

## **NEW 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 [apply@prism](mailto:apply@prism). For more information on CRIS, please refer to [http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/CRIS.html](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](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](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 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.

### **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 / Pager 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

- 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 Manufacture'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

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

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

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 Addresses**

The section requires the applicant to furnish this information

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

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

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 Particulars**

The section requires applicant to furnish this information

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 and the scope of accreditation. You will only need to give a brief description of the scope of accreditation

4) If the contract testing laboratory is accredited to any international quality system standards

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 applicant to furnish this information

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

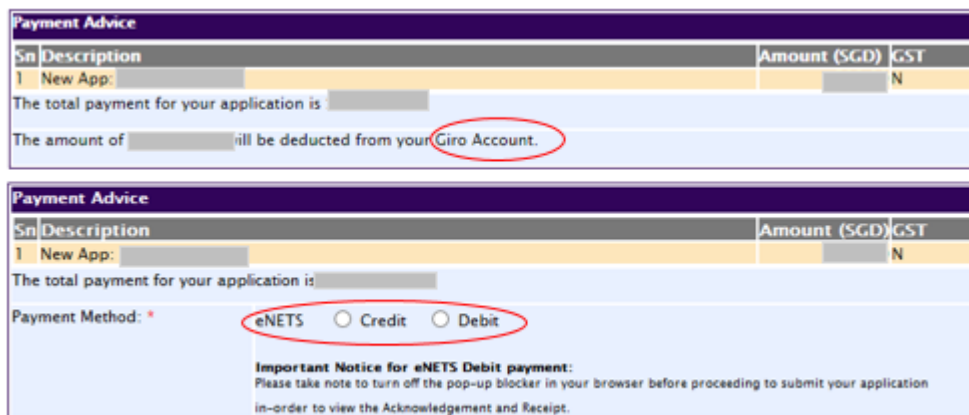
1) Licence duration which is set to one year as a default duration

## 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	New App: [redacted]	[redacted]	N

The total payment for your application is: [redacted]

The amount of [redacted] will be deducted from your Giro Account.

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**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.

1. www.enets.sg

TRANSACTION INFORMATION

<p>Merchant Name Merchant Reference Code NETS Reference Code Amount</p>	<p><b>MasterCard Verified by VISA</b> SECURECODE</p> <p>Health Sciences Authority ECT170003K 20170109153742290 SGD 500.00</p>
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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.

CVV / CV2  [What is CVV/CV2?]

Expiry Date   (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](#).

▶ PROCEED
▶ CANCEL

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**

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## 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.

1. www.enets.sg
2. dbcd2play.dbs.com (for DBS/POSB Account holders)
3. pibenets.uob.com.sg (for UOB Account holders)
4. www.citibank.com.sg (for Citibank Account holders)
5. www.ocbc.com (For OCBC account holders)
6. www.plus.com.sg (For Plus! account holders)
7. bank.standardchartered.com.sg (For Standard Chartered account holders)

TRANSACTION INFORMATION

<p>Merchant Name Merchant Reference Code NETS Reference Code Merchant Hostname Amount</p>	<p>Health Science Authority ECT170003K 20170109153742290 http://hsa.gov.sg SGD [REDACTED]</p>
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Important notice: Please note down the transaction information in this section just in case you need to raise any query on this transaction.

BANK/POSB BANK SELECTION

Bank:

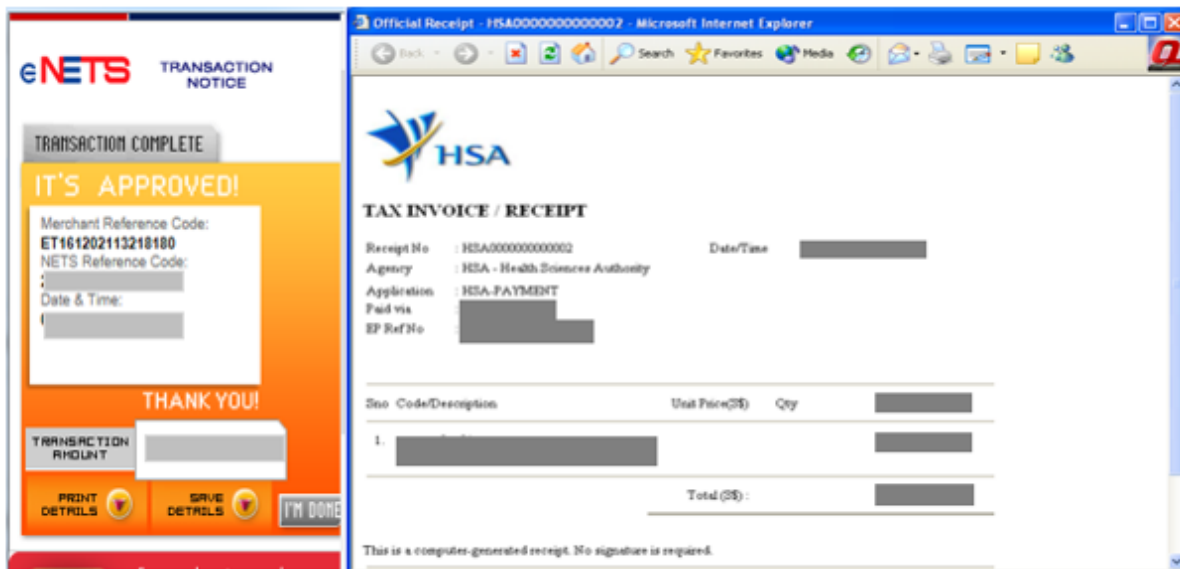
▶ PROCEED
▶ CANCEL

Important:

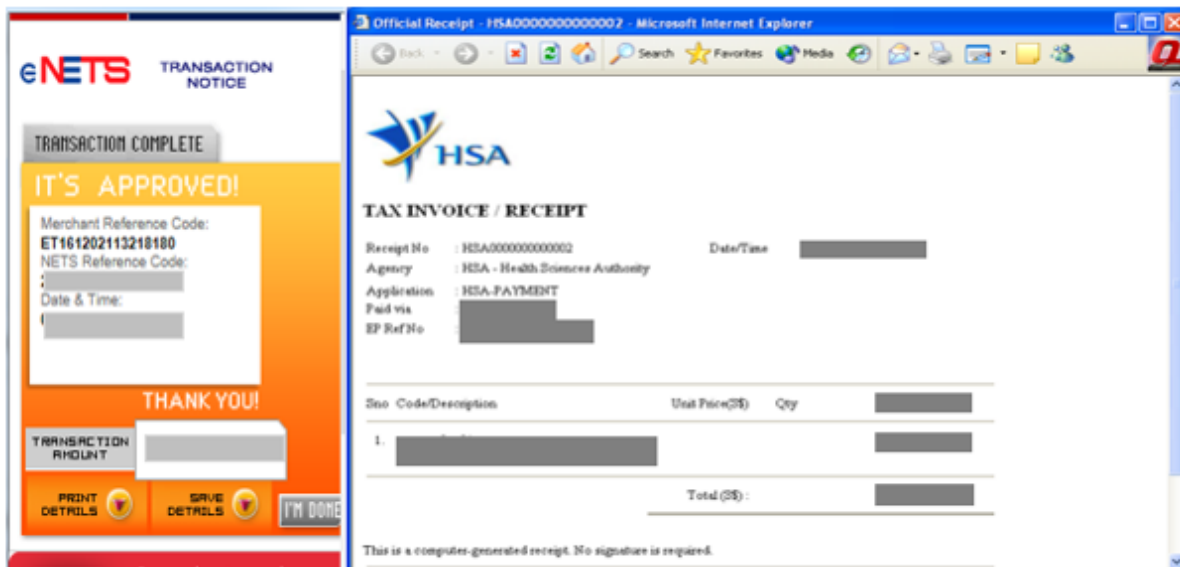
Please do not use your BACK or RELOAD/REFRESH browser functions or CLOSE your browser while using this service.

© 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.



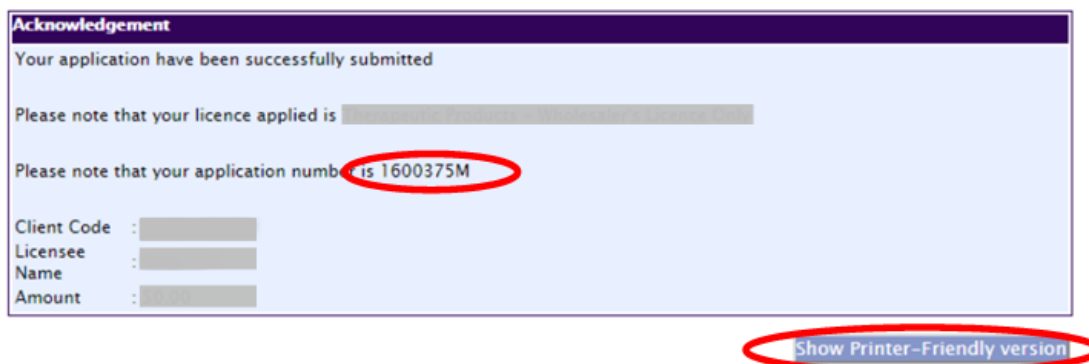
To submit the completed application, click the **'Submit'** button. Applicant will be prompt to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.



## 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.



The screenshot shows a web interface titled "Acknowledgement". The main text reads: "Your application have been successfully submitted". Below this, there are two lines of text: "Please note that your licence applied is" followed by a greyed-out field, and "Please note that your application number is 1600375M" where the number "1600375M" is circled in red. At the bottom left, there are four labels with corresponding greyed-out fields: "Client Code", "Licensee Name", and "Amount". At the bottom right, there is a button labeled "Show Printer-Friendly version" which is also circled in red.

*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](mailto: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](mailto: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>