

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

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](mailto: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. 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. 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.

0. Licence/Permit/Certificate/Listing Summary	
0.1 Licence/Permit/Certificate/Listing No:	<input type="text" value="800004"/>
0.2 Start Date:	<input type="text" value="2"/> /2018
0.3 Expiry Date:	<input type="text" value="5"/> /2022
0.4 Amendment Details:	<input type="text"/>
0.5 Site Inspection (Please refer to the guidelines, available at the top right hand corner, before selection)	<input type="radio"/> This amendment requires site inspection <input type="radio"/> This amendment does not require site inspection

### Part 1. 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 make changes to this information, please submit the changes via the “**Amend Company Information**” module under the [amend@prism](mailto: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 detail relating to the company in the ‘**Other Address Details**’ field. *(If applicable)*
- (5) Click ‘**Next**’ button to proceed to **Part 2. 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 ? *	<input checked="" type="radio"/> Yes		<input type="radio"/> No
1.8 Unique Entity No.(UEN) :	PatchUEN1		

Next Reset

## Part 2. Applicant Particulars

This section requires the applicant to enter 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 Error! Reference source not found. Wholesale / Manufacture Licence section.

Fields marked with an asterisk \* are mandatory.

3. Applicant Particulars			
3.1 Name: *	<input type="text"/>	(as in NRIC/FIN)	
3.2 NRIC/FIN: *	<input type="text"/>	(Example: S1234567A, F1234567A)	
3.3 Designation: *	<input type="text"/>		
3.4 Contact Details			
3.4.1 Tel: *	<input type="text"/>	3.4.2 Fax:	<input type="text"/>
3.4.3 Handphone:	<input type="text"/>	3.4.4 Pager:	<input type="text"/>
3.4.5 Email:	<input type="text"/>		
3.5 Preferences			
3.5.1 Preferred Contact Mode: *	<input checked="" type="radio"/> Email <input type="radio"/> Fax <input type="radio"/> SMS		
(Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this 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 requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)			

Previous Next Reset

### **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.

Fields marked with an asterisk \* are mandatory.

3. Wholesale/Manufacture Licence	
3.1 Form A/Form C Licence No.:	<input type="text"/>
3.2 CD Wholesale Dealer's Licence No.:	<input type="text"/>
3.3 Manufacturer's Licence No.:	<input type="text"/>

### **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

Fields marked with an asterisk \* are mandatory.

4. Controlled Drugs to Manufacture	
4.1 Substance Name :*	<div style="border: 1px solid black; padding: 2px;">                     (+)-Lysergide (Lysergamide)                      (6aR,10aR)-6a,7,10,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol                      (6aR,10aR)-6a,7,8,9,10,10a-hexahydro-6,6-dimethyl-9-methylene-3-pentyl-dibenzo[b,d]pyran-1-ol                 </div>
	<input type="button" value="Add"/> <input type="button" value="Remove"/>

## **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.

Fields marked with an asterisk \* are mandatory.

5. Pharmaceutical Dosage Form	
5.1 Dosage Form: *	Select One
5.2 Please state details if Others is selected.	
5.3 Activity: *	<input type="radio"/> Manufacture <input type="radio"/> Primary Assembly <input type="radio"/> Secondary Assembly

## **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.

Fields marked with an asterisk \* are mandatory.

6. Forensic Classification	
6.1	<input type="checkbox"/> Prescription Only
6.2	<input type="checkbox"/> Pharmacy Only
6.3	<input type="checkbox"/> General Sale List

## **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.

Fields marked with an asterisk \* are mandatory.

7.Manufacturing/Assembly Particulars	
<b>7 Manufacturing/Assembly Address</b>	
7.1 Address Type : *	Local
7.2 Postal Code : *	<input type="text"/> <input type="button" value="Retrieve Address"/>
7.3 Block / House No :	7.4 Level – Unit : # <input type="text"/> - <input type="text"/>
7.5 Street Name :	
7.6 Building Name :	
7.7 Country :	SINGAPORE

## **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.

Fields marked with an asterisk \* are mandatory.

8. Warehouse Particulars	
<b>8.1 Warehouse Address</b>	
8.1.1 Address Type : *	Local
8.1.2 Postal Code : *	<input type="text"/> <a href="#">Retrieve Address</a>
8.1.3 Block / House No :	8.1.4 Level - Unit : # <input type="text"/> - <input type="text"/>
8.1.5 Street Name :	
8.1.6 Building Name :	
8.1.7 Other Address Details : <i>(To input specific identification number for the warehouse which is not reflected above, e.g. for address of 1, ABC Road, #01-01, XYZ Building, Annex A, SINGAPORE 123456, 'Annex A' can be entered in the 'Other Address Details')</i>	<input type="text"/>
8.1.8 Country :	SINGAPORE
<b>8.2 Storage Condition of Warehouse</b>	
8.2.1 Temperature: *	<input type="checkbox"/> 15°C to 30°C (Room Temperature) <input type="checkbox"/> 8°C to 15°C (Cool) <input type="checkbox"/> 2°C to 8°C (Refrigerate, Do not freeze) <input type="checkbox"/> -10°C to -20°C (Freeze) Others <input type="text"/>
8.2.2 Relative Humidity:	Min <input type="text"/> % - Max <input type="text"/> %
8.2.3 Approved By:	Select One <input type="button" value="v"/>

[Add Warehouse](#)

[Previous](#) [Next](#) [Reset](#)

## 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.

- 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.

Fields marked with an asterisk \* are mandatory.

9. Other Products Manufactured in Same Premise	
9.1 Categories of Products: *	
<input type="checkbox"/> Biological	<input type="checkbox"/> Penicilins
<input type="checkbox"/> Cephalosporins	<input type="checkbox"/> Cytotoxics
<input type="checkbox"/> Steroids	<input type="checkbox"/> Not Applicable
<input type="checkbox"/> Non-medicinal products	
<input type="checkbox"/> Hormones	
9.2 If non-medicinal products, state whether contain hazardous or toxic substances	
<input type="text"/>	

[Previous](#) [Next](#) [Reset](#)



## **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.

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:

- 1) Name and address of the contract testing laboratory.
- 2) 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.
- 3) 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.
- 4) 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.

Fields marked with an asterisk \* are mandatory.

10. Contract Testing Laboratories Particulars	
Is a contract testing lab engaged? *	<input checked="" type="radio"/> Yes <input type="radio"/> No
10.1 Company Name : *	<input style="width: 100%;" type="text"/>
10.2 Type of analytical test performed : *	<input style="width: 100%;" type="text"/>
10.3 Are the contract testing laboratories accredited to ISO/IEC 17025 or other quality system standards?:	<input type="radio"/> Yes <input type="radio"/> No
10.4 If yes, please specify the standard and scope of accreditation	<input style="width: 100%;" type="text"/>
<b>10.5 Business Address</b>	
10.5.1 Address Type : *	<input checked="" type="radio"/> Local <input type="radio"/> Overseas
10.5.2 Postal Code : *	<input style="width: 50%;" type="text"/> <input style="width: 50%; background-color: #4b4b8b; color: white; border: none;" type="button" value="Retrieve Address"/>
10.5.3 Block / House No :	10.5.4 Level - Unit : # <input style="width: 30%;" type="text"/> - <input style="width: 30%;" type="text"/>
10.5.5 Street Name :	<input style="width: 100%;" type="text"/>
10.5.6 Building Name :	<input style="width: 100%;" type="text"/>
10.5.7 Country :	SINGAPORE

## **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.

Fields marked with an asterisk \* are mandatory.

11. Personnel Particulars		
11.1 Person in Charge*	<input type="radio"/> Production/Assembly	<input type="radio"/> Quality Operations
11.2 Name as in NRIC/Passport :*	<input type="text"/>	
11.3 NRIC/FIN No :*	<input type="text"/>	
11.4 Designation :*	<input type="text"/>	
11.5 Experience:*	<input type="text"/>	
11.6 Directly report to:*	<input type="text"/>	

## **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.

Fields marked with an asterisk \* are mandatory.

12. Licence/Permit/Certificate/Listing Duration	
12.1 Duration of licence/permit/certificate/listing:*	<input type="text" value="1 Year"/>

## **Part 13. Attachment of supporting documents:**

This section allows the attachment of any supporting documents for the application, such as the company's Site Master File, and lists of manufacturing and quality control equipment.

Fields marked with an asterisk \* are mandatory.

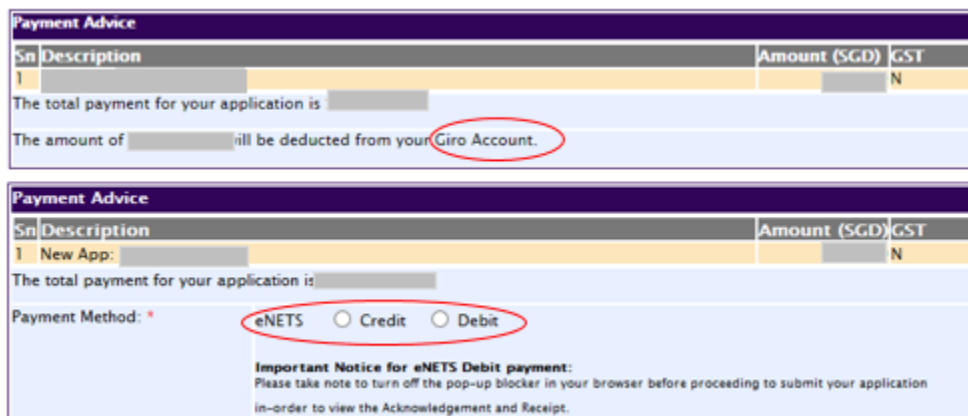
13. Supporting Documents	
To add an attachment, type in the path or hit the browse button. Then <b>hit the Attach Files button to save the attachment</b> to the list below. Please click <a href="#">here</a> for guideline on document attachment.	
Documents	
13.1 Site Master File (Required for manufacturing/primary assembly activity) :	<input type="text"/> Browse...
13.2 Certificate of Accreditation :	<input type="text"/> Browse...
13.3 Letter of approval for the usage of store :	<input type="text"/> Browse...
13.4 List of Manufacturing Equipment available and their function : *	<input type="text"/> Browse...
13.5 List of Quality Control equipment available and function of each equipment : *	<input type="text"/> Browse...
13.6 Details of Products Manufactured :	<input type="text"/> Browse...
13.7 CD Submission :	<input type="text"/> Browse...
13.8 Other Supporting Documents :	<input type="text"/> Browse...
<input type="button" value="Attach Files"/>	
<p><b>Note :</b> Please fill up the template (<a href="#">download here</a>) if you are sending the supporting attachment(s) via CD, after which you are required to save a copy and attach it under "CD Submission."</p>	

## 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 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.

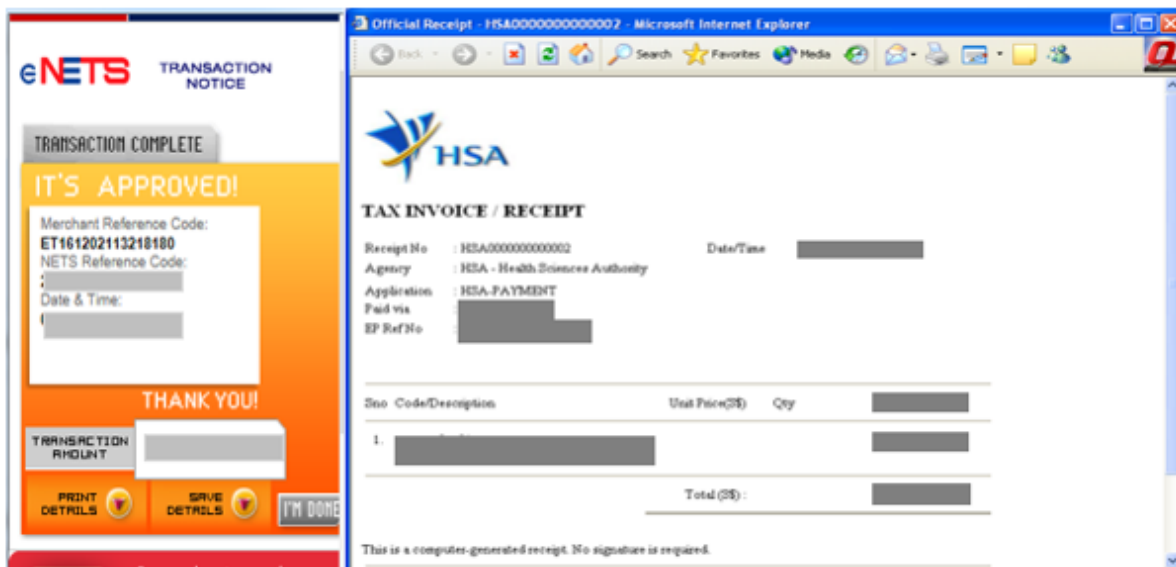
This is applicable for applicants with Non-GIRO Payment Method.

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.



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.

**Acknowledgement**

Your application have been successfully submitted

Please note that your licence applied is [REDACTED]

Please note that your application number is 1600375M

Client Code : [REDACTED]  
Licensee : [REDACTED]  
Name : [REDACTED]  
Amount : [REDACTED]

[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](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)  
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>