

NEW APPLICATION FOR IMPORTER'S LICENCE AND/OR WHOLESALE'S LICENCE FOR ACTIVE INGREDIENTS

Please note that companies must register with Client Registration and Identification Service (CRIS) and applicants must have valid CRIS user rights to submit applications on behalf of the company via apply@prism. For more information on CRIS, please refer to <https://www.hsa.gov.sg/e-services/cris>

1. The online form may take an average of 10 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. The following information/item(s) are required to complete the form:

- (A) **Current layout plan for the premises**, specifying the storage area(s) (Mandatory)
The layout floor plan will need to have the following information:
 - (i) The full address of the warehouse
 - (ii) The dimensions (length and width) of the warehouse
 - (iii) Indication of various storage areas, e.g. receiving bay, quarantined products area, released products area, rejected products area, returned products area, recalled products area, outgoing staging area, etc.
- (B) **Pharmacist Practising Certificate** (applicable for a Responsible Person who is a pharmacist registered with the Singapore Pharmacy Council)
- (C) **List of Active Ingredient(s) handled by the company**
- (D) **Standard Operating Procedures[^]**
- (E) **Records or Recording Templates[^]**

[^]Note: Documents should be prepared in accordance with the requirements stipulated in the [HSA Guidance Notes on Good Distribution Practice](#).

3. The applicant will require a Corppass* or Singpass 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* / Singpass or HSA PIN login is necessary for authentication and authorisation 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 Corppass, please refer to <http://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:

- GIRO (Preferred mode of payment)
- 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

Fields marked with an asterisk * are mandatory.

Part 1. Application Details

This section allows the selection of the licence for submission.

- (1) Select **Licence Applied**. The screen will be refreshed accordingly.

Fields marked with an asterisk * are mandatory.

1. Application Details	
1.1 Licence Applied: *	<input type="radio"/> Active Ingredients – Importers Licence Only <input type="radio"/> Active Ingredients – Wholesalers Licence Only <input type="radio"/> Active Ingredients – Importers Licence and Wholesalers Licence
1.2 Licence Type	
1.2.1 Importer: *	<input type="radio"/> Full Scope <input type="radio"/> Limited Scope
1.3 Licence Duration	

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You can refer to the following table when selecting the licence type:

	Active Ingredients Importer's Licence – Full Scope	Active Ingredients Importer's Licence – Limited Scope	Active Ingredients Wholesaler's Licence
Importing Active Ingredients intended for the manufacture of relevant health products for application of or use by humans in Singapore	✓	×	×
Importing and Wholesaling Active Ingredients intended for the manufacture of relevant health products for application of or use by humans in Singapore	✓	×	✓
Restricted Activities: a) Importing AI solely for export b) Importing AI for purposes other than in the manufacture of relevant health products ¹ c) Importing AI for the manufacture of relevant health products for non-clinical purposes	✓* *Full scope licensees may perform Restricted Activities if included in the importer's license	✓	×

¹Relevant Health Products refer to:

Effective Date: 18 December 2023

- a) Therapeutic Products
- b) Cell, Tissue or Gene Therapy Products (CTGT) product that is not the result of only minimal manipulation of cell or tissue
- c) Medical devices

Please refer to the [ICA website](#) for details on the checkpoints where the Active Ingredients may be imported.

- (2) Click on **Next** button to go to the **Company Particulars** section.

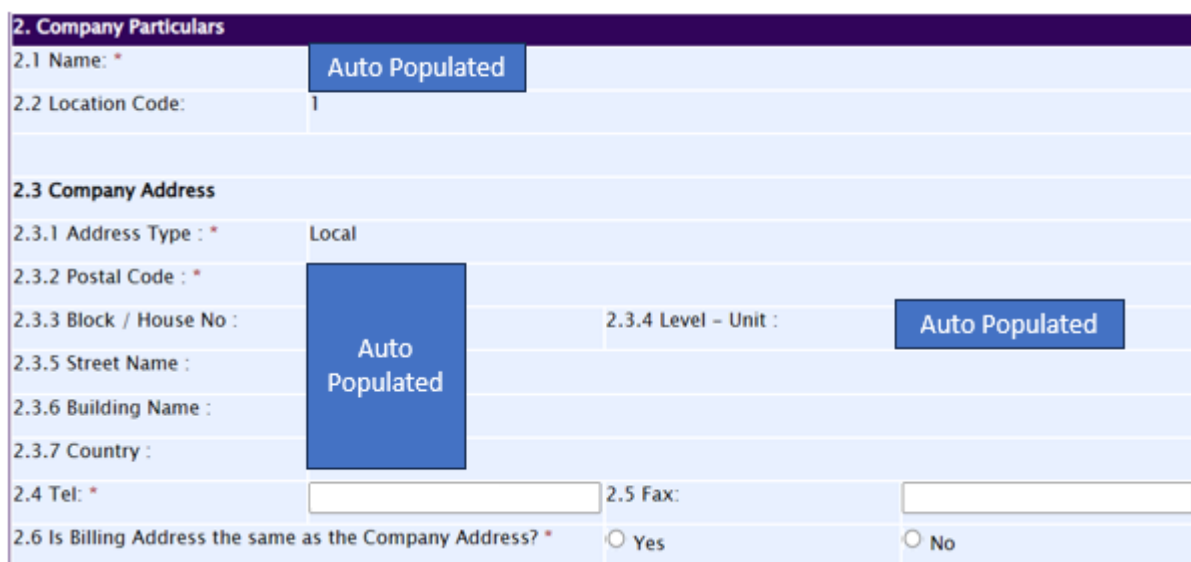
Part 2. Company Particulars

- (1) Details such as **Name** of company and **Company Address** will be populated on screen 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.

Input the information of **Tel** and/or **Fax**.

- (2) Indicate if the Billing Address is the same as Company Address.
- (3) If the Billing Address is not the same as Company Address, fill in the postal code and click on the **Retrieve Address** button. The Block/House No, Street Name and Building Name will be populated on screen. Fill in **Level-Unit** information if applicable. Fill in the other details.
- (4) Click on the **Next** button to go to the **Applicant Particulars** section.



2. Company Particulars	
2.1 Name: *	Auto Populated
2.2 Location Code:	1
2.3 Company Address	
2.3.1 Address Type: *	Local
2.3.2 Postal Code: *	Auto Populated
2.3.3 Block / House No :	Auto Populated
2.3.4 Level - Unit :	Auto Populated
2.3.5 Street Name :	Auto Populated
2.3.6 Building Name :	Auto Populated
2.3.7 Country :	Auto Populated
2.4 Tel: *	
2.5 Fax:	
2.6 Is Billing Address the same as the Company Address? *	<input type="radio"/> Yes <input type="radio"/> No

Part 3. Applicant Particulars

This section allows the input of applicant particulars.

- (1) Fill in **Name**, **ID No** and **Designation**.
- (2) Fill in the **Contact Details** and **Preferred Contact Mode**.
- (3) Click on the **Next** button to go to the **Warehouse Particulars** section.

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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 type="radio"/> Email <input type="radio"/> Fax <input type="radio"/> SMS <small>(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.)</small>		

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Part 4. Warehouse Particulars

This section allows the input of warehouse particulars.

Add 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) and any additional details relating to the premises in the **other address details** field (if applicable).
- (3) Fill in the **Storage Condition of Warehouse**.
- (4) Fill in **Approved By** information.
- (5) Click on the **Add Warehouse** button.

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

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

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

- (7) Click on the **Next** button to go to **Importer's Licence** section.

(Note: If you are applying for TPWL only, the next section will be **Wholesaler's Licence** section.)

Update Warehouse(s) Information

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

Remove Warehouse(s)

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

Fields marked with an asterisk * are mandatory.

4. Warehouse Particulars

4.1 Warehouse Address

4.1.1 Address Type: *

4.1.2 Postal Code: * [Retrieve 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, ABC Road, #01-01, XYZ Building, Annex A, SINGAPORE 123456, 'Annex A' can be entered in the 'Other Address Details')

4.1.8 Country: SINGAPORE

4.2 Storage Condition of Warehouse

4.2.1 Temperature: * Cold Chain (Not more than 8°C)
 Non Cold Chain (Above 8°C)

4.2.1.1 Actual Temperature Range: * 15°C to 30°C (Room Temperature)
 8°C to 15°C (Cool)
 2°C to 8°C (Refrigerate, Do not freeze)
 -10°C to -20°C (Freeze)
 Others

4.2.2 Relative Humidity (Cold Chain): Min % - Max %

4.2.3 Relative Humidity (Non Cold Chain): Min % - Max %

4.2.4 Approved By:

4.3 This warehouse is applicable for: * Active Ingredients - Importers Licence
 Active Ingredients - Wholesalers Licence

[Add Warehouse](#)

SN	Select All	Address of Warehouse	Storage Condition	Relative Humidity	Approved By	Applicable Licence(s)
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Part 5. Importer's Licence Details

This section allows the input of particulars of products to be imported.

- (1) Select **Aspect of Importation**.
- (2) Click on the **Next** button to go to **Responsible Person** section.

Fields marked with an asterisk * are mandatory.

5. Importers Licence Details

5.1 Aspect of Importation: * Active Ingredients supplied for the manufacture of therapeutic product, CTGT product or medical device intended for any application of or use by humans in Singapore
 Active Ingredients solely for export
 Active Ingredients imported for purposes other than in the manufacture of therapeutic products, cell, tissue or gene therapy products, or medical devices
 Active Ingredients imported for manufacturing of therapeutic products, cell, tissue or gene therapy products, or medical devices, for non-clinical purposes
 Other specific activity

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Part 6. Wholesaler's Licence Details

This section allows the input of wholesale dealing particulars.

- (1) Select **Aspect of Wholesaler Dealing**.
- (2) Click on the **Next** button to go to the **Responsible Person** section.

Fields marked with an asterisk * are mandatory.

6. Wholesalers Licence Details	
6.1 Aspect of Wholesaler Dealing: *	<input type="checkbox"/> Active Ingredients supplied for the manufacture of therapeutic product, CTGT product or medical device intended for any application of or use by humans in Singapore
	<input type="checkbox"/> Other specific activity

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Part 7. Responsible Person

This section allows the input of details of Responsible Person.

Add Responsible Person(s)

- (1) Fill in the details of the **Responsible Person** and contact information.
- (2) If more than 1 Responsible Person is appointed by your company and the Responsible Persons are in charge of the GDP aspects for different Division, site, etc., you can input the relevant information into the field of "Scope". This portion may also be left empty if there is no differentiation of scope and duties of the RP
- (3) Click on the **Add Responsible Person** button.
The screen will be automatically refreshed and the refreshed screen will display the Responsible Person particulars that were added.
- (4) Repeat steps (1) to (3) to add other responsible person(s) information.
- (5) Click on the **Next** button to go to **Supporting Attachments** section.

Update Responsible Person(s)

- (1) Click on the Responsible Person requiring amendment from the **Responsible Person List** table.
- (2) Make the required changes.
- (3) Click on the **Update** button.

Remove Responsible Person(s)

- (1) Click on the checkbox adjacent to the Responsible Person from the **Responsible Person List** table.
- (2) Click on the **Remove** button to delete the Responsible Person.

Fields marked with an asterisk * are mandatory.

7. Responsible Person	
7.1 Is the responsible person a registered pharmacist? *	<input type="radio"/> Yes <input type="radio"/> No
7.2 Pharmacist Registration Number (PRN): *	<input type="text"/>
7.3 Is the responsible person the same as the applicant? *	<input type="radio"/> Yes <input type="radio"/> No
7.4 Name (as in NRIC/FIN): *	<input type="text"/>
7.5 NRIC/FIN: *	<input type="text"/>
7.6 Designation: *	<input type="text"/>
7.7 Contact Details	
7.7.1 Tel: *	<input type="text"/>
7.7.2 Fax:	<input type="text"/>
7.7.3 Handphone:	<input type="text"/>
7.7.4 Email:	<input type="text"/>
7.8 Please define the responsible person scope (eg Regulatory affairs, Quality control, division, etc) (if applicable):	<input type="text"/>
7.9 This responsible person is applicable for? *	<input type="checkbox"/> Active Ingredients-Importers Licence <input type="checkbox"/> Active Ingredients-Wholesalers Licence

[Add Responsible Person](#)

S/N	Select All	Name of Responsible Person	NRIC/FIN	Pharmacist Registration Number (PRN)	Scope	Applicable Licence(s)

Part 8. Supporting Attachments

This section allows the attachment of the supporting documents for the application.

Add Attachment

- (1) Click '**Choose File**' button to select the required file for attachment.
- (2) Select the required file.
- (3) Click '**Open**' button in the pop-out window.
- (4) Click on the '**Attach File**' button for the file to be attached to this application.
- (5) Fill in the remarks in the '**Remark**' field with regards to the file attached (if required).
- (6) Repeat steps (1) to (5) to add other documents. All supporting documents should be provided.

Remove Attachment

- 1) Click on the checkbox beside the attachment or attachments from the **List of Attachments** table.
- 2) Click on the '**Remove**' button to delete the attachment.

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

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

Note :

If the file size is big (estimate about 2MB and above), the uploading time may be longer.

Documents to be submitted	Application for Importer's Licence (IL)	Application for Wholesaler's Licence (WL)
Current Store layout plan for premise(s) specifying storage area(s)	Yes *	Yes *
Pharmacist Practising Certificate	Yes*, for Responsible Person who is a pharmacist	Yes*, for Responsible Person who is a pharmacist
List of Active Ingredient(s) handled by the company	Yes	Yes
Material Safety Data Sheet or Safety Data Sheet of the Active Ingredient(s) handled by the company	Yes	Yes
GDP Operating Procedures	Yes	Yes
GDP Records or Recording Templates	Yes	Yes
Store Approval Letter	Yes	Yes

** denotes mandatory items*

Fields marked with an asterisk * are mandatory.

8. Supporting Documents		
To add an attachment, type in the path or hit the browse button. Then hit the Attach Files button to save the attachment to the list below.		
Please click here for guideline on document attachment.		
Documents		
8.1 Store Layout Plan : *	<input type="button" value="Choose File"/>	No file chosen
8.2 Pharmacist Practising Certificate (applicable for responsible person who is a registered pharmacist) : *	<input type="button" value="Choose File"/>	No file chosen
8.3 List of Active Ingredient(s) handled by the company :	<input type="button" value="Choose File"/>	No file chosen
8.4 Material Safety Data Sheet or Safety Data Sheet of the Active Ingredient(s) handled by the company :	<input type="button" value="Choose File"/>	No file chosen
8.5 Good Distribution Practice Standard Operating Procedures :	<input type="button" value="Choose File"/>	No file chosen
8.6 Good Distribution Practice Records or Recording Templates :	<input type="button" value="Choose File"/>	No file chosen
8.7 Store Approval Letter :	<input type="button" value="Choose File"/>	No file chosen
8.8 Other Supporting Documents :	<input type="button" value="Choose File"/>	No file chosen
<input type="button" value="Attach Files"/>		

Part 9. Confirmation

Once all the relevant sections are completed the confirmation page would display all the information from the sections earlier. Click **Validate** to check if all fields are filled up correctly.

Alternatively, you may select **Save** to save a copy of the draft application if you wish to complete the application at a later time.

Part 10. Declaration

After validation is successful, you can read through the declaration section carefully before accepting to undertake the conditions. Then click **Submit**.

All applicants under the Health Product Act (HPA) must comply with HPA and their regulations. This is to ensure that all active ingredients in Singapore meet the required standards. Applicants must also comply with all other applicable laws and their regulations.

Declaration	
1.	I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
<input type="radio"/> Accept <input type="radio"/> Decline	

Payment Advice

This section shows the application fee for the licence applied.
There are 2 modes of payment available:

- GIRO
- Non-GIRO: eNETS (Credit/Debit Card)

Payment Advice			
Sn	Description	Amount (SGD)	GST
1	New App: [REDACTED]	[REDACTED]	N

The total payment for your application is SGD [REDACTED]

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

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 eNETS payment, please choose the applicable (Credit or Debit). The page will be re-directed to the relevant screen for the applicant to make payment.

If the payment made via eNETS is not completed successfully, the applicant will need to contact HSA HelpDesk (contact information on final page) for assistance.

Acknowledgment

This section acknowledges that the application has been submitted to HSA for processing. An application number will be generated for the application.

PR1001 APPLICATION FOR ACTIVE INGREDIENTS DEALER'S LICENCES

Acknowledgement

Your application have been successfully submitted

Please note that your licence applied is Active Ingredients – Importers Licence and Wholesalers Licence

Please note that your importer's application number is [REDACTED]

Please note that your wholesaler's application number is [REDACTED]

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

[Show Printer-Friendly version](#)

You may wish to print a copy of this acknowledgement page or take note of the application number for ease of reference. You also need to provide the application number if you wish to communication with HSA.

- (1) Show Printer Friendly version
This allows you to print or view the application.

PR1001 APPLICATION FOR ACTIVE INGREDIENTS DEALER'S LICENCES

Acknowledgement

Your application have been successfully submitted

Please note that your licence applied is Active Ingredients – Importers Licence and Wholesalers Licence

Please note that your importer's application number is [REDACTED]

Please note that your wholesaler's application number is [REDACTED]

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

[Show Printer-Friendly version](#)

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 Active Ingredients Importer's or Wholesaler's Licence Application Form(s).

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.
- Secondary Input Request requires applicant's explanation to certain matters pertaining to the application form submitted.

Responding to Primary Input Request

- (1) Log on to track@prism. Enter the mandatory fields of 'Application/Submission Type', 'Licence/Permit/Certificate/Listing/Notification/Registration Type', 'Enquiry Type' and any other information relating to the application. Click the '**Search**' button.

PZ0951 TRACK@PRISM

Important Notes:

For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

General Search

Enter Transaction No or Application/Submission No for fast and exact matched look-up

Application/Submission Type *

Licence/Permit/Certificate/Listing/Notification/Registration Type *

Enquiry Type *

Transaction No.

Application/Submission No.

Licence/Permit/Certificate/Listing/Notification/Registration No.

Product Name.

Submission Date (dd/mm/yyyy) To

Last Update Date (dd/mm/yyyy) To

[Please click here to extend your draft](#)

- (2) Click on the **'HSA Input Request'** to view if any reply is required from the applicant. Click the **'Submit'** button and an alert message will pop up to prompt you to make the necessary changes in the application form.

Please do not access the record using the new window via right mouse click.

1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Amendment for Active Ingredients – Importer's Licence (Input Request)								
S/No	Application No	Transaction No	Licence/Registration No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	2302230M			NA	Input Request	14/12/2023	12/12/2023	Click here for Primary IR (12/12/2023)

Please do not access the record using the new window via right mouse click.

1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

INPUT REQUEST LIST (PRIMARY)

Application No : 2302230M

Please reply with comments for each item in the action list if necessary.
Please also update / amend the relevant section and resubmit your application as specified by selecting the appropriate application no. on track@prism.

1 Records

Action List			
SN	Action	Due Date	Applicant's Response (if any)
1.	IR 1	14/12/2023	

- (3) Click on the **'Application No.'** to make changes directly on the Active Ingredients Licence Application for response to Primary Input Request.

Please do not access the record using the new window via right mouse click.

1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Amendment for Active Ingredients – Importer's Licence (Input Request)								
S/No	Application No	Transaction No	Licence/Registration No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	2302230M			NA	Input Request	14/12/2023	12/12/2023	Click here for Primary IR (12/12/2023)

Please do not access the record using the new window via right mouse click.

1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

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

Responding to Secondary Input Request

- (1) **Enter the Application Number** of the Active Ingredients Importer's or Wholesaler's Licence Application to retrieve the application that requires amendment to the submitted information in track@prism.

PZ0951 TRACK@PRISM

Important Notes:

For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

General Search

Enter Transaction No or Application/Submission No for fast and exact matched look-up

Application/Submission Type *

Licence/Permit/Certificate/Listing/Notification/Registration Type *

Enquiry Type *

Transaction No.

Application/Submission No.

Licence/Permit/Certificate/Listing/Notification/Registration No.

Product Name.

Submission Date (dd/mm/yyyy) To

Last Update Date (dd/mm/yyyy) To

[Please click here to extend your draft](#)

- (2) Click on the **'HSA Input Request'** to view the comments left by the HSA officer and the necessary action to be taken with regards to the Active Ingredients Importer's or Wholesaler's Licence Application.

Please do not access the record using the new window via right mouse click.

1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Amendment for Active Ingredients - Importer's Licence (Input Request)								
S/No	Application No	Transaction No	Licence/Registration No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1						14/12/2023	12/12/2023	Click here to Secondary IR (12/12/2023)

Please do not access the record using the new window via right mouse click.

1 Matching Record(s) Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

- (3) Fill in any response in the text box for response to Secondary Input Request and click the **'Submit'** button.

INPUT REQUEST LIST (SECONDARY)

Application No	<input type="text"/>
Please reply with comments for each item in the action list and submit this secondary input request. Please note that resubmission of the application is not required.	

1 Records

Action List			
SN	Action	Due Date	Applicant's Response (if any)
<input type="text"/>	<input type="text"/>	<input type="text"/>	

 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, or any enquiry relating to the CRIS account.

HSA HelpDesk
Hotline : 6776 0168 (from 7:00 am to midnight daily)
Email : helpdesk@hsahelp.gov.sg

3. For general enquiries or questions related to the importation and wholesaling of TP, please contact the Audit and Licensing Division.

Audit & Licensing Division
Tel : 6866 1111
Email : hsa_gdp@hsa.gov.sg