Amendment Application for Therapeutic Product Registration

Information to note

1. The online Amendment Application Form for Therapeutic Product Registration may take about 5 – 10 minutes to complete.

2. The time taken varies depending on the application type, the complexity of the application (e.g. number of manufacturers), the number and size of attachments, applicant PC and network configurations, the Internet performance, etc. Please note that the time stated above excludes time taken for preparatory work in relation to filing the online form (e.g. scanning documents for file attachments).

3. Please refer to the Appendix 17 Guideline on PRISM Submission and the Guidance on Therapeutic Product Registration for more details.

4. User registration with HSA CRIS is required for a company who is intending to submit an application with HSA for the first time.

5. Users will require either a Corppass or a HSA Pin to login the system for authentication and authorization.

6. The modes of payment available are as follows
   - GIRO (preferred option)
   - Credit Card / Debit Card

7. GIRO payment will require pre-registration with HSA. The registration process will take around 3 to 4 weeks after the submission of the application form. The applicant will need to submit the GIRO application form to HSA Finance Department. The address can be found in the application form.

Common Icons and Navigation Links

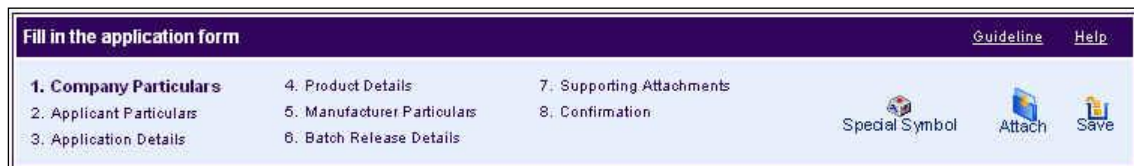The following are the common icons and links in all sections:

- Attach icon. This will allow user to go to the **Supporting Attachments** page to attach relevant documents.

- Save icon. This will allow the user to save the form information at any desired point of time.

- Application form links. This will allow the user to toggle to different sections of the application form.

- This will allow the user to proceed to the next section of the application form.

- Previous button. This will allow the user to proceed to the previous section of the application form.

- Reset button. This will clear the information the user has input in the page.

- Fields with a red asterix * are mandatory input fields. Unless it is entered, the system validation will highlight error and application submission will be disabled.

Search Application for Amendment

1) Select Licence/Permit/Certificate/Listing/Registration Type as 'Therapeutic Product – Product Registration'. This field is mandatory that needs to be entered before a Search can be performed.

2) Optionally, you can also enter the Licence/Permit/Certificate/Listing/Registration **No** and/or **Product Name** to narrow down the search.

PZ4001 AMEND@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.

Search Criteria

Licence/Permit/Certificate/Listing/Notification/Registration Type *	Therapeutic Products - Product Registration ⌄
Licence/Permit/Certificate/Listing/Notification/Registration No	
Product Name	

Search Reset

3) If the Search is successful, the results will be listed as shown below.

Search Criteria

Licence/Permit/Certificate/Listing/Notification/Registration Type *	Therapeutic Products - Product Registration
Licence/Permit/Certificate/Listing/Notification/Registration No	
Product Name	

Search Reset

Please do not create amendment application using the new window via right mouse click.

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Active Therapeutic Products – Product Registration

S/No	Registration No	Product Name	Start Date	Retention Date	Action
141	SIN910285P	Name	15/01/2004	19/09/2019	Amend
142	SIN910286P	Name	15/01/2004	19/09/2019	Amend
143	SIN910287P	Name	15/01/2004	19/09/2019	Amend
144	SIN910288P	Name	15/01/2004	19/09/2019	Amend
145	SIN910289P	Name	15/01/2004	19/09/2019	Amend
146	SIN910290P	Name	15/01/2004	19/09/2019	Amend
147	SIN910291P	Name	15/01/2004	19/09/2019	Amend
148	SIN910298P	Name	15/01/2004	19/09/2019	Amend
149	SIN910299P	Name	15/01/2004	19/09/2019	Amend

Please do not create amendment application using the new window via right mouse click.

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4) To amend a product registration, click on its respective **Amend** link under **Action** Column to proceed.

5) Amendment type page will be displayed, for user selection of type of amendment to perform, as shown below:

6) Select one of the radio options for the type of amendment to perform, and click on Submit button.

7) Note that multiple MIV1 (up to 5) and MAV1 (up to 3) amendment applications are allowed.

The application form consists of 9 sections:

0	Licence Summary
1	Company Particulars
2	Applicant Particulars
3	Application Details
4	Product Details
5	Manufacturer Particulars
6	Batch Release Details
7	Supporting Attachments
8	Confirmation

It is recommended for users to fill in the amendment application form details in a systematic serial manner as the later sections could reference information in the frontal section.

Please take note of the Transaction No. which is generated when you create an amendment application. The Transaction No. is found at the top right hand corner of every page of the online application form. You need to use the Transaction No. to retrieve your draft amendment application via Track@PRISM.

Application Form

The application form would be pre-populated with the latest registration information of the product registration. Applicants should only amend the sections of the application form that the change in this application relates to.

1. Registration Summary

    The Registration Summary section for a MAV-1 and MAV-2 application consists of an amendment summary text field.

PT0101 AMENDMENT TO A REGISTRATION OF THERAPEUTIC PRODUCT

Fill in the application form			Guideline	Help
0. Licence Summary	3. Application Details	6. Batch Release Details		
1. Company Particulars	4. Product Details	7. Supporting Attachments	Special Symbol	Attach	Save
2. Applicant Particulars	5. Manufacturer Particulars	8. Confirmation		

Next

0. Registration/Permit/Certificate/Listing/Registration Summary	
0.1 Registration/Permit/Certificate/Listing/Registration No.:	SIN70707P
0.2 Start Date:	22/09/2003
0.3 Retention Date:	25/10/2021
0.4 Remarks:	
0.5 Table of Summary of Changes:	Table of Summary of Changes template (attach under section 7 Supporting Attachments).
0.6 Does this change affect other therapeutic product registrations(Y/N)?:	○ Y ● N

Next

The Registration Summary section for a MIV-1 and MIV-2 application consists of a dropdown list for the MIV Checklist Number (Primary Change), and a shuttle field for the MIV Checklist Number (Secondary Change).

0. Registration/Permit/Certificate/Listing/Registration Summary	
0.1 Registration/Permit/Certificate/Listing/Registration No.:	SIN70707P
0.2 Start Date:	22/09/2003
0.3 Retention Date:	25/10/2021
0.4 MIV Checklist Number (Primary Change):*	Please Select One ⌄
0.5 MIV Checklist Number (Secondary Change(s)):	Available MIV Checlist / Selected MIV Checlist B1 Chg/Addn of Altn Mfr/site of DS [C B2 Chg/Addn of Altn Mfr/site of DS [C B3 Major Chg of Mfg Proc of DS [CEP n B4 Major Chg of Mfg Proc of DS [CEP A B5 Addn or Repl of Mfg Site of DP B6 Addn or Repl of Altn Site for Pri Pac B7 Chg of Spec of DS [CEP not Avail] /L B8 Chg of Spec of DS [CEP Avail] B9 Chg of Batch Size of Sterile DP B10 Chg of Batch Size of Non-sterile D B11 Major Chg in Mfg Proc for DP B12 Qual or Quan Chg of Excipient B13 Quan Chg in Coat W or Caps Shell B14 Chg in Pri Pac Mtl for Sterile Pdt B15 Chg or Addn of Size/Shape of CCS B16 Inclusion or Repl of Solvent/Diluer B17 Chg of Shelf-life of DP B18 Chg of Storage Conds of DP B19 Addn or Chg of Score/Break Line o B20 Chg of Sterility Testing to Paramet >> <<
0.6 Remarks:	
0.7 Table of Summary of Changes:	Table of Summary of Changes template (attach under section 7 Supporting Attachments).
0.8 Does this change affect other therapeutic product registrations(Y/N)?:	◯ Y ◉ N

- Details such as Registration No, Start Date and Expiry Date of the selected Licence to be amended will be populated on screen.
- Fill in the Amendment Remarks field (for MAV applications) or select the appropriate MIV Checklist Number (for MIV applications).
- Click the Next button to go to Company Particulars section.

2. Section 1 - Company' s Particulars

    In this section, applicant is required to fill in the following information:

    a) Company name
    b) Company address
    a) Company telephone number
    b) Company UEN

    Applicant could also fill the billing address if it is different from the company address.

    If the company is registered with CRIS, the above information will be pre-populated.

3. Section 2 – Applicant Particulars

    In this section, applicant is required to fill in the following information:

    a) Applicant name
    b) Applicant NRIC/Fin No.
    c) Designation
    d) Contact details like telephone/handphone number and e-mail address

    e) Preferred contact mode

    - The NRIC/FIN must be the same as user Login ID.
    - 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.

4. Section 3 – Application Details

   In this section, applicant is required to fill in the following information:

   a) Application type
   b) Product type
   c) Reference product
   d) Dossier type
   e) Format type

5. Section 4 – Product Information

   In this section, applicant is required to fill in the following information:

   a) Product name
   b) Product formula - substance name, type, grade and strength
   c) Indicate whether product is derived from human blood or animal sources
   d) ATC code
   e) Dosage form
   f) Route of administration
   g) Packaging – container closure system, quantity/container, shelf life, storage condition, pack size and shelf life (after first opening and after reconstitution)
   h) Forensic classification in Singapore
   i) Registration status and other details in other countries
   j) Product owner information

   - Fill in the necessary details under each individual subsection and click on the Save button to capture the data keyed in. Note: - For the product formula, the input data will be encrypted once saved.
   - Multiple entries are allowed for the section 4.3, via the Save button (below the State Source label).
   - For the product owner address, if Address Type is Local, fill in Postal Code and click on Retrieve Address. The Blk/House No, Street Name and Building Name

will be populated on screen. Fill in Level-Unit information if applicable. If Address Type is Overseas, fill in the required overseas addresses in the given fields.

- Click on the Next button to go to the Manufacturer's Particulars section.

6. Section 5 – Manufacturer's Particulars

In this section, applicant is required to fill in the following information:

a) Manufacturer type
b) Manufacturer's particulars
c) Manufacturing operation

If the Manufacturer Type is **Active Substance** Manufacturer: -

- Fill in Name of Manufacturer.
- For the site address, if Address Type is Local, fill in Postal Code and click on Retrieve Address. The Blk/House No, Street Name and Building Name will be populated on screen. Fill in Level-Unit information if applicable. If Address Type is Overseas, fill in the required overseas addresses in the given fields.
- Indicate if the Office Address is the same as Site Address.
- If No, repeat step (2) to fill in the office address.
- Select an active ingredient to be added to this manufacturer.
- Click on the Save Manufacturer button to save particulars.
- To add another manufacturer information, click on the New Manufacturer button.

If Manufacturer Type is **Finished Product Manufacturer** (Local): -

- If local manufacturer had been audited by HSA and had obtained a manufacturer's licence from HSA, select "*Audited by HSA*" under Regulatory GMP Audit / Overseas Audit, and
  - o Fill in **Manufacturer's Licence No** and click on Retrieve button. The relevant data will be retrieved from the MQA database table and populated on screen.

- o Fill in Name of Manufacturer.
- o Select Manufacturing Operation from the dropdown list.
- o Click on the Save Manufacturer button to save particulars.
- o To add another manufacturer information, click on the New Manufacturer button.

- If local manufacturer is currently under audit by HSA, select "*Pending Audited by HSA*" under Regulatory GMP Audit / Overseas Audit, and
    - o Fill in **Manufacturer's Licence Application No** and click on Retrieve button. The relevant data will be retrieved from the MQA database table and populated on screen.
    - o Fill in Name of Manufacturer.
    - o Select Manufacturing Operation from the dropdown list.
    - o Click on the Save Manufacturer button to save particulars.
    - o To add another manufacturer information, click on the New Manufacturer button.

- If local manufacturer had yet to be audited by HSA, and does not have a pending manufacturer's licence application, select "*None of the above*" under Regulatory GMP Audit / Overseas Audit,
    - o Click on the given link to be redirected to the application for manufacturer licence page. After the application is submitted, select Pending Audit by HSA and provide the application number.
    - o Fill in Name of Manufacturer.
    - o Select Manufacturing Operation from the dropdown list.
    - o Click on the Save Manufacturer button to save particulars.
    - o To add another manufacturer information, click on the New Manufacturer button.

If Manufacturer Type is **Finished Product Manufacturer** (Overseas): -

- Fill in the necessary details.
- If Address Type is Local, fill in Postal Code and click on Retrieve Address. The Blk/House No, Street Name and Building Name will be populated on screen. Fill

in Level-Unit information if applicable. If Address Type is Overseas, fill in the required overseas addresses in the given fields.

To Update Manufacturer

1) Click on the required manufacturer from the Manufacturer List table.

2) Make the required changes.

3) Click Update button (next to Cancel button).

To Remove Manufacturer

1) Click on the checkbox adjacent to the manufacturer(s) from the Manufacturer List table.

2) To delete all manufacturers, click on the checkbox beside Select All.

3) Click on the Remove Manufacturer button to delete the manufacturer(s).

Click on the Next button to go to the Batch Release Details section.

7. Section 6 – Batch Release Details

This section requires applicant to fill in the information of company responsible for batch release in the exporting country.

- Fill in the necessary details.

- If Address Type is Local, fill in Postal Code and click on Retrieve Address. The Blk/House No, Street Name and Building Name will be populated on screen. Fill in Level-Unit information if applicable. If Address Type is Overseas, fill in the required overseas addresses in the given fields.

- Select from the 6.4 Finished Product Manufacturer Drop Down List for the current Batch Releaser. Click on the Save Manufacturer button to save the selected record. Repeat the step if Batch Releaser has multiple Finished Product Manufacturers.

- Click on the Save Batch Releaser button to save the current batch releaser details. Otherwise, the current batch releaser details will not be saved.

- Click on the New Batch Releaser button, to enter a new batch releaser. Repeat the above steps for the new batch releaser.
- All saved Batch Releaser records is shown in a tabular list as shown in above diagram.
- Select the checkbox beside the Batch Releaser row, and click on the Remove Batch Releaser button to remove those selected rows.
- Click on the Next button to go to the Supporting Attachments section.

8. Section 7 – Supporting Attachments

- Please refer to the list of supporting documents required in each application in the online application form. The mandatory documents will be marked with an asterisk.
- Transmission of Information is dependent on various factors such as network speed and file size. Hence, it is not advisable to attach all documents at the same time. Total upload per time should not exceed 10 MB.
- Optionally, the applicant can choose to send the supporting documents via CD. For such case, the applicant is required to download the template provided and fill up accordingly. The completed copy must be attached under item "7.1 CD Submission". Once a 'CD Submission' document is attached, all the other document types will be optional.

Add Attachment

1) Click on the Browse button to select the required file for attachment.
2) Select the required file.
3) Click on the Ok button.
4) Click on the Attach File button for the file to be attached to this application.
5) Fill up remarks with regards to the attachment if required.

Remove Attachment

1) Click on the checkbox beside the attachment or attachments from the List of Attachments table.

2) To delete all attachments, click on the checkbox beside Sn.

3) Click on the Remove button.

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

- tif
- jpg
- pdf
- doc
- xls
- ppt
- avi (audio visual, if required)
- mpeg(audio visual, if required)

9. Section 8 – Confirmation & Declaration

This section shows all the information the user has input into the different sections of the application form. It allows the user to manually verify all the information fields.

To proceed with the system verification the information on the application form,

1) Click on the Validate button.

2) If there are any missing mandatory information or details, which do not meet the application requirements, a pop up screen will appear with the details of the validation error.

3) This will allow the user to take note of the relevant changes to be made and return back to the application form and amend accordingly. Once this is done, repeat the system verification check by clicking on the Validate button. A pop up screen stating 'Validation Successful' will appear upon successful system verification.

Applicant is required to:

a) Make a declaration on the information given in the application.

b) Select either Full or Progressive payment

To submit the completed application, click on the Submit button. The application will then be submitted to HSA for the relevant personnel's processing.

An Application number will be generated for the application. The applicant is advised to print out the acknowledgement page for future reference. The application number should be used when corresponding with HSA.