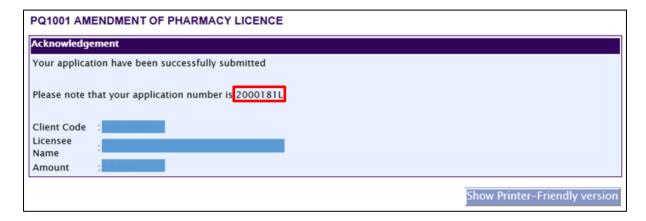


(6) To submit the completed application, click the 'Submit' button. Applicant will be prompted to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

Acknowledgment

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 <u>Application</u> <u>Number</u> for ease of reference. Applicant may provide the application number if he/she wishes to communicate with HSA.



Note: The show Printer Friendly version allows applicant 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 Pharmacy Licence Application Form.

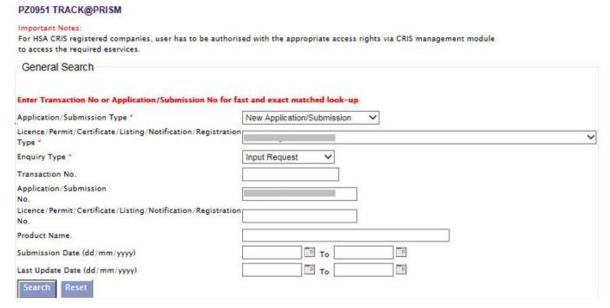
A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

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) 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.



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



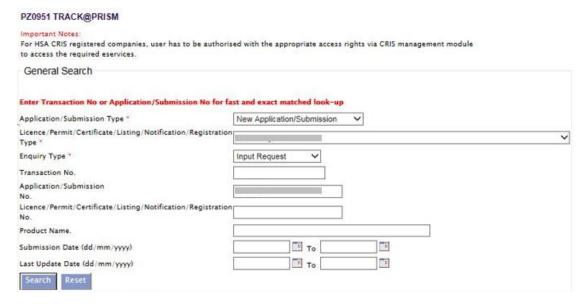
- (3) The webpage will display the application form as per previously submitted.
- (4) Proceed to make the necessary changes for the section(s) that required amendment, click 'Save' button and submit the revised application form.

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Responding to Secondary Input Request

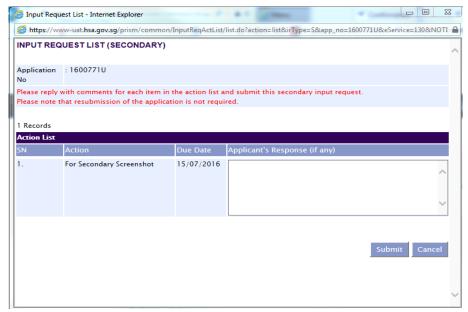
(1) Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click 'Search' button.



(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 under 'Applicant's Response (if any)' and click 'Submit' button.



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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: (65) 6776 0168

from 7:00 am to midnight daily Email : helpdesk@hsahelp.gov.sg

3. For general enquiries or questions related to licences and certificates of manufacturers, importers and wholesalers, please contact the Audit and Licensing Division at Tel: 6866 1111.

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