

AMENDMENT APPLICATION FOR LICENCE TO KEEP AND SELL CONTROLLED DRUGS BY WHOLESALE

Companies and its applicants must register with Client, Registration, and Identification Service (CRIS) with valid CRIS user rights in order to be able to submit applications on behalf of the company via apply@prism.

The applicant will also require a Corppass before he/she can login to PRISM to retrieve the application form. A person who drafts an application on behalf of his/her company and is not a Singaporean Citizen, Permanent Resident or Employment Pass holder can apply for a HSA PIN to login to PRISM. The Corppass or HSA PIN is necessary for authentication and authorization purposes.

Note: 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 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 20 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 <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.



Application Form

Part 0. Licence Summary

The applicable Licence No., the start 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

The 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 on 'Next' button to go to the Part 1. Licence Information section.

| | PR1001 AMENDMENT O | F LICENCE TO KEEP & SELL CON | TROLLED DRUGS BY WHOLE | SALE | |
|--|---|---|---|---|-------------------------------|
| | Fill in the application fo | rm | | <u>Guideline</u> <u>Help</u> | |
| | 0. Licence Summary 1. Licence Information 2. Company Particulars | 3. Applicant Particulars 4. Warehouse Particulars 5. Controlled Drugs For Wholesale Dealing | 6. Licence Duration 7. Supporting Attachments 8. Confirmation | Special Symbol Attach | |
| | 1. Licence/Permit/Certif | icate/Listing Summary | | | |
| | 1.1 Licence/Permit/Certifica | te/Listing No.: WLCD1600008 | | | |
| | 1.2 Start Date: | 25/02/2016 | | | |
| | 1.3 Expiry Date: | 24/02/2017 | | | |
| | 1.4 Amendment Details: | | | <u>`</u> | |
| | 1.5 Site Inspection (Please r | efer OThis amendment re | equires site inspection O This am | endment does not requires | |
| | to t he guidelines, available a the top right hand corner, before selection) | site inspection | | | |
| | | | | Next | |
| amples of spection: | of amendments that | t require site Exa | mples of amendmoection: | ents that do not | t require sit |
| Inclusion | of new warehouse | or change in | Deletion of existing | warehouse | |
| location/a storage c | address of current wa of controlled drugs | rehouse for the | Addition or deletion | of controlled drugs | |
| Inclusion of new storage conditions (e.g. Cold chain) to the warehouse | | tions (e.g. Cold Whi insp | le the aforementione ection, the authority r | ed generally do n eserves the right to | ot require si make the fin |
| Renovati change in respect to | on of warehouse wh n layout and infrastruct o security and storage | ich involves a ure namely with facilities | sion and site inspection | on may be required | |

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



Next Reset

Part 1. Licence Information

This section requires the applicant to verify and fill in any other relevant licence information. If there is relevant licence or application number, enter the number and click **'Retrieve Licence / Application No'**. The information regarding the licence or application will be displayed.

| Fields marked with an asterisk * | are mandatory. |
|--|------------------|
| 1. Licence Information | |
| 1.1 Poisons Licence/Application No. : | Retrieve Licence |
| 1.2 Valid Till : | |
| 1.3 Therapeutic Product Wholesaler's Licence/Application No. : | Retrieve Licence |
| 1.4 Valid Till : | |
| 1.5 Therapeutic Product Importer's Licence/Application No. : | Retrieve Licence |
| 1.6 Valid Till : | |
| 1.7 Pharmacist Registration Number (PRN) :* | |
| 1.8 Other Relevant Approvals (Eg Medical Device Dealer's Licences, Special Access Routes) : : | |
| | |

Click on 'Next' button to proceed to Part 2. Company Particulars section.

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 <u>amend@prism</u> 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 3. Applicant Particulars section.



| 1. Company Particulars | | | |
|---------------------------------|----------------------------|---|------------|
| 1.1 Name : * | ABC Co Ltd.,! | | |
| 1.2 Location Code : | 1 | | |
| 1.3 Company Address | | | |
| 1.3.1 Address Type : * | Local | | |
| 1.3.2 Postal Code : * | 541111 | | |
| 1.3.3 Block / House No : | 111A | 1.3.4 Level – Unit : | # - |
| 1.3.5 Street Name : | RIVERVALE WALK | | |
| 1.3.6 Building Name : | MULTI STOREY CAR PARK | | |
| 1.3.7 Country : | SINGAPORE | | |
| 1.4 Tel : * | 12345678 | 1.5 Fax : Your Fax No. is necessary for our future correspondence | |
| 1.6 Is Billing Address the same | as the Company Address ? * | Yes | ○ No |
| | | | |
| 1.8 Unique Entity No.(UEN) : | PatchUEN1 | | |
| | | | Next Reset |

Part 3. 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.
- (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. Warehouse Particulars section.

| 2 American Destination | | | |
|-------------------------------|--|---|--|
| 5. Applicant Particulars | متعيياته وتذبعها الاصياد | فسيستعرج وتتبعين والمتعيد والمتعاد | ومعاجبا المؤاصلين المتشهدين المتحا معتصد ومعا |
| 3.1 Name: * | | (as in NR | IC/FIN) |
| 3.2 NRIC/FIN: * | | (Example: \$1234567A, | F1234567A) |
| 3.3 Designation: * | | | |
| 3.4 Contact Details | | | |
| 3.4.1 Tel: * | | 3.4.2 Fax: | |
| 3.4.3 Handphone: | | 3.4.4 Pager: | |
| 3.4.5 Email: | | | |
| 3.5 Preferences | | | |
| 3.5.1 Preferred Contact Mode: | Email OFax OSMS (Please ensure that the relit this preferred contact mod course of this application, your email address above. | evant contact details above is entered fo le is the mode which you will receive th you will receive our input requests (i.e. regardless of your selected preferred c | or your preferred contact mode. Please note that e final notification of this application. During the queries), if any, via email if you have indicated ontact mode.) |



Part 4. Warehouse Particulars

This section requires the applicant to fill in the following information if there is an amendment to the warehouse particulars. Otherwise, please do not amend any details at this section.

Add new warehouse(s)

(1) Fill in Postal Code and click 'Retrieve Address'.

The Block/House No, Street Name and Building Name will be populated on the screen.

- (2) Fill in **Level-Unit** information if applicable.
- (3) Fill in the **Storage Condition of Warehouse**.
- (4) Click on the Add Warehouse button.

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

(5) Repeat steps (1) to (4) to add other warehouse(s) information.

Addresses of all warehouses where the products will be stored should be provided.

(6) Click on the 'Next' button to proceed to Controlled Drugs for Wholesale Dealing section.

Update Warehouse(s)

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

Remove Warehouse(s)

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



| 4.1 Warehouse Address | | | | | |
|--|--|--------------------------|-------------|----------|------------|
| 4.1.1 Address Type : * Local | | | | | |
| 4.1.2 Postal Code : * | R | etrieve Address | | | |
| 4.1.3 Block / House No : | | 4.1.4 Level - Unit : | # | - | |
| 4.1.5 Street Name : | | | | | |
| 4.1.6 Building Name : | | | | | |
| 4.1.7 Other Address Details : (To input specific identification number for the warehouse which is not reflected above, e.g. for address of 1, AdC Read, e01-01, NV2 Building, Annex A, SINCAPOBE 123456, Monex A' can be entered in the 'Other Address Detail)? | | | | | |
| 4.1.8 Country : | SINGAPORE | | | | |
| 4.2 Storage Condition of Wa | rehouse | | | | |
| 4.2.2 Relative Humidity: Min | C to 15°C (Cool) C to 8°C (Refrigeration 0°C to -20°C (Freez Others | e, Do not freeze) :e) | | | |
| 4.2.3 Approved By: Select | One V | | | | |
| Add Warehouse | | To add add | itional war | ehouse | |
| SN Select All Warehou 1 2 | se List | | | | |
| Remove | | | | Previous | Next Reset |
| amend/remove e | xisting war | ehouse(s) |] | | |

Part 5. Controlled Drugs for Wholesale Dealing

The section requires the applicant to furnish this information if there is an amendment to the controlled drugs the company is dealing with.

You can select the new controlled drug(s) your company is dealing with from the list provided, or remove controlled drugs from the list you have previously selected. You can also update the classes of products your company is dealing with.

Click 'Next' to proceed to Part 6. Licence Duration section.



| Fields marked with | n an asterisk * are mandatory. |
|--------------------------------------|---|
| 5. Controlled D | rugs For Wholesale Dealing |
| 5.1 Classification of Products: * | Finished Therapeutic Products For Human Use Vet Products Labortatory Test Chemicals Drugs Of Abuse Test Kits |
| 5 0 House of | Active Pharmaceutical Ingredients(API) |
| substances to be sold: * | Select Drugs |
| | |
| | Alfentanil |
| | Previous Next Reset |

Part 6. Licence Duration

The licence duration of one year by default is displayed for your verification.

Click 'Next' to proceed to Part 7. Supporting Attachments section.

| Fields marked with an asterisk * are mandatory. | |
|--|---------------------|
| 6. Licence/Permit/Certificate/Listing Duration | |
| 6.1 Duration of licence/permit/certificate/listing: * 1 Year V | |
| | Previous Next Reset |

Part 7. Supporting Attachments

This section allows the attachment of supporting documents for the application. For amendment applications for licences to keep and sell controlled drugs by wholesale, please attach the following, as applicable:

- List of controlled drugs (CDs) to sell by wholesale
- Standard Operating Procedures for handling of CDs
- Store layout plan with warehouse address (including floor and unit number) and clear indication of CD storage area(s)
- Any other supporting documents

To Add Supporting Attachments:

- (1) Click '**Browse'** to select the required file for attachment.
- (2) Select the required file.
- (3) Click '**Ok'**.
- (4) Click 'Attach File' for the file to be attached to this application.
- (5) Fill up remarks with regards to the attachment if required.
- (6) Click 'Next' to proceed to Part 8 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 'Remove'.

ends and all states and a set of a set of a

| es button to save the attachment to |
|-------------------------------------|
| |
| Browse |
| |

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

- tif (Black & White)
- pdf (Adobe Acrobat files)
- xls (Microsoft Excel files)
- avi (audio visual, if required)
- jpg (graphics files)
- doc (Microsoft Word files)
 - ppt (Microsoft PowerPoint files)
 - mpeg (audio visual, if required)

(Note: If the file size is too big (estimate about 2MB and above), the attachment time may take a longer time to upload.)

Part 8. Confirmation

This section shows the information provided in all sections of the Application Form for a Licence to Keep and Sell Controlled Drugs by Wholesale.

(1) The applicant is required to confirm that the information provided in all sections are correct and click **'Validate'**.

(Note: Applicant may click '**Save**' 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 'Submit' to submit the application.



All applicants under the Misuse of Drugs Act (MDA) must comply with the MDA and their regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

| Decla | Declaration | | | | |
|--------|--|--|--|--|--|
| 1. | I, on behalf of my company, confirm that the information submitted in this application is true and accurate. | | | | |
| | Accept O Decline O | | | | |
| Paym | ent Advice | | | | |
| Sn D | escription Amount (SGD)GST | | | | |
| 1 | | | | | |
| The to | tal payment for your application is SGD | | | | |
| The a | mount of SGD will be deducted from your Giro Account. | | | | |
| | Previous Validate Submit Reset | | | | |

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 | | N |
| The total payment for your a | application is | |
| The amount of | ill be deducted from your Giro Account. | |
| Payment Advice | | |
| SnDescription | | Amount (SGD)GST |
| 1 New App: | | N |
| The total payment for your a | pplication is | |
| Payment Method: * | eNETS O Credit O Debit | fore appreciation to submit usur application |

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

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

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



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



If the Debit option is selected, the page will be re-directed to the relevant screen for the applicant to select the bank first before being re-directed to input the debit card details. This mode of payment is a one-time deduction only.





| | Official Receipt - HSA00000000002 - Microsoft Internet Explorer | |
|---|---|---|
| | 🔇 lock - 🜍 - 🖹 🗟 🏠 🔎 Seach 👷 Favortes 😵 Meda 🚱 🙆 - 🌺 📼 - 🛄 🎎 - | a |
| | TAX INVOICE / RECEIPT | ~ |
| Merchant Reference Code: ET161202113218800 NETS Reference Code: | Receipt No : HEA000000000002 Date/Time Agency : HEA - Health Econnece Authority Application : HEA - FAYMEINT Paid via : EP Ref No : | |
| THANK YOU! | Sao Code/Description Unit Price(38) Qty | |
| TRANSACTION RHOUNT | L. A Comparison of the second s | |
| | Total (SI): | |
| | This is a computer-generated receipt. No signature is required. | ~ |

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 <u>HSA HelpDesk</u> 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 <u>Application Number</u> for ease of reference. Applicants may provide the application number if they wish to communicate with HSA.

| Acknowledgement |
|--|
| Your application have been successfully submitted |
| Please note that your licence applied is provide the second statement of the s |
| Client Code : Licensee Name Amount : 500000000000000000000000000000000000 |
| Show Printer–Friendly version |

Note: The show Printer Friendly version allows applicant to print or view the application.

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) Email : <u>helpdesk@hsahelp.gov.sg</u>

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