

AMENDMENT APPLICATION FOR A LICENCE TO MANUFACTURE/ASSEMBLE PREPARATIONS CONTAINING CONTROLLED DRUGS

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 http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html

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).

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. You may need the following information/item(s) to fill the form:

- Business profile registered with ACRA (formerly known as RCB)
- Site Master File (a mandatory requirement for a company involves in manufacturing and/or primary assembly)
- Certificate of Accreditation of the contract testing laboratory, if any
- Letter of approval issued by the agency/institution that approves the use of the warehouse(s) for the storage of health products, if applicable
- List of manufacturing equipment available and their function, if applicable. Please only provide a brief description of the information requested
- List of quality control equipment available and function of each equipment, if applicable. Please only provide a brief description of the information requested
- Details of the name and type (i.e. dosage forms) of products manufactured / assembled

3. 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

4. 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 0. Licence Summary

The section requires the applicant to furnish this information

- 1) Amendment Details (Please provide in this entry the reason for the amendment)

You will not need to amend any other details at this section. The applicable Licence No, the effective and expiry dates of the existing licence will be displayed for your information.

Part 1. Company's Particular

These details should be automatically displayed for your confirmation.

- 1) Company Name
- 2) Company Business Address, Postal Code, Level and Unit number
- 3) Company Telephone/Fax number
- 4) Company/Business Registration number (ACRA Number)

Applicant should also provide the billing address if it is different from the Company address. You will not need to amend any other details on this section. The company particulars will be displayed for your information.

Part 2. Applicant Particulars

The section requires the applicant to furnish this information

- 1) Applicant Name
- 2) Applicant NRIC/Fin
- 3) Designation
- 4) Postal Code, Level and Unit number (The details of the Applicant Residential Address will be reflected automatically through the Postal Code retrieval function)
- 5) Contact Details like Telephone / Fax / Handphone number and E-mail address
- 6) Preference Contact mode

(Please note that your preferred contact mode is the delivery mode of 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.)

Part 3. Wholesale / Manufacture Licence

The section requires the applicant to furnish this information if there is an amendment to the details. Otherwise, please do not amend any details at this section

- 1) A valid Poisons Licence No. The Poisons Licence should be held by the applicant of the application for a Licence to Manufacture/Assemble Preparations Containing Controlled Drugs
- 2) CD Wholesale Dealer's Licence No, if applicable. Dealers who wish to resell or re-supply the controlled drugs manufactured / assembled will be required to hold a valid CD Wholesale Dealer's Licence before the Licence to Manufacture / Assemble Preparations Containing Controlled Drugs will be issued. The CD Wholesale Dealer's Licence should be held by the applicant of the application for a Licence to Manufacture / Assemble Preparations Containing Controlled Drugs
- 3) Therapeutic Products Manufacturer's Licence No. if you are manufacturing / assembling a therapeutic product containing controlled drugs, your company will be required to hold a corresponding Therapeutic Products Manufacturer's Licence. The licence no. or the application no. of a Therapeutic Products Manufacturer's Licence should be furnished.

Part 4. Controlled Drugs to Manufacture

The section requires the applicant to furnish this information if there is an amendment to the details. Otherwise, please do not amend any details at this section

- 1) Substance name. You can select the controlled drug(s) your company is dealing with from the list provided

Part 5. Pharmaceutical Dosage Form

The section requires the applicant to furnish this information if there is an amendment to the details. Otherwise, please do not amend any details at this section. To amend the dosage form, you will just have to click on the dosage form of interest, and the page will refresh to display the particulars of the dosage form. Click on "Update" to update any changes you have made. You may also choose to add or remove any of the previously applied dosage forms. To add:

- 1) Dosage form. You can select the dosage form(s) your company is dealing with from the list provided. If a dosage form you are dealing with is not included in the list provided, please select the option "Others" from the list provided, and give details of the dosage form in section 5.2
- 2) Activity. Please select the relevant activity for each dosage form you are dealing with, and save the entry. You will see the page refreshes, and the refreshed page will display the details of the dosage form with its associated activity you have added

Part 6. Forensic Classification

The section requires the applicant to furnish this information if there is an amendment to the details. Otherwise, please do not amend any details at this section

- 1) Forensic classification. Please select the relevant forensic classification(s) of the products you

manufacture or assemble. You can select more than one option

Part 7. Manufacturing / Assembly Particulars

The section requires the applicant to furnish this information if there is an amendment to the manufacturing site particulars. Otherwise, please do not amend any details at this section. To amend the manufacturing site particulars, you will just have to click on the manufacturing site of interest, and the page will refresh to display the particulars of the manufacturing site. Click on “Update” to update any changes you have made. You may also choose to add or remove any of the previously approved manufacturing site. To add manufacturing site:

1) Manufacturing / Assembly Addresses (addresses of all the sites where the therapeutic products would be manufactured or assembled). You will see the page refreshes, and the refreshed page will display the details of the manufacturing / assembly addresses you have added after you click on the “Save” button

Part 8. Warehouse Particulars

The section requires the applicant to furnish this information if there is an amendment to the warehouse particulars. Otherwise, please do not amend any details at this section. To amend the warehouse particulars, you will just have to click on the warehouse of interest, and the page will refresh to display the particulars of the warehouse. Click on “Update Warehouse” to update any changes you have made. You may also choose to add or remove any of the previously approved warehouses. To add warehouses:

1) Warehouse Addresses (addresses of all the sites where the therapeutic products would be stored). You will see the page refreshes, and the refreshed page will display the details of the warehouse addresses you have added

2) Storage condition of the warehouse. You will have to provide the optimized warehouse temperature and relative humidity. You can select more than one option for the warehouse temperature

3) Warehouse approved by. Please give details of the agency/institution that approves the use of the warehouse(s) for the storage of health products

4) Add the warehouse address by clicking on the “Add Warehouse” button. You will see the page refreshes, and the refreshed page will display the details of the warehouse particulars you have added

Part 9. Other Products Manufactured in Same Premise

The section requires applicant to furnish this information if there is an amendment to the details. Otherwise, please do not amend any details at this section

1) Categories of products. Please select from the list provided the substance(s) your company is also manufacturing / assembling. You can select more than one option

Part 10. Contract Testing Laboratories Particular

The section requires applicant to furnish this information if there is an amendment to the details. Otherwise, please do not amend any details at this section

- 1) Is a contract testing laboratory engaged to conduct laboratory tests for your company? If your answer to the question is “No”, you can proceed to the next Part. If your answer is “Yes”, you will be required to give details of the contract testing laboratory in the following sections
- 2) Name and address of the contract testing laboratory
- 3) Type of analytical test performed by the laboratory based on your contract. You will only need to give a brief description of the test(s) performed
- 4) If the contract testing laboratory is accredited to any international quality system standards, and the scope of accreditation. You will only need to give a brief description of the scope of accreditation
- 5) Add the contract testing laboratory by clicking on the “Save” button. You will see the page refreshes, and the refreshed page will display the details of the contract testing laboratory you have added

Part 11. Personnel Particulars

The section requires the applicant to furnish this information if there is an amendment to the personnel. Otherwise, please do not amend any details at this section. To amend the personnel, you will just have to click on the personnel of interest, and the page will refresh to display the particulars of the personnel. Click on “Update” to update any changes you have made. You may also choose to add or remove any of the previously approved personnel. To add personnel:

- 1) Particulars of the persons in-charge of production / assembly and quality operations. The name, identity number, designation, experience, and the designation supervisor to whom they directly report to should be furnished. Add the record by clicking on the “Save” button. You will see the page refreshes, and the refreshed page will display the details of the personnel you have added. You can add more than one record.

Part 12. Licence Duration

These details should be automatically displayed for your confirmation

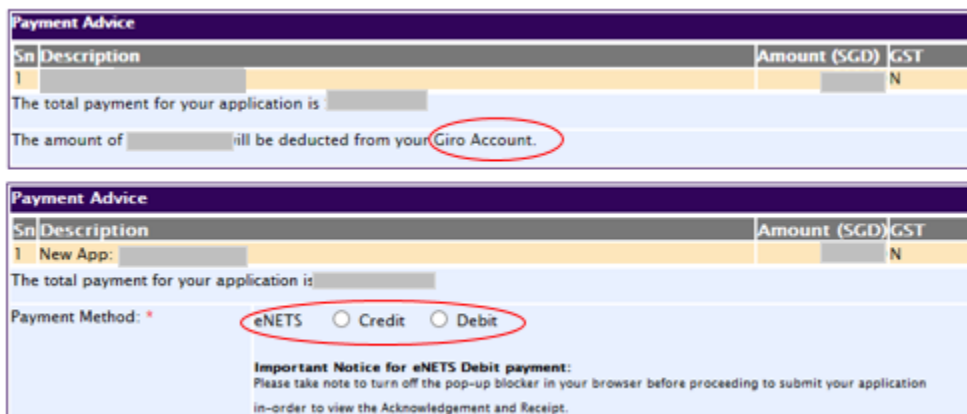
- 1) Licence duration which is set to one year as a default duration

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	[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]	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 relevant 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: SCT17000204
NET's Reference Code: 20170109152042902
Amount: S\$0 500.00

MasterCard Verified by SECUREPASS VISA

Fast, Secure & Hassle-free transactions

CREDIT/DEBIT CARD INFORMATION

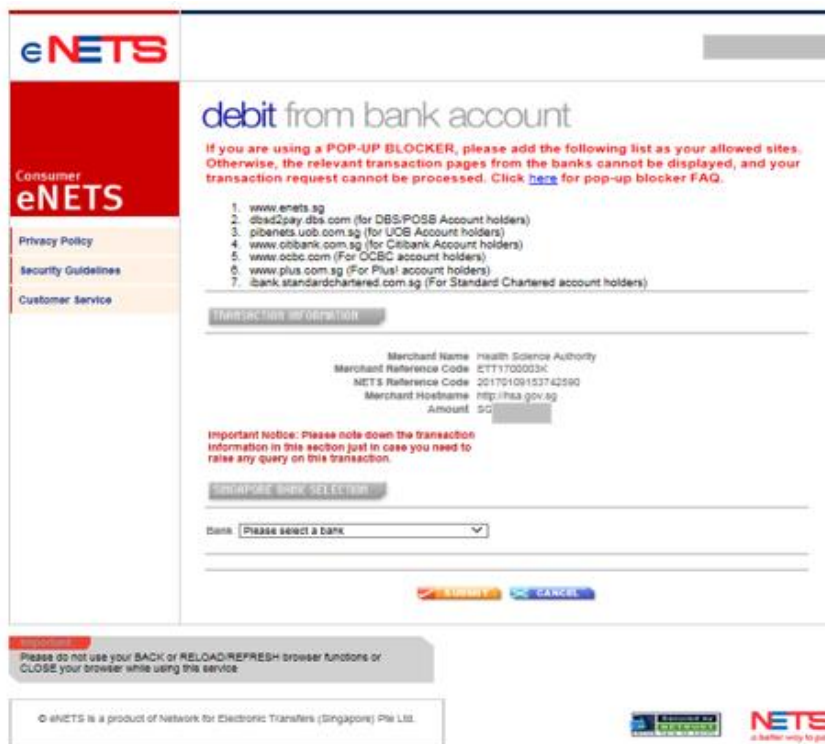
Name on Card: [input]
Card Number: [input]
Please note that the Credit Card number should be 13 or 16 digits. Please input your card number without space or dash.
CVV / CVC2: [input] [What is CVV/CVC2?]
Expiry Date: [Month] [Year] (eg. 2017)

I have read, understood and accepted the following:

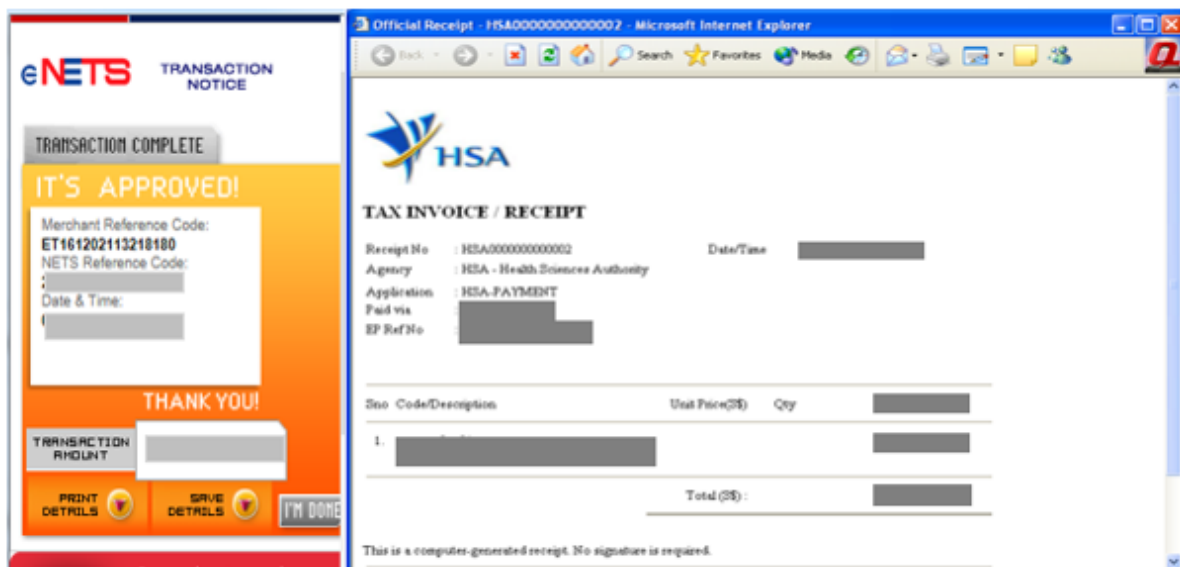
- The return & refund policy for the purchase of relevant products / services.
- The collection, use, disclosure and sharing of this information, which to the best of my knowledge and belief is true and accurate and is for purposes reasonably required to process my application which are set out in **NETS'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

NETS **CONNECT**

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.



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.

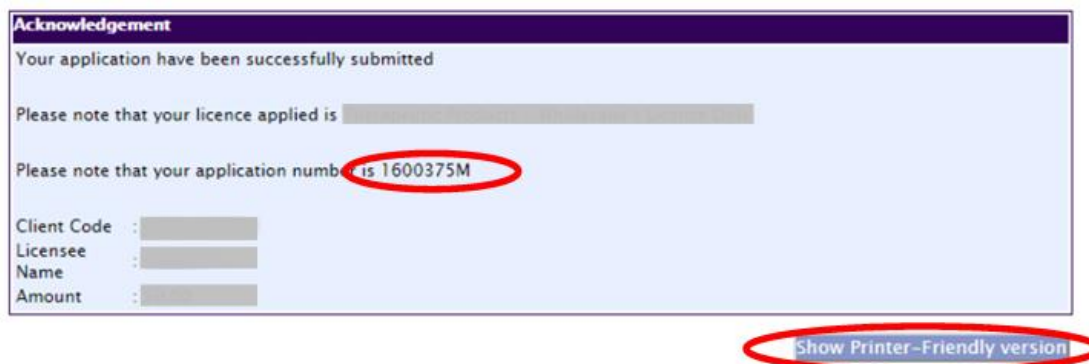


To submit the completed application, click the **'Submit'** button. Applicant will be prompt to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

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.

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>