APPENDIX 17 *GUIDELINE ON PRISM SUBMISSION*

This appendix primarily describes the processes for:

(1) Submitting a new product application

(2) Submitting a variation product application

(3) Responding to Input Request (IR) from HSA

(4) Withdrawing a pending application

1 SUBMITTING A NEW PRODUCT APPLICATION

HSA only accepts applications online via PRISM. Applicants are advised to visit the PRISM@HSA webpage for further details on PRISM.

> **NOTE**: NEW applicants must have a CRIS account to register therapeutic products via PRISM. For information on setting up a CRIS account, refer to the following weblink:
>
> https://www.hsa.gov.sg/e-services/cris

A separate product registration, and therefore a separate application, is required for each pharmaceutical dosage form, strength and presentation of the therapeutic product. Separate application forms are also required for the following (see Example 1):

- Powders for solution for injection containing different amounts of drug substance per container;
- Solution for injection presented in vials/ampoules versus single-use pre-filled syringe;
- Solution for injection presented with different labelled strengths in the product names;
- Concentrates labelled with the total amount of drug substance in the container closure system; and

- All single-use pre-filled syringes containing different amounts of drug substance in each syringe.

Example 1. Injectable products which require separate registrations:

Examples	Labelled strength before reconstitution	Application
Powder for Solution for Injection	25 mg/vial	Submit as 2 separate applications
	50 mg/vial	
Solution for Injection	2 mg/mL in a vial containing 1 mL of the solution	Submit as 2 separate applications
	2 mg/mL in a 1 mL pre-filled syringe	
Solution for Injection	5 mg/2.5mL in a vial containing 2.5 mL of the solution	Submit as 2 separate applications
	5 mg/5.0mL in a vial containing 5.0 mL of the solution	
Concentrate	10 mg/5mL	Submit as 2 separate applications
	20 mg/10mL	
Single-use Pre-filled Syringe containing different amounts of active ingredient in each syringe	100 iu/mL	Submit as 2 separate applications
	400 iu/4mL	

Example 2. Injectable products which are allowed to be registered under one product registration (as pack sizes):

Examples	Labelled strength before reconstitution	Application
Solution for Injection	2 mg/mL in a vial containing 1 mL of the solution	Submit as one application with two pack sizes (i.e. 1 mL and 2 mL)
	2 mg/mL in a vial containing 2 mL of the solution	
Concentrate	2 mg/mL: presented in 5 mL vial and 10 mL vial	Submit as one application with two pack sizes (i.e. 5 mL and 10 mL)

1.1 Sections of a PRISM Application

1.1.1 Section 1 – Company Particulars

Each application for a product registration is company-specific. The company named in this section must be based and registered in Singapore. The company must be authorised by a responsible person in the company/organisation that owns the therapeutic product before it can apply for a product registration for a specific therapeutic product in Singapore.

In this section, input the company's local telephone number. The name, address and Business Registration number (UEN) will be automatically populated. If there is a direct local telephone number, input it into this section to ensure no communication delays between HSA and the applicant.

The company bears full responsibility for ensuring that all available and relevant information is submitted in support of an application. For every successful application for registration of a therapeutic product granted approval, a product

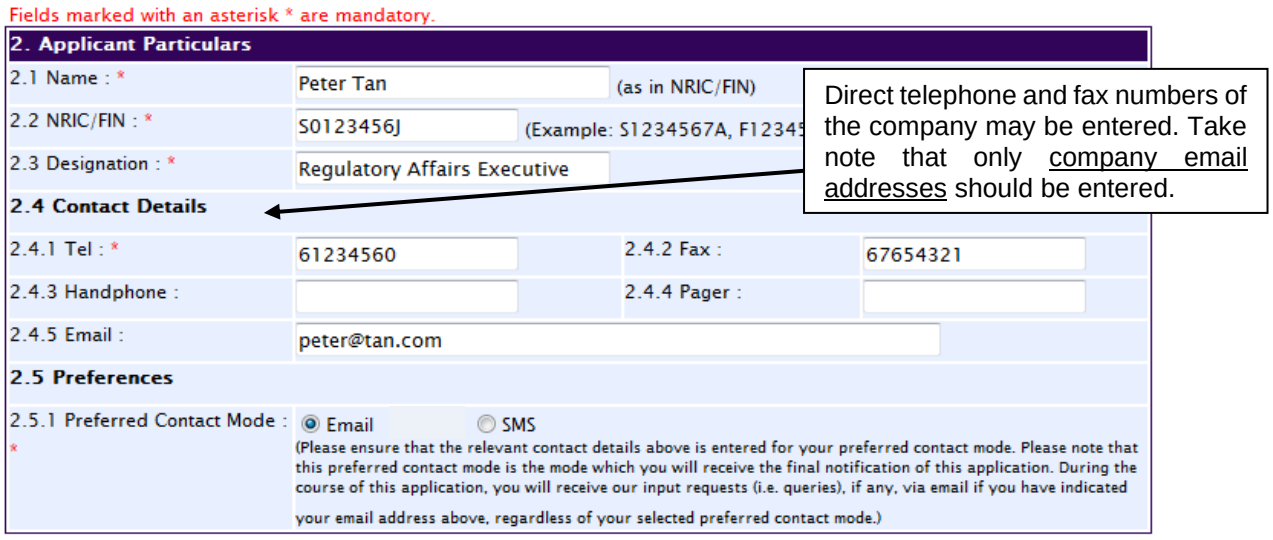
registration will be issued in the name of the company, which will be the Product Registrant.

1.1.2 Section 2 – Applicant Particulars

The applicant of a product registration refers to the local company that is applying for the product registration. The applicant company may authorise officers, permanent employees, or designated external parties, all of whom are referred to as the "applicant representative", to submit the application for product registration in Singapore.

In this section, input the particulars of the applicant representative – name, NRIC/FIN and designation. The NRIC/FIN entered must be the same as that used to login to access the PRISM application.

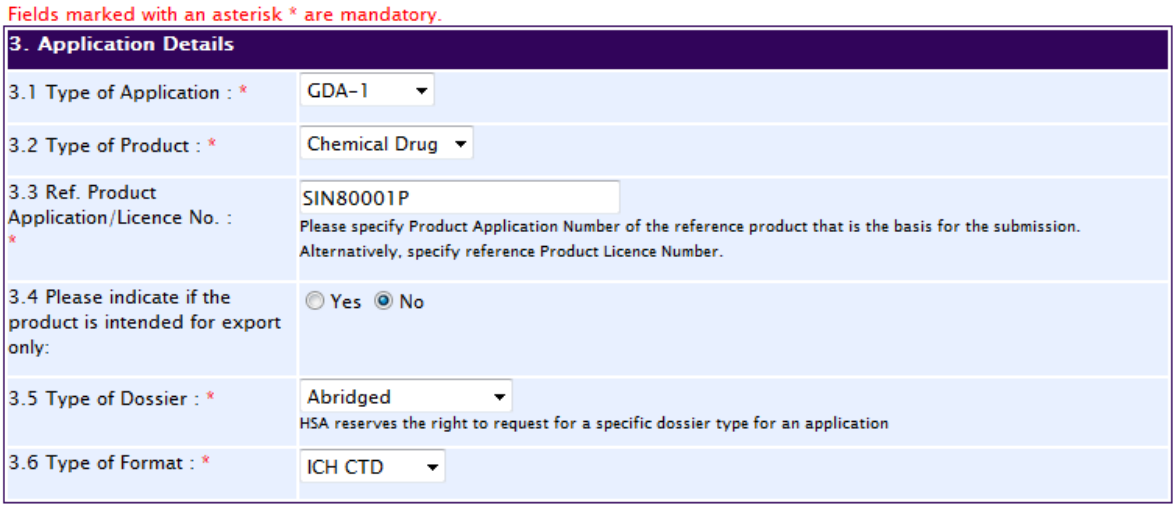
For PRISM sections 2.4.5, please enter only ONE email address.



Care should be taken to ensure that the local contact details are entered correctly to ensure no communication delays between HSA and the applicant representative. Applicant representatives are advised to notify HSA immediately via Amend@PRISM (select '*Amend Applicant's Details for registrations and applications*') if there is any change to this PRISM section, especially to the contact details.

1.1.3 Section 3 – Application Details

In this PRISM section, enter specific details of the application, such as the application type, dossier type (evaluation route), format type and any reference product(s), if applicable. A screenshot of PRISM section 3 is shown below:



a) *Section 3.1 – Type of Application*

Input the type of application to be submitted to HSA.

Note:

After the application has been submitted, if the type of application is selected incorrectly and it needs to be changed

- within the same application type (e.g. from NDA-2 to NDA-3), then HSA will notify the applicant and change the application form on behalf of the applicant at the point of acceptance of the application; or
- to a different application type (e.g. NDA-1 to GDA-1), then the original PRISM application must be withdrawn first before re-submission under the correct application type.

HSA reserves the right to re-categorise the application type if deemed appropriate.

b) *Section 3.2 – Type of Product*

Input either '*Chemical Drug*' for chemical drug products or '*Biological Drug*' for biologic drug products. Applicants are advised to note that once the product type is set, it cannot be changed throughout the entire life cycle of the product.

A 'Chemical Drug' refers to a product containing a chemical entity as the active ingredient(s). A chemical entity refers to any chemical element, naturally occurring chemical material or chemical product obtained by chemical change or synthesis (including macromolecules produced by chemical synthesis, such as peptides/oligo-nucleotides) or any metabolites from a micro-organism (such as antibiotics).

A 'Biological Drug' refers to a product containing a biological entity as the active ingredient(s). A biological entity refers to any macromolecule extracted from an organism (such as proteins, nucleic acids, proteoglycans, cytokines and growth factors); or any substance derived from a biological system, including any of the following:

i. a whole cell or micro-organism, such as a whole virus or bacterium used as a vaccine;
ii. a part of a micro-organism, such as a sub-unit vaccine;
iii. a plasma-derived product; or
iv. a biotechnology-derived substance, such as a protein or polypeptide.

c) *Section 3.3 – Reference Product*

This section applies to all application types except for NDA-1 application.

For all NDA-2 Biosimilar and GDA applications, applicants need to specify the Singapore reference product's SIN number, which can be obtained from the Register of Therapeutic Products. If a GDA-2 application is not submitted at the same time as a GDA-1 application, then both the Singapore reference product's and the GDA-1 product's SIN numbers should be specified.

For related NDA or GDA applications that are submitted at different timings, the NDA-1/2 or GDA-1's registration/application number must also be inserted in the reference product field.

d) *Section 3.5 – Type of Dossier*

This refers to the four evaluation routes mentioned in section 5.3 of the main guidance.

Only one option can be selected from the drop-down menu – full, abridged or verification. For applications under the Special Scheme for registration of Indian generic products, choose the '*Verification – CECA*' option.

NOTE: After the application has been submitted, if the dossier type is selected incorrectly or the applicant wishes to change the dossier type, the original PRISM application must be withdrawn first before re-submission with the correct dossier type.

HSA reserves the right to re-categorise the dossier type if deemed appropriate. The applicant will be informed if re-categorisation is necessary.

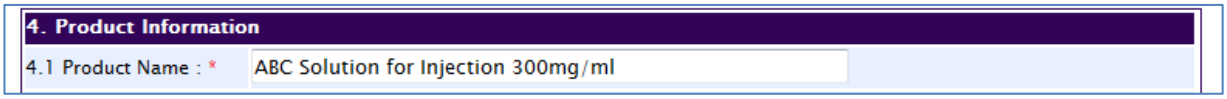
e) *Section 3.6 – Type of Format*

Indicate whether the dossier format is ICH CTD or ACTD. Once the format type has been set in PRISM, it cannot be changed throughout the entire life cycle of the product.

Applicants are expected to organise the documents into the respective CTD sections before submitting the dossier to HSA. Explanatory notes on the application dossier format can be found in section 6.2 of the main guidance.

1.1.4 Section 4 – Product Information

a) *Section 4.1 – Product Name*



The Product Name is the product's trade name that is shown on the product labelling.

From this point on, the term '*product labels'* or *'product labelling*' will refer to the inner label, outer carton, package insert (PI) and/or patient information leaflet (PIL) of the product.

Applicants should ensure that the product name:

- does not suggest greater safety or efficacy than that supported by clinical data;
- does not imply superiority over another similar product in Singapore;
- does not imply the presence of substance(s) not present in the product; and
- shall not be confused with another product.

In addition, proposed product names comprising of the international non-proprietary name (INN) should include a differentiator (e.g. name of the product owner) to allow better product differentiation from other currently registered products. For example, the proposed product name for a paracetamol tablet from product owner ABC could be 'ABC-Paracetamol Tablet 500 mg'.

If the proposed product name is not acceptable, the applicant will be informed of the reasons, and will be asked to amend it.

It is recommended that the Product Name be entered with each word capitalised and in the following format:

Brand Name	Pharmaceutical Dosage Form	Product Strength	Product Standard (optional)
ABC		300MG/ML	

Applicants are advised to use the same format for the product labelling. However, the International Non-proprietary Name (INN) or common name of the active substance(s) may be used when referring to the active ingredient(s)'s properties in the PI.

The pharmaceutical dosage form should be as specific to the product's actual dosage form as possible (e.g. "Film-coated Tablet" instead of "Tablet").

The product strength represents the amount of the active substance in the pharmaceutical dosage form, which is stated as amount per unit dose or concentration. Concentration can be stated as a unit of mass (e.g. mg/g), a unit of volume (e.g. mg/mL) or as a percentage (e.g. %w/v or %w/w).

The product strength may be omitted from the product name if:

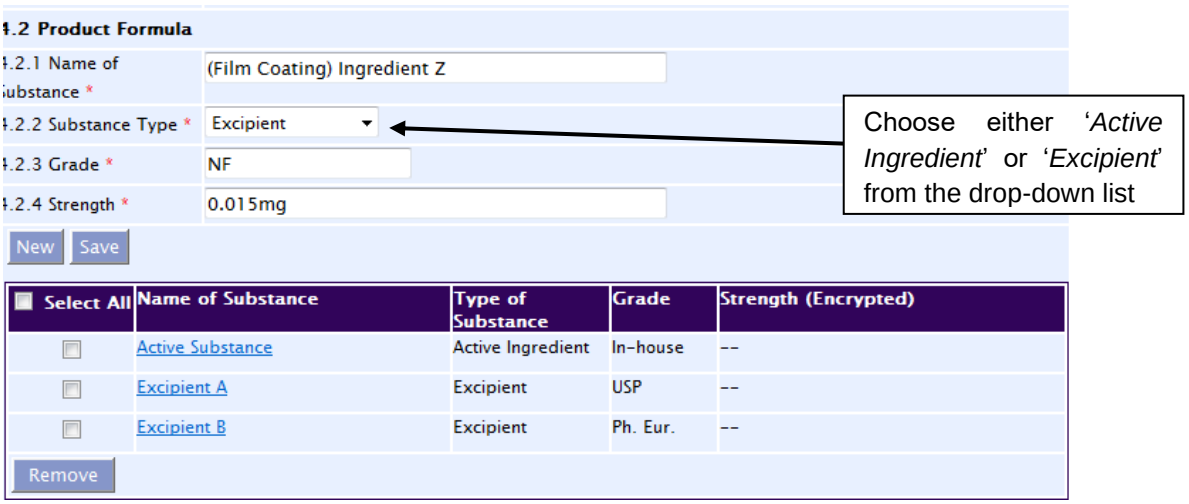
- The product has more than one active substance and the proposed product name is sufficiently unique so as to identify/differentiate the product from other strengths or other similar products; and/or
- It would be difficult to include the strength in the product name (e.g. vaccines, total parenteral nutrition solution, haemofiltration solution, etc.).

For specific pharmaceutical dosage forms, there are additional points to take note of as shown in the following table:

Product	Format	Example
Fixed-combination	Strength of each active ingredient separated by a '***/***'	MULTI-TAB® TABLET 100MG/25MG
Single-dose preparation, total use	State the amount of active ingredient per unit dose	INGREDIENT® 300MG PER VIAL
Multi-dose preparation	State the concentration	per mL, per drop, per kg, per m^2, etc.
Powder for reconstitution, oral	State the concentration <u>after</u> reconstitution	ANTIBIOTIC® 200MG/5ML
Powder for reconstitution, injection or infusion	State the amount of active ingredient <u>before</u> reconstitution or dilution	INGREDIENT® 300MG PER VIAL
Transdermal patches	State the amount of active ingredient released in <u>24 hours</u>	TRANS-PATCH® 24MG/24 HRS
Concentrate solution for injection	State the product name as 'concentrate for solution for injection'	ABC® CONCENTRATE FOR SOLUTION FOR INJECTION 200MG/ML
Metered dose inhaler (aerosol)	State the dose per actuation	ABC® INHALER 100MCG/DOSE OR ABC® INHALER 100MCG/PUFF

b) *Section 4.2 – Product Formula*

The Product Formula is a list of <u>all</u> the active substance(s) <u>and</u> excipients (including water) that are present in the final pharmaceutical dosage form, as seen in the following screenshot:

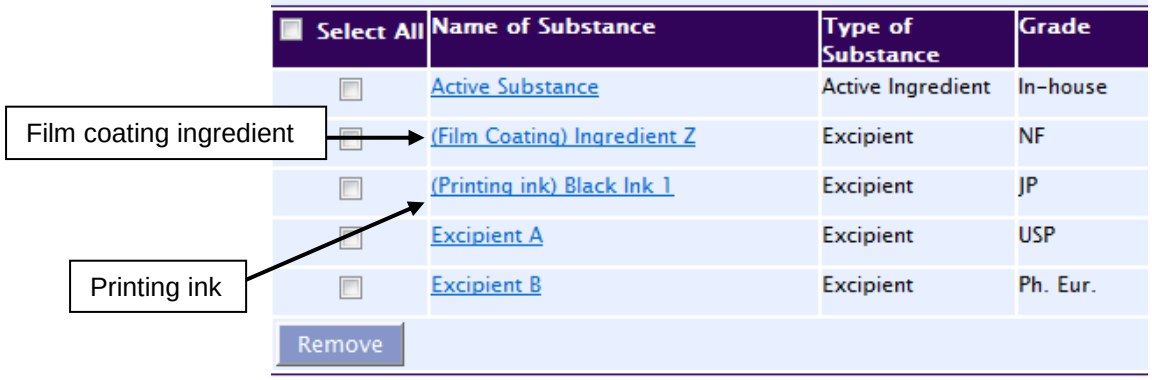


Proper or commercial names for ingredients, such as printing inks or colourants, are permissible but internal abbreviations, acronyms or codes for any ingredient are not acceptable. The grade for each ingredient should be specified, e.g. in-house, BP, USP, Ph. Eur., etc.

Full compositions of all ingredients (e.g. colourants, flavouring agents, etc.) used in the product should be stated in the Product Formula, and their uses differentiated as stated in the following sections.

Differentiating the use of excipients in the product

Ingredients relating to the pharmaceutical dosage form, such as tablet film coating or capsule shell, should be indicated within parentheses before the ingredient name, as shown in the following screenshot:

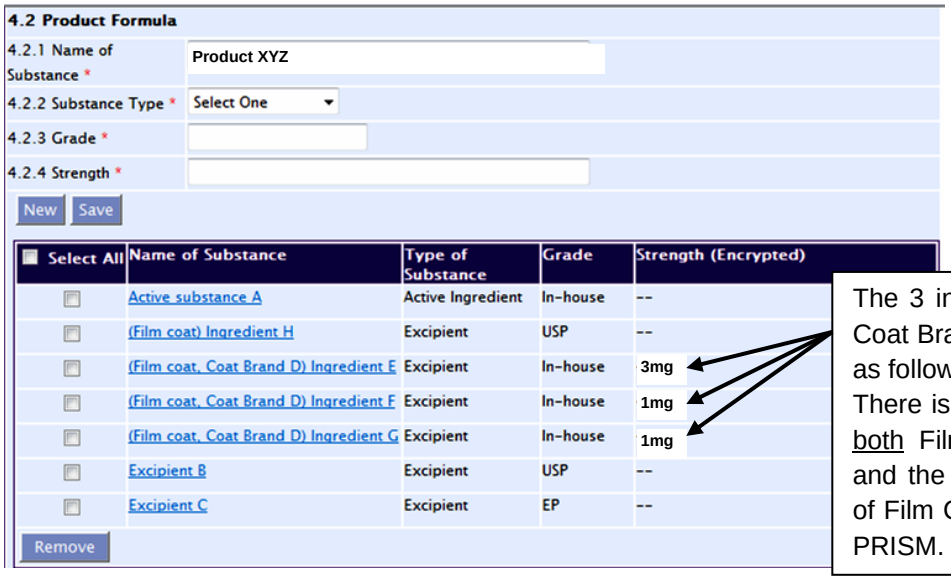


If the product contains proprietary ingredients, relating to the dosage form *(*such as tablet film coating, capsule shell, flavourings, colourants, perfumes and/or printing inks), this information should be captured in PRISM as shown in Example 3. Applicants are advised not to use internal codes but rather give commercial names for such ingredients. In cases where the formula of the proprietary ingredient is confidential, only the total quantity of the proprietary ingredient present in the final product needs to be captured in PRISM.

Example 3. Entry of proprietary ingredients relating to the dosage form for Product XYZ:

Name of Substance	**Type of Substance**	**Grade**	**Strength**	**Remarks**
(Film coat) **Ingredient H**	Excipient	USP	Qs	**Ingredient H** is used in the film coat, but it is not part of the Coat Brand D
(Film coat, Coat Brand D) **Ingredient E**	Excipient	In-house	3mg	Coat Brand D is a proprietary film coat composing of **3mg of Ingredient E**
(Film coat, Coat Brand D) **Ingredient F**	Excipient	In-house	1mg	Coat Brand D is a proprietary film coat composing of **1mg of Ingredient F**
(Film coat, Coat Brand D) **Ingredient G**	Excipient	In-house	1mg	Coat Brand D is a proprietary film coat composing of **1mg of Ingredient G**
~~(Film coat) Coat Brand D~~	Excipient	~~In-house~~	~~5mg~~	There is **no need** to state the *total* amount of the proprietary film coat, Coat Brand D.

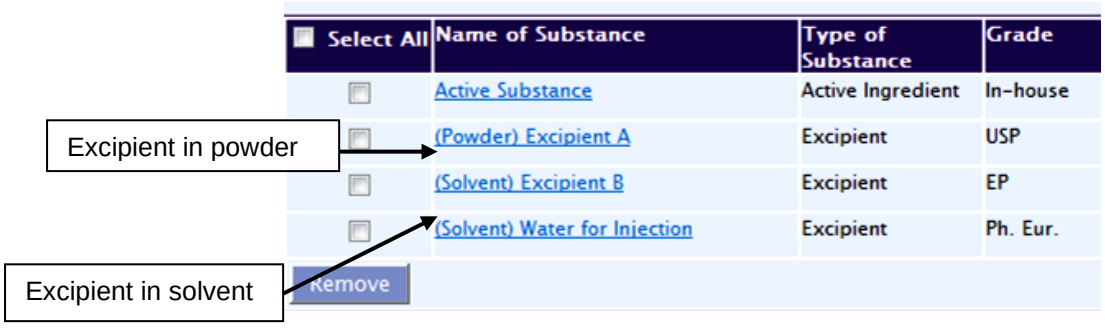
The ingredients in the preceding table should be entered in PRISM as follows:



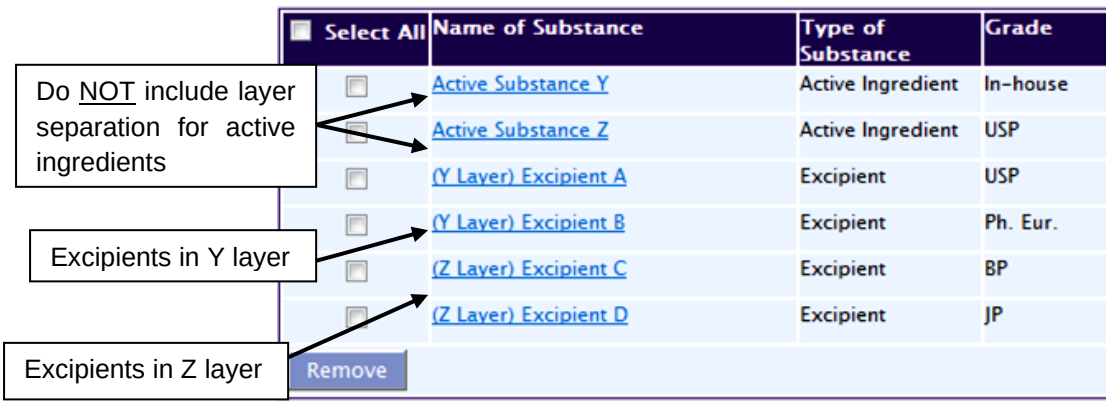
The 3 ingredients in Film Coat Brand D are entered as follows.
There is no need to enter <u>both</u> Film Coat Brand D and the total composition of Film Coat Brand D into PRISM.

If the product contains ingredients relating to a particular portion of the finished drug product, such as powder (active substance) and solvent (solution for reconstitution) or a multi-layered tablet, the portion of the drug product should be stated in parentheses before the ingredient name of the excipients, as shown in Examples 4 and 5:

<u>Example 4</u>. A product with powder and solvent:



<u>Example 5</u>. A multi-layered tablet:



Entering the strength of ingredients

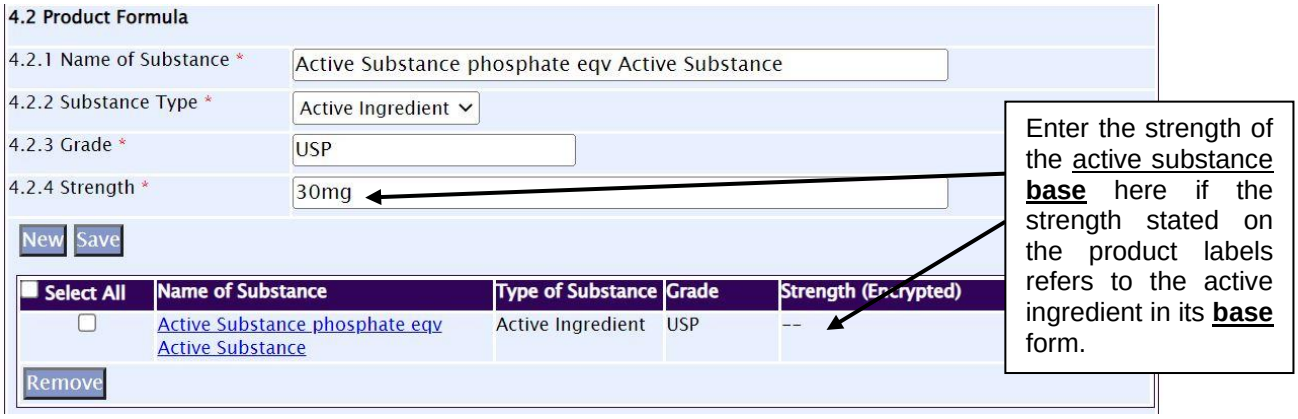
The strength and unit of the active ingredient must be aligned to the strength reflected in the PRISM product name.

Quantities of each active substance and excipient must be expressed in international units of measure, wherever appropriate (see the following table and Examples 6 to 9):

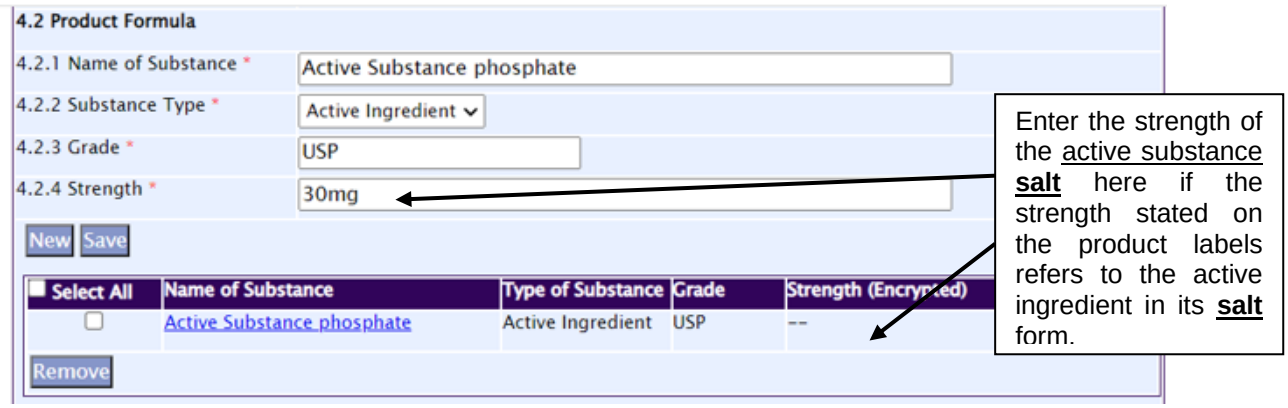
Eg	Scenario	Product strength stated on product label	Name of active ingredient to be stated in PRISM	Strength of active ingredient to be stated in PRISM
1	Strength on the label refers to the **base form** of the active substance. *(see Example 6)*	30mg Active Substance	Active Substance phosphate eqv Active Substance	30mg
2	Strength on the label refers to the **salt form** of the active substance. *(see Example 7)*	30mg Active Substance phosphate	Active Substance phosphate	30mg
3	Strength on the label refers to the **hydrate**	30mg Active Substance	Active Substance	30mg

	form of the active substance *(see Example 8)*	potassium dihydrate	potassium dihydrate	
4	Strength refers to **neither the base nor salt form** of the active substance. *(see Example 9)*	30mg Active Substance sodium	Active Substance sodium	30mg

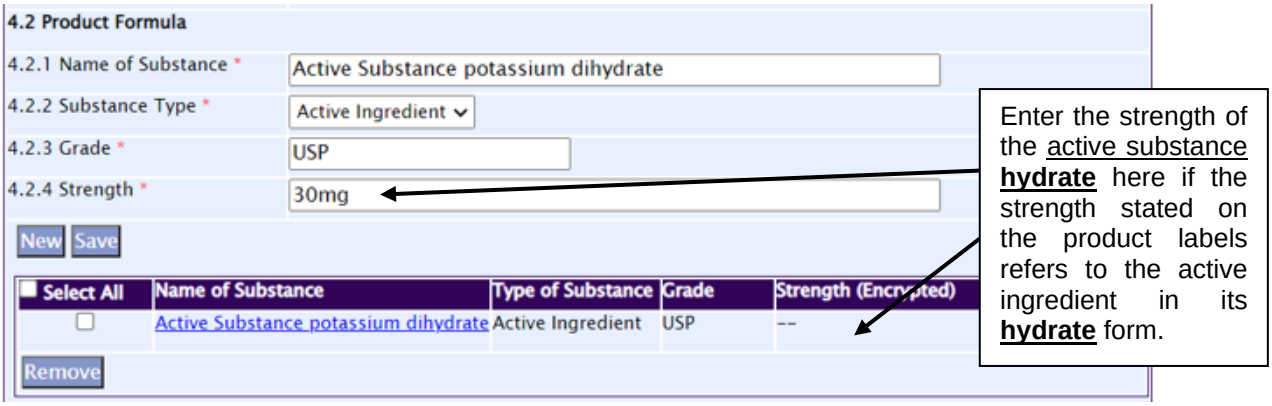
Example 6. Strength on label refers to **base form** of active substance:



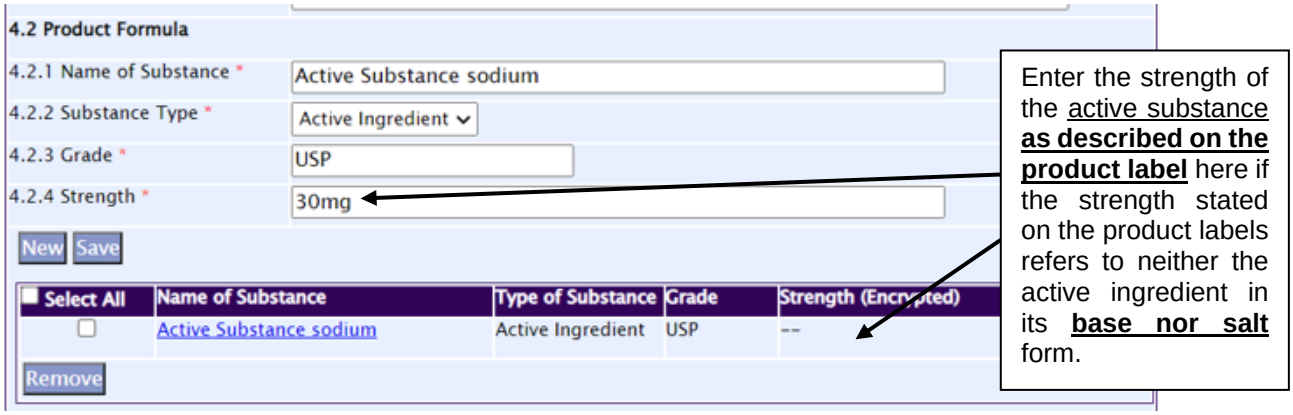
Example 7. Strength on label refers to **salt form** of active substance:



Example 8. Strength on the label refers to the **hydrate form** of the active substance:



Example 9. Strength on label refers to **neither base nor salt form** of active substance:



Ingredients of residual amounts in the product

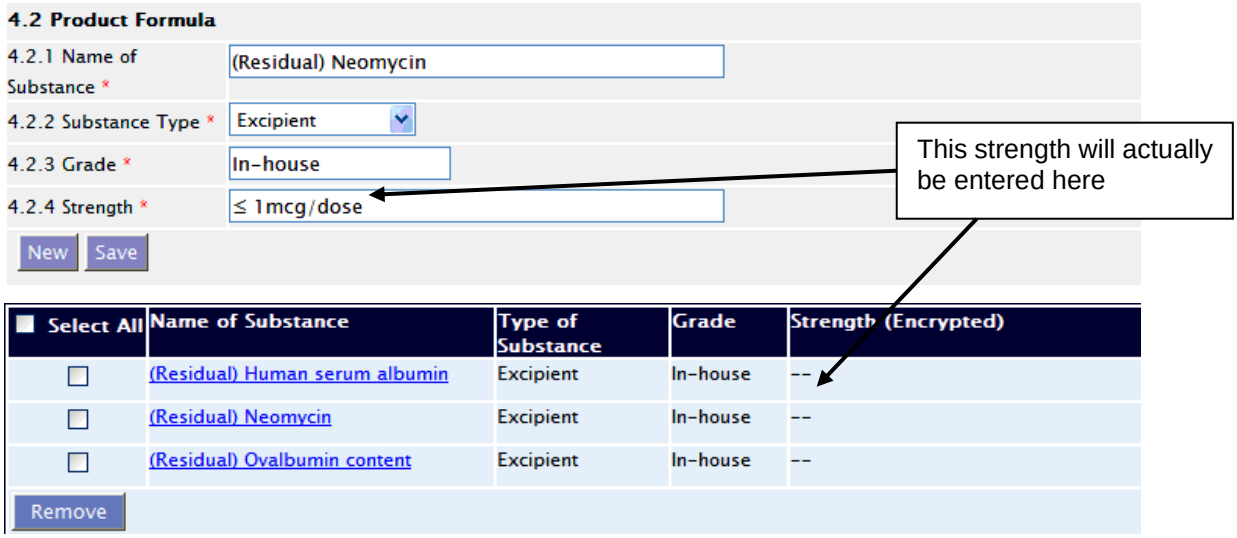
Information on substances which were removed during the manufacturing process, such as water or ethanol which evaporates during drying, should be included in the Product Formula, but with the strength stated as '*trace*'.

Information on residual amounts of materials of allergic potential (e.g. antibiotics and preservatives) and biological origin (e.g. human serum albumin) added or present in the drug product must be declared. Information to declare includes the following:

- the material's name – enter '(Residual)', followed by the material's name in the *Name of Substance* field;
- the material's grade, if applicable; and

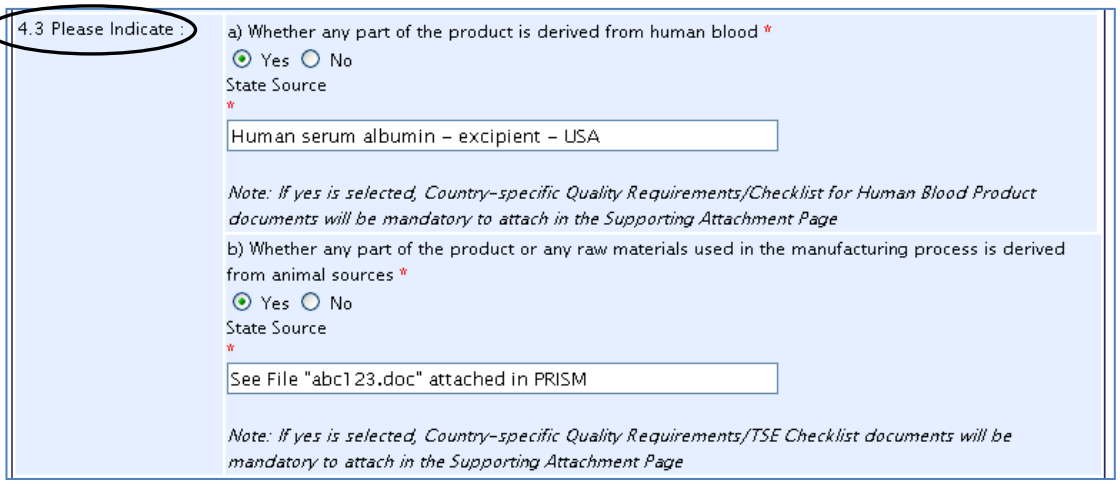
- the material's limit in the product – enter '≤', followed by the limit in the *Strength* field.

Example 10. Screenshot of product containing residual amounts of certain materials:



If the strength of the residual material is not available, then the strength may be captured as 'trace'.

c) *Section 4.3 – Ingredients Derived From Human Blood/Animal Sources*



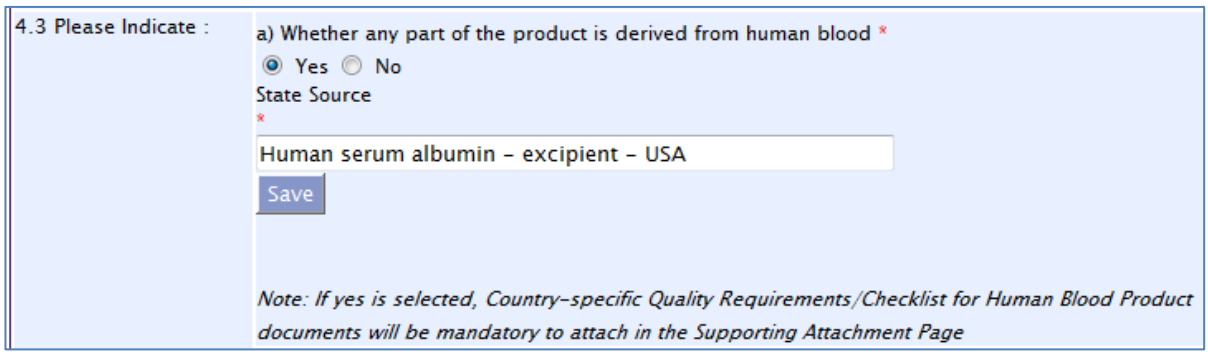
Section 4.3a – Ingredients Derived From Human Blood

Human plasma-derived products used as an active substance, as an excipient or within the manufacturing process, must be declared in this PRISM section.

If the answer is '**Yes**', the following information must be inserted as per the format below:

- the type of product derived from blood and its role in the drug product, i.e. as an active substance, excipient or within the manufacturing process; and
- the country of the source product.

A screenshot of a PRISM section 4.3(a) entry is given:



If constrained by PRISM's text limit, reference can be made to a document uploaded into PRISM section 7 – e.g. '*Yes – see file xyz.pdf attached in PRISM*'.

NOTE: additional information is required when human plasma-derived products are used. Refer to Appendix 8 for details on the data requirements for submission.

Section 4.3b – Ingredients Derived From Animal Sources

Animal-derived materials used either as an excipient or within the manufacturing process must be declared in this PRISM section.

If the answer is '**Yes**', the following information must be inserted as per the format below:

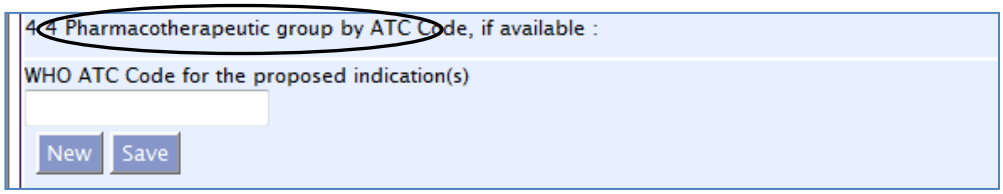
- the source product and species the ingredient is derived from;
- its role in the drug product (i.e. excipient or within the manufacturing process); and
- the country of the source product.

A screenshot of a PRISM section 4.3(b) entry is given:

If constrained by PRISM's text limit, reference can be made to a document uploaded into PRISM section 7, e.g. '*Yes – see file xyz.pdf attached in PRISM*'.

NOTE: refer to Appendix 9 for details on the data requirements for submission.

d) *Section 4.4 – Pharmacotherapeutic Group*

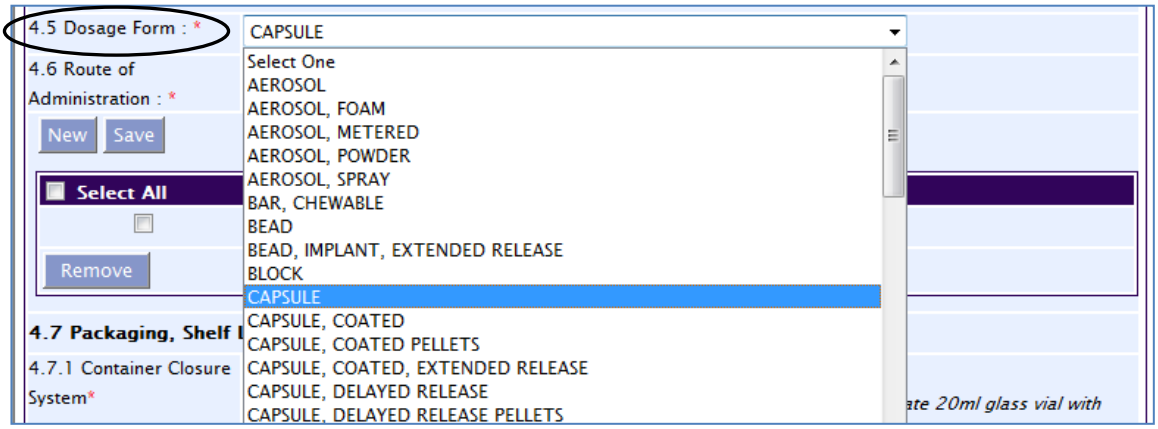


Indicate the WHO ATC code for each distinct therapeutic indication proposed for a product, if available. Applicants may refer to the WHO Collaborating Centre for Drug Statistics Methodology for the ATC Code and more information.

If the WHO ATC code is not available at the time of application submission, "Pending" should be stated in this field.

e) *Section 4.5 – Dosage Form*

A screenshot of PRISM section 4.5 is seen below:



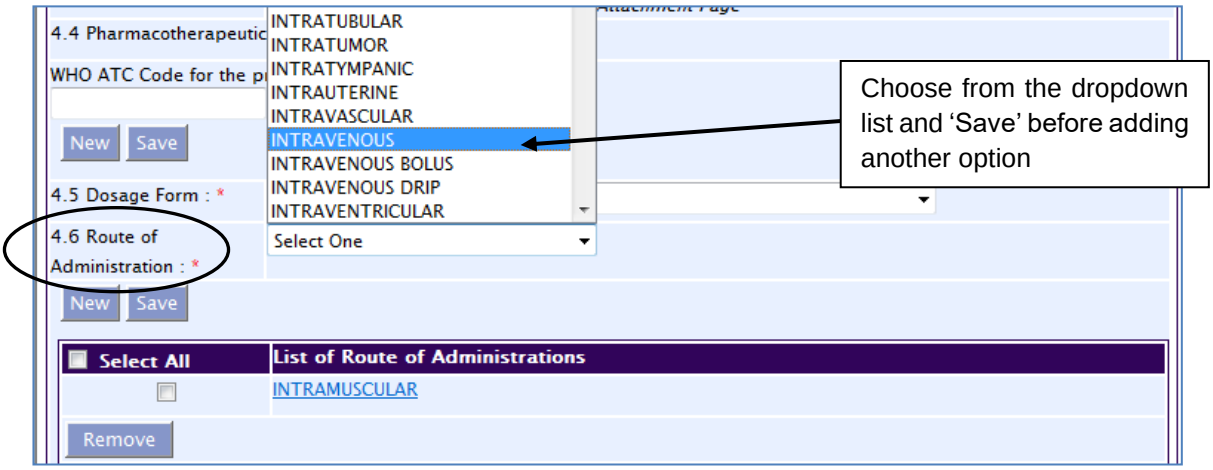
Dosage Form refers to the pharmaceutical dosage form of the drug product, e.g. tablet, injection and cream. The dosage form should be as specific as possible because each form is considered distinct, e.g. ”Tablet, Film-coated, Extended Release” instead of “Tablet””.

The dosage form of a product cannot be amended via any variation application post approval. Similar products of a different dosage form should be submitted as a new product registration.

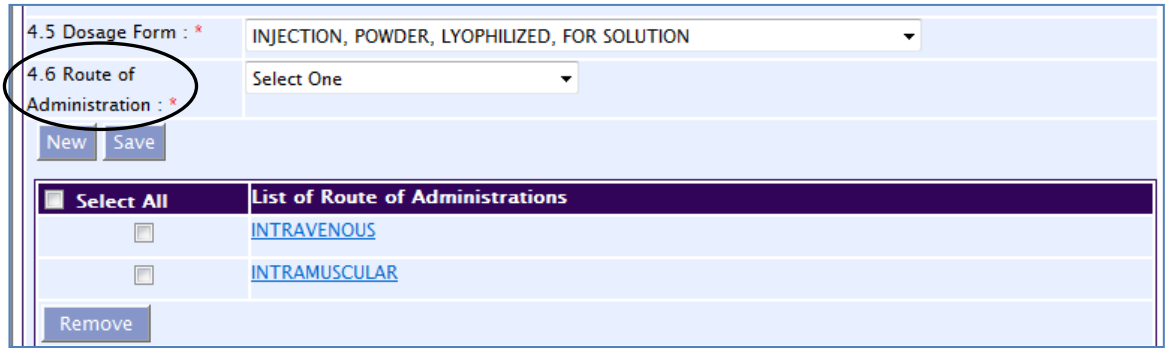
In certain cases, the dosage form may also include information about the container closure system, e.g. pre-filled syringe, spray pump and pressurised container.

f) *Section 4.6 – Route of Administration*

Screenshots of PRISM section 4.6 is given below:

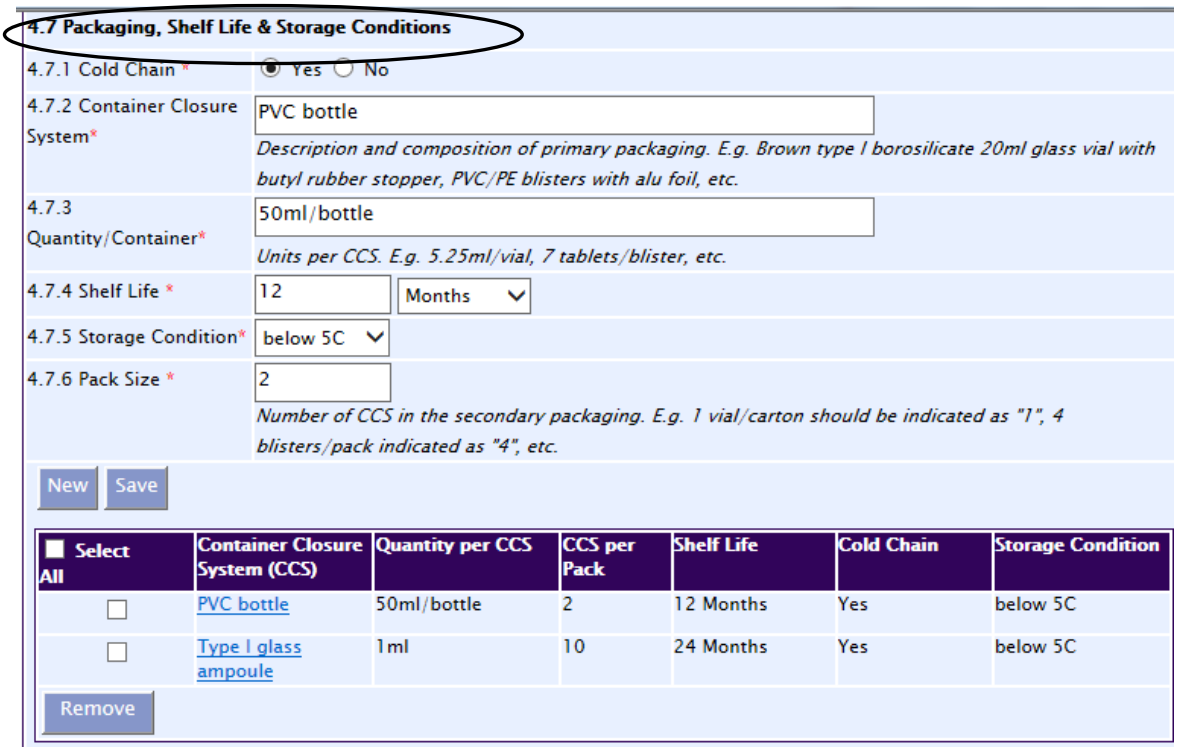


Include all routes of administration proposed for the product.



Please note that after the application is approved, this field can only be amended via the submission of a MAV-1 application.

g) *Section 4.7 – Packaging, Shelf Life and Storage Conditions*



Section 4.7.1 – 'Cold Chain'

This section refers to the storage condition (cold chain: Yes/No) for each of the Container Closure System (CCS) for this product. Cold chain products are defined as products which are registered with the requirement of cold chain management. It usually refers to products which are required to be stored at 2 - 8°C or below.

Section 4.7.2 – '*Container Closure System (CCS)*'

This section refers to the container immediately enclosing the dosage form. Information should be specific, including the type of material(s) used, colour, size, etc. For example, '*Type I 1mL amber glass vial*' and '*Transparent PVC/PVdC blister with Alu foil*' should be entered instead of '*Amber glass vial*' and '*PVC/PVdC blister*', respectively.

If a medical device (e.g. vial adaptor, syringe and needle) is packed together with the drug product, applicants should include information of the medical device and its description, as appropriate, as a single entry with the drug product.

Section 4.7.3 – '*Quantity per CCS*'

This section refers to the quantity/amount of the dosage form per container closure system. For example, '*10 tablets/blister*', '*5ml/vial*' and '*15g/tube*' may be entered.

Section 4.7.4 – '*Shelf Life*'

This section refers to the proposed shelf life of the drug product, which should be supported by stability data. If there is more than one component in a drug product (e.g. powder for injection and diluent as a composite pack) and each component has a different shelf life, the shorter shelf life is to be used as the shelf life of the composite pack. HSA reserves the right to amend the proposed shelf life after review of the stability data submitted in the dossier.

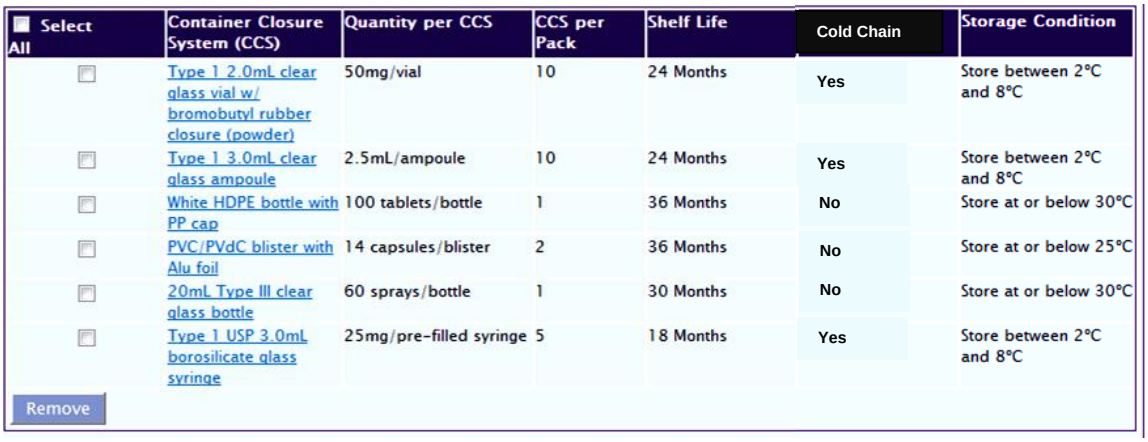
Section 4.7.5 – '*Storage Condition*'

This section refers to the proposed storage condition of the drug product which should be supported by stability data. HSA reserves the right to amend the proposed storage condition after review of the stability data submitted in the dossier.

Section 4.7.6 – '*CCS per Pack Size*'

This section refers to the number of container closure systems in each commercial pack of the product. For example, for a box of 50 tablets packed as 5 blister strips of 10 tablets in each strip, the Pack Size should be entered as '*5*'. All pack sizes should be included.

A screenshot with PRISM section 4.7 entries is shown below:



Select All	Container Closure System (CCS)	Quantity per CCS	CCS per Pack	Shelf Life	Cold Chain	Storage Condition
☐	Type 1 2.0mL clear glass vial w/ bromobutyl rubber closure (powder)	50mg/vial	10	24 Months	Yes	Store between 2°C and 8°C
☐	Type 1 3.0mL clear glass ampoule	2.5mL/ampoule	10	24 Months	Yes	Store between 2°C and 8°C
☐	White HDPE bottle with PP cap	100 tablets/bottle	1	36 Months	No	Store at or below 30°C
☐	PVC/PVdC blister with Alu foil	14 capsules/blister	2	36 Months	No	Store at or below 25°C
☐	20mL Type III clear glass bottle	60 sprays/bottle	1	30 Months	No	Store at or below 30°C
☐	Type 1 USP 3.0mL borosilicate glass syringe	25mg/pre-filled syringe	5	18 Months	Yes	Store between 2°C and 8°C

Remove

NOTE: Click '*Save*' after each complete CCS entry. Thereafter, to enter a new CCS, click '*New*' first.

Furthermore, information on the shelf life after the first opening of the product (e.g. eye drops) and shelf life after reconstitution (e.g. lyophilised powder for reconstitution) should be provided and supported by stability data. The information should be inserted in PRISM sections 4.7.6 and 4.7.7, respectively:

h) *Section 4.8 – Forensic Classification*

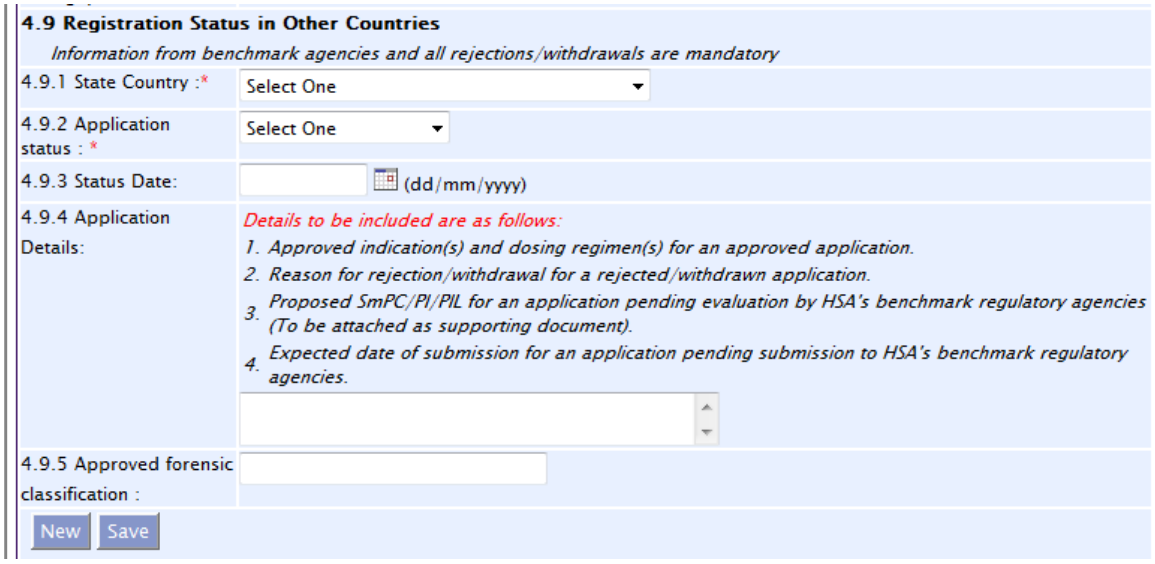
State the forensic classification proposed for the drug product in Singapore.

HSA reserves the right to approve the product under a different forensic classification, if deemed appropriate.

Please note that after the application is approved, this field can only be amended via the submission of a MAV-2 application.

i) *Section 4.9 – Registration Status in Other Countries*

Applicants are required to provide information on the registration status of the application in other countries at the time of submission. A screenshot of PRISM section 4.9 is given:



For each country, the applicant must state the application status, status date and forensic classification (if applicable). For all HSA's reference agencies, the applicant must state the application status, status date, application details and forensic classification. This is described in Table 13.

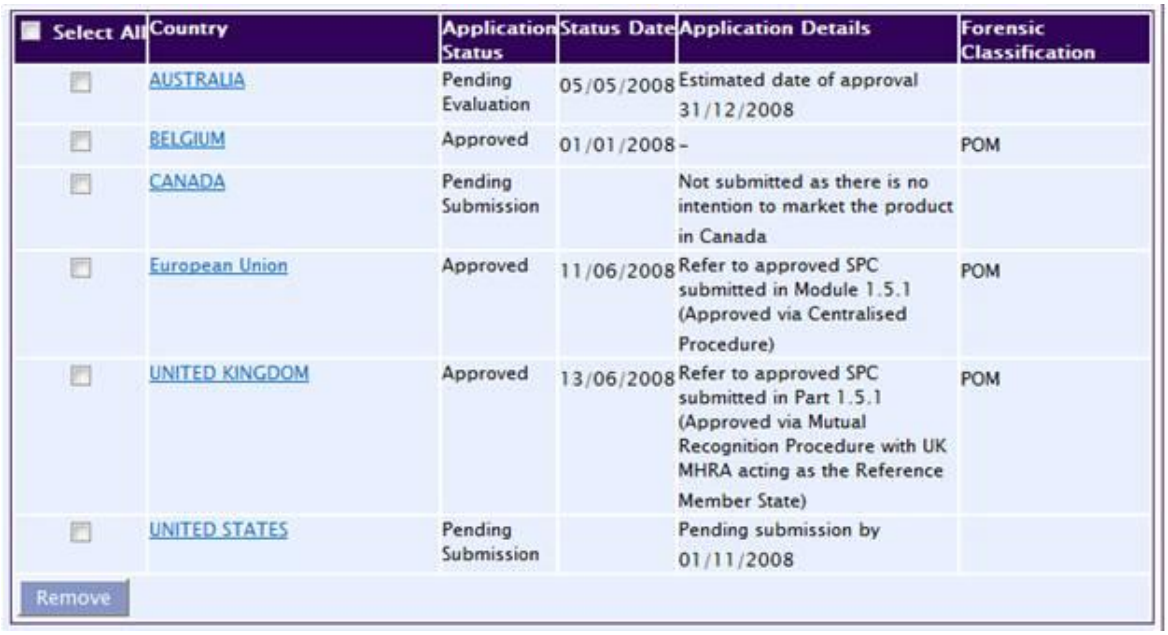
Table 13. Registration Status of Drug Product in Other Countries.

Country	**Application Status**	**Status Date**	**Application Details[#]**	**POM/P/GSL**
For all countries	APPROVED	State the approval date	–	POM/P/GSL
	REJECTION or WITHDRAWAL	State the date of rejection/withdrawal	State the reason(s)	–
	DEFERRAL e.g. non-approvable, approvable, conditional approval, conditional marketing authorization, etc.	State the date of deferment	State the reason(s)	–
For HSA's reference agencies (if applicable)	PENDING EVALUATION	State the submission date	State the expected regulatory decision date, if applicable	POM/P/GSL
	PENDING SUBMISSION	–	State the expected submission date or reason(s) for not registering	POM/P/GSL

[#] For approved indication(s) and dosing regimen(s) for an approved application, you can make reference to the approved PI of the reference agency instead of typing out the information under Application Details.

For products approved via an appeal process, following either a negative opinion/rejection/non-approvable decision or an approvable/conditional approvable decision, the applicant must provide reasons for the initial regulatory decision along with the subsequent approval.

The following screenshot displays some entries into PRISM section 4.9:



Select All	Country	Application Status	Status Date	Application Details	Forensic Classification
	AUSTRALIA	Pending Evaluation	05/05/2008	Estimated date of approval 31/12/2008	
	BELGIUM	Approved	01/01/2008	-	POM
	CANADA	Pending Submission		Not submitted as there is no intention to market the product in Canada	
	European Union	Approved	11/06/2008	Refer to approved SPC submitted in Module 1.5.1 (Approved via Centralised Procedure)	POM
	UNITED KINGDOM	Approved	13/06/2008	Refer to approved SPC submitted in Part 1.5.1 (Approved via Mutual Recognition Procedure with UK MHRA acting as the Reference Member State)	POM
	UNITED STATES	Pending Submission		Pending submission by 01/11/2008	

Remove

For applications submitted or approved by:

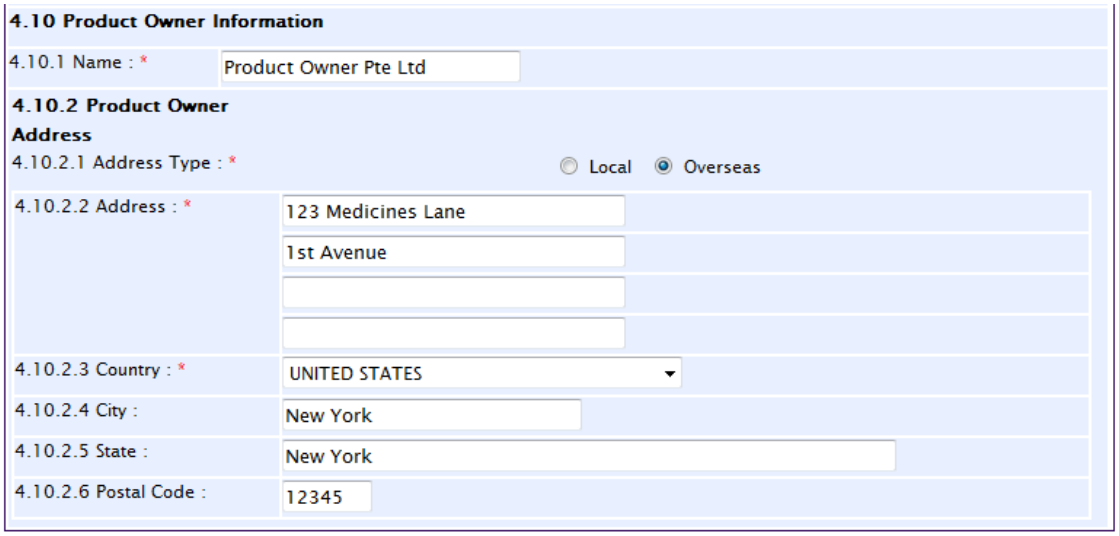
- Individual countries:
  i. Select the name of the country under *4.9.1 State Country*; and
  ii. For approval in EU Countries via the national procedure, state "*National procedure*" under *4.9.4 Application Details*.
- European Union:
  i. Select "*European Union*" under *4.9.1 State Country* and specify the type of application submitted to the agencies (Centralised, Decentralised or Mutual Recognition Procedure) under *4.9.4 Application Details*; and/or
  ii. For applications approved via Decentralised or Mutual Recognition Procedure, either state "*All EU countries*" or list the EU countries which participated in the procedure under *4.9.4. Application Details*; and
  iii. For applications approved via Decentralised or Mutual Recognition Procedure, state the EU country which acted as the Reference Member

State (RMS) and Concerned Member State (CMS) under *4.9.4 Application Details*.

The applicant is required to update HSA on the registration status of any pending applications in other countries while the application is under evaluation by HSA. The applicant shall inform HSA of any rejection, withdrawal or deferral of any application and provide details of the reason(s) once it becomes known.

In the event that the PRISM text space does not allow the input of the full details of the indication(s), dosing regimen(s), and/or reason(s), a brief description may be entered. The full details should be attached in softcopy (PDF) in PRISM section 7 (Supporting Attachments). The document should be in the format as seen in Table 8 of the main guidance.

j) *Section 4.10 – Product Owner Information*



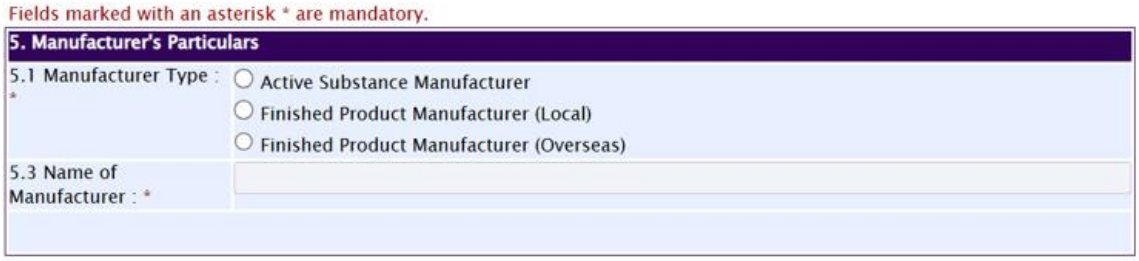
Input the full name and address of the legally registered owner of the product formulation, i.e. the drug product.

1.1.5 Section 5 – Manufacturer Particulars

All manufacturers involved in the manufacture of the product for supply in Singapore must be stated in the PRISM application form.

Information to be entered include:

- Manufacturer type;
- Manufacturer's name;
- Manufacturing operation (for Finished Product Manufacturer);
- Manufacturer's address.


Fields marked with an asterisk * are mandatory.

5. Manufacturer's Particulars

5.1 Manufacturer Type : *	○ Active Substance Manufacturer ○ Finished Product Manufacturer (Local) ○ Finished Product Manufacturer (Overseas)
5.3 Name of Manufacturer : *	

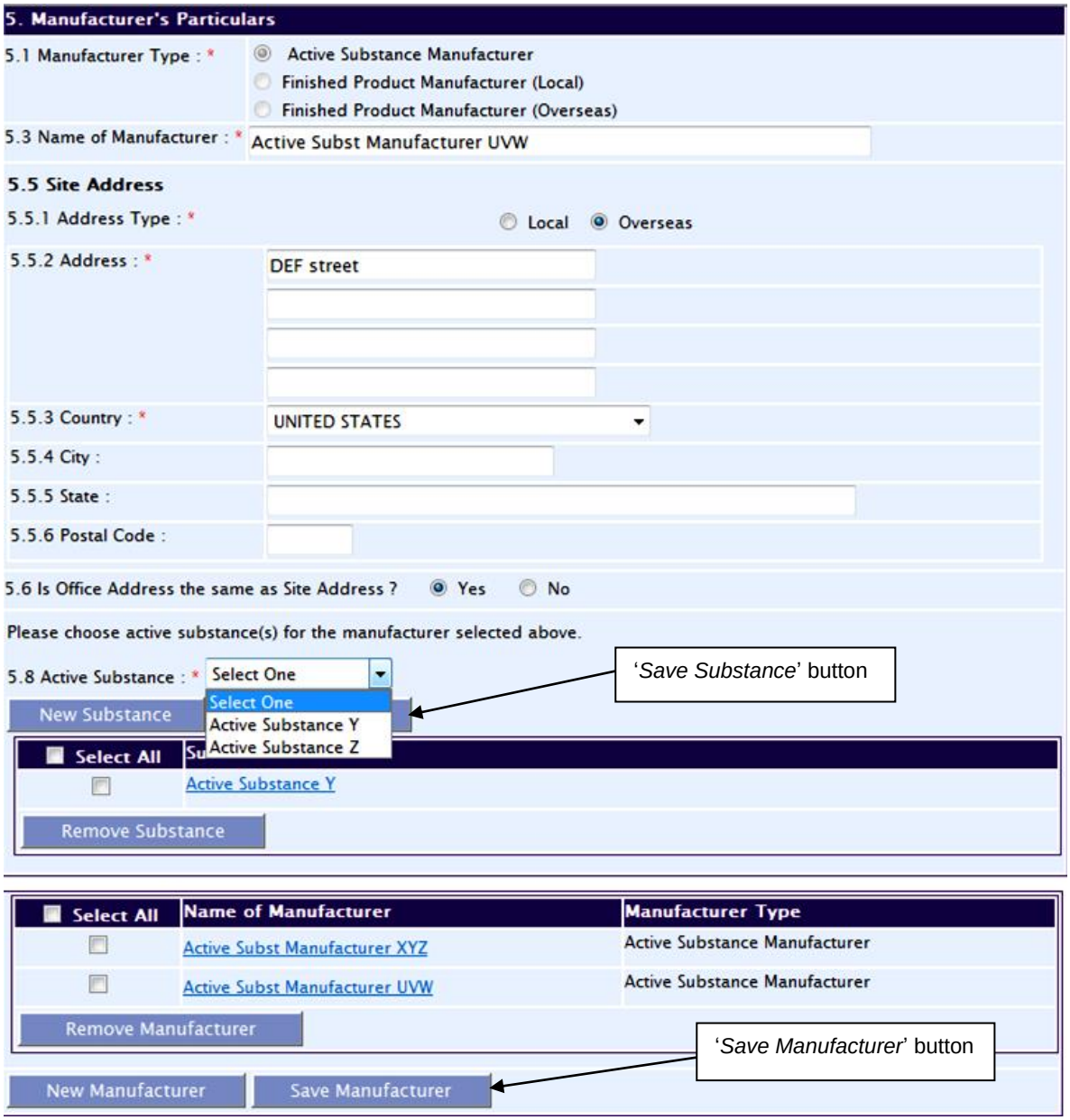
NOTE: ALL Manufacturers' names and addresses should be consistent throughout all of the documents submitted in the application, i.e. CPP's, GMP certificates, Letters of Authorisation, Module 3/Part II of the CTD and so forth.

a) *Active Substance Manufacturer*

Sites that carry out critical parts of the drug substance manufacturing process should be captured in PRISM, these include but not limited to sites which purify, crystallise or micronise the drug substance or which produce the crude drug substance.

When entering the details of the Active Substance Manufacturer, select the active substance(s) that is manufactured by that particular manufacturer from the drop-down list in section 5.8 of the PRISM application form. After selecting the Active Substance, click the '*Save Substance*' button; this may be repeated for other substances if the Manufacturer produces multiple substances for the drug product.

Once complete, click the '*Save Manufacturer*' button to save the entire section for that Active Substance Manufacturer:

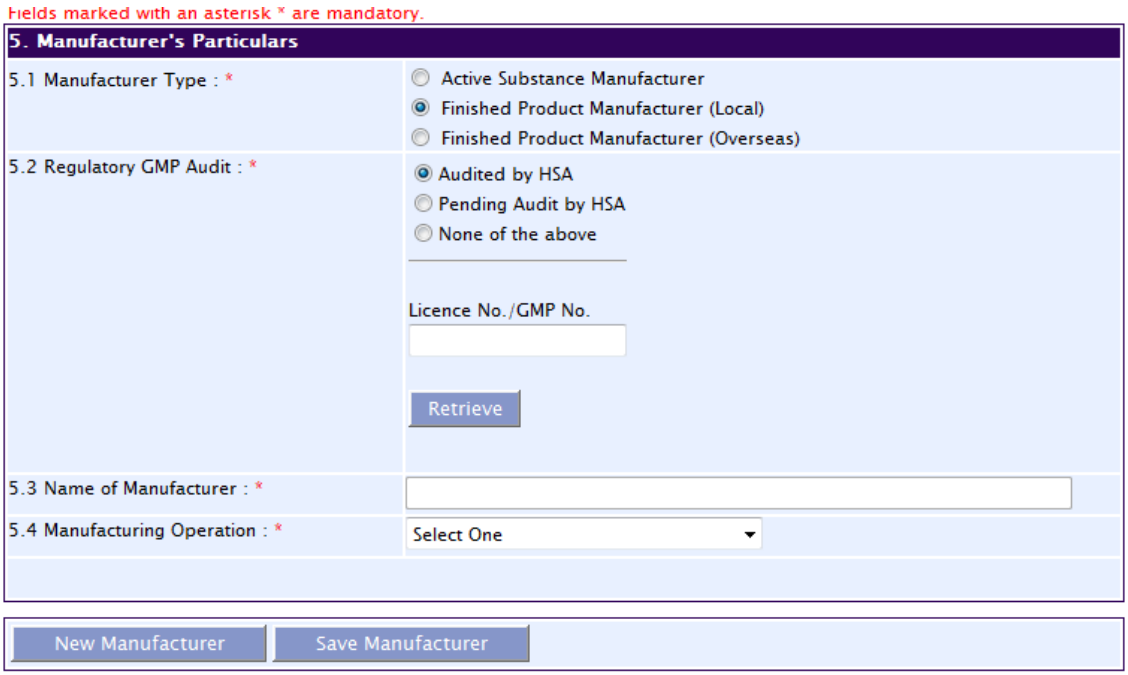


b) *Finished Product Manufacturer*

The Finished Product Manufacturer can be either a local manufacturing site in Singapore, or an overseas manufacturer. Multiple local and/or overseas manufacturing sites can be entered for each product application.

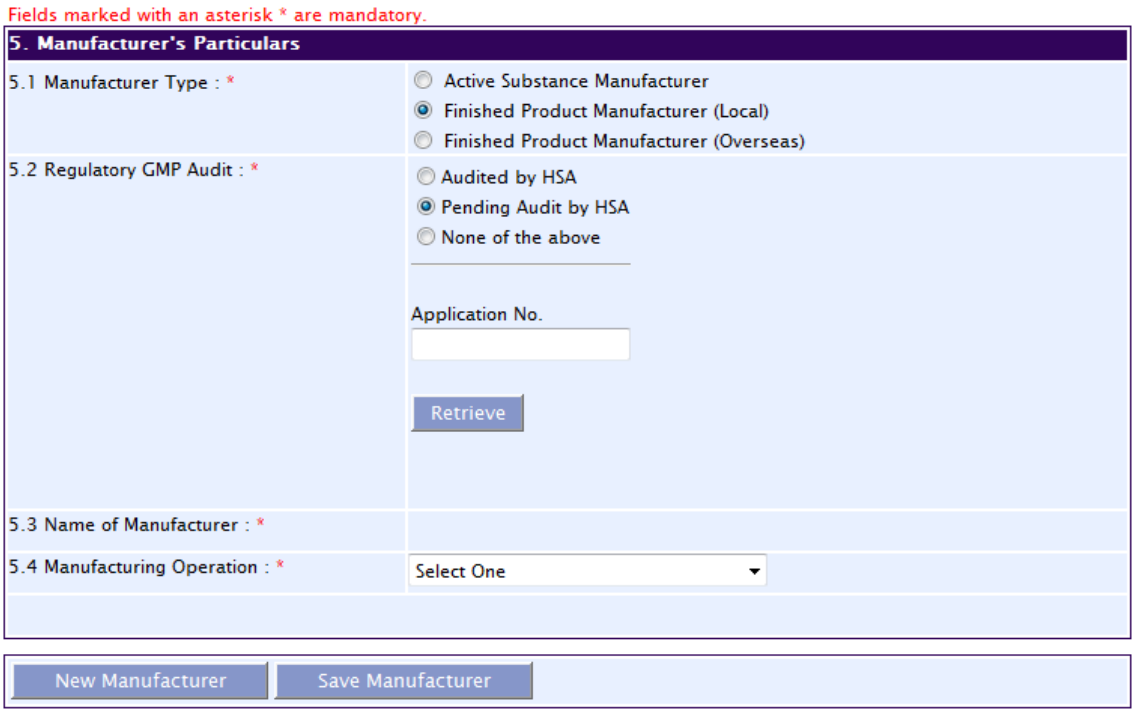
(i) Local Finished Product Manufacturer

For a local finished product manufacturer that had been audited by HSA, enter the HSA issued **Manufacturer's Licence No**. in the field provided and click on the "Retrieve" button. The manufacturer's name should be auto-populated if the Manufacturer's Licence No. entered is correct and valid.



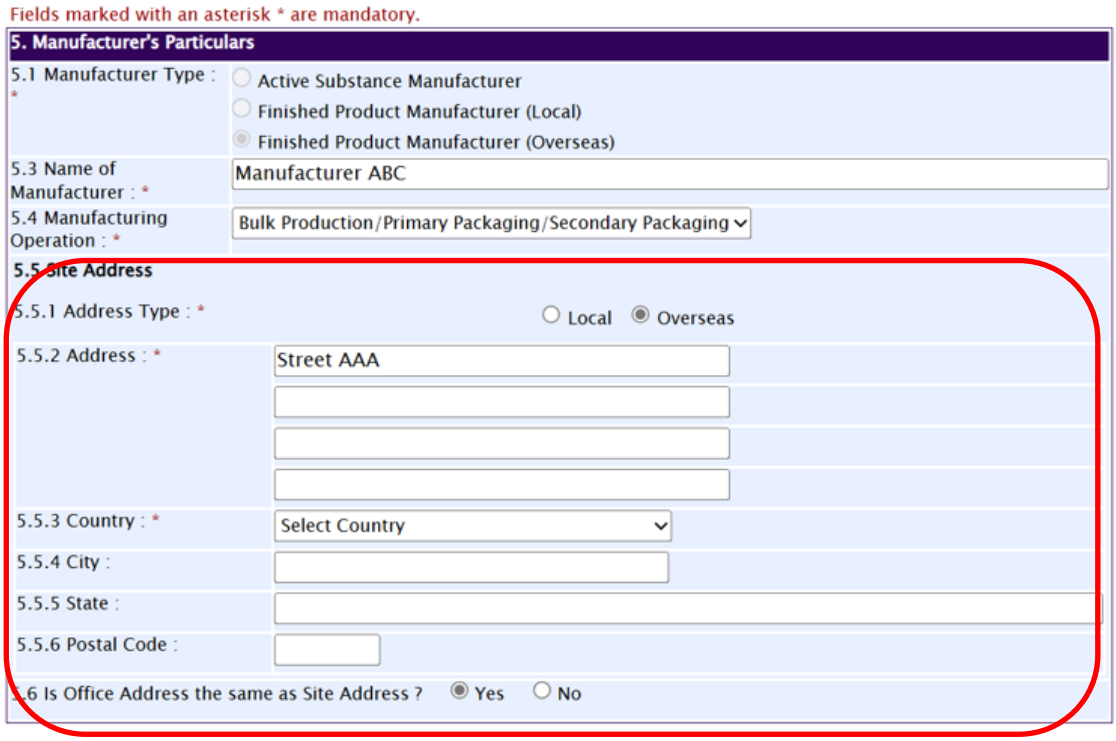
NOTE: Do not enter the local GMP Certificate No./ GMP Certificate Application No. instead of the Manufacturer's Licence No./Manufacturer Licence Application No.

For a local finished product manufacturer that is pending audit by HSA, enter the Manufacturer's Licence Application No. in the field provided and click on the "Retrieve" button. The manufacturer's name will be auto-populated if the Manufacturer's Licence Application No. entered is correct and valid. It should be noted that the Manufacturer's Licence application has to be approved before the product registration or variation application can be approved.

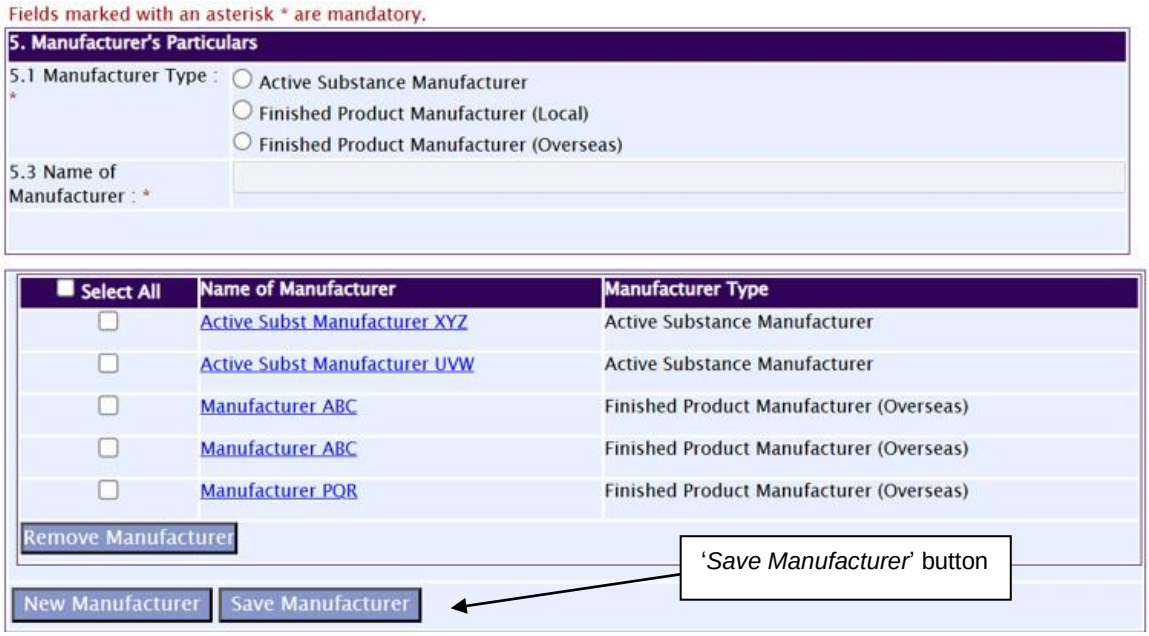


(ii) Overseas Finished Product Manufacturer

For an overseas finished product manufacturer, enter both the manufacturing site and office (i.e. headquarters) address.



After entering the details of each Finished Product Manufacturer, click the '*Save Manufacturer*' button to save the entire section for that Finished Product Manufacturer:



For both local and overseas finished product manufacturer, manufacturers performing the following manufacturing operations (manufacturing activities) are to be entered in the application form:

- Bulk Production
- Primary Packaging
- Secondary Packaging
- Bulk Production (Solvent/Diluent)
- Bulk Production (Drug Product Intermediate)
- Quality Control Testing

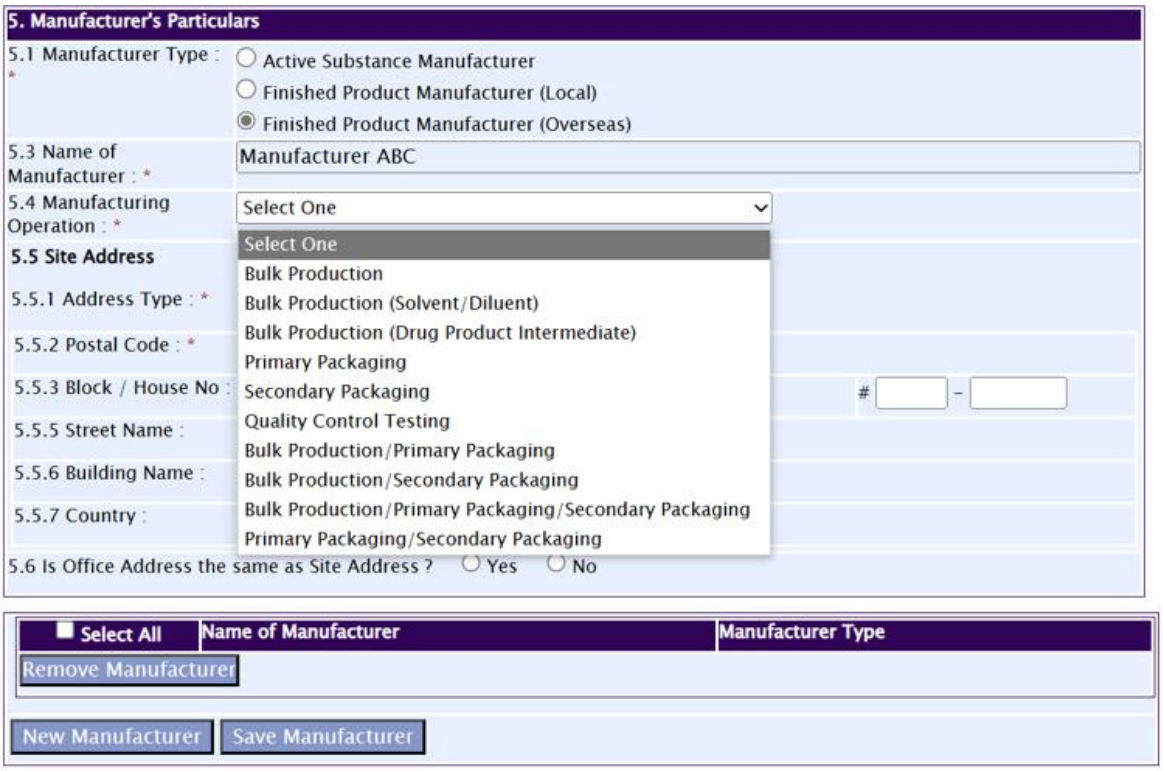
Definitions of the different manufacturing operations are as follows:

Manufacturing Operation	**Definition**	**Examples of Activities**
Bulk Production	Any or all processing steps carried out in the course of making the bulk drug product.	• Production of tablets packaged in interim bulk

		packaging, e.g. LDPE bags.
Bulk Production (Solvent/Diluent)	Any or all processing steps carried out in the course of making the solvent/diluent.	• Production of solvent or diluent filled in bulk packaging, and/or in the final packaging, e.g. glass vials or glass ampoules.
Bulk Production (Drug Product Intermediate)*	Any or all processing steps carried out in the course of making the drug product intermediate	• Production of granules packaged in interim bulk packaging, e.g. LDPE bags.
Primary Packaging	Placing and sealing of the drug product within the finished product packaging material, which is in direct contact with the drug product.	• Packaging of tablets in blister packs or unlabelled bottles.
Secondary Packaging	Labelling or enclosing of the drug product, which is already sealed within its primary packaging material, with an outer packaging material.	• Packaging of tablets in blister packs with desiccant in an overpouch. • Labelling of vials and/or enclosing labelled vial in an outer carton. • Local redressing (e.g. stickering of colour labels for better product differentiation).
Quality Control Testing	Testing of drug product samples against the release specifications in CTD P.5.1.	

*: This is only applicable to sites that do not perform the main bulk production manufacturing activity for the product.

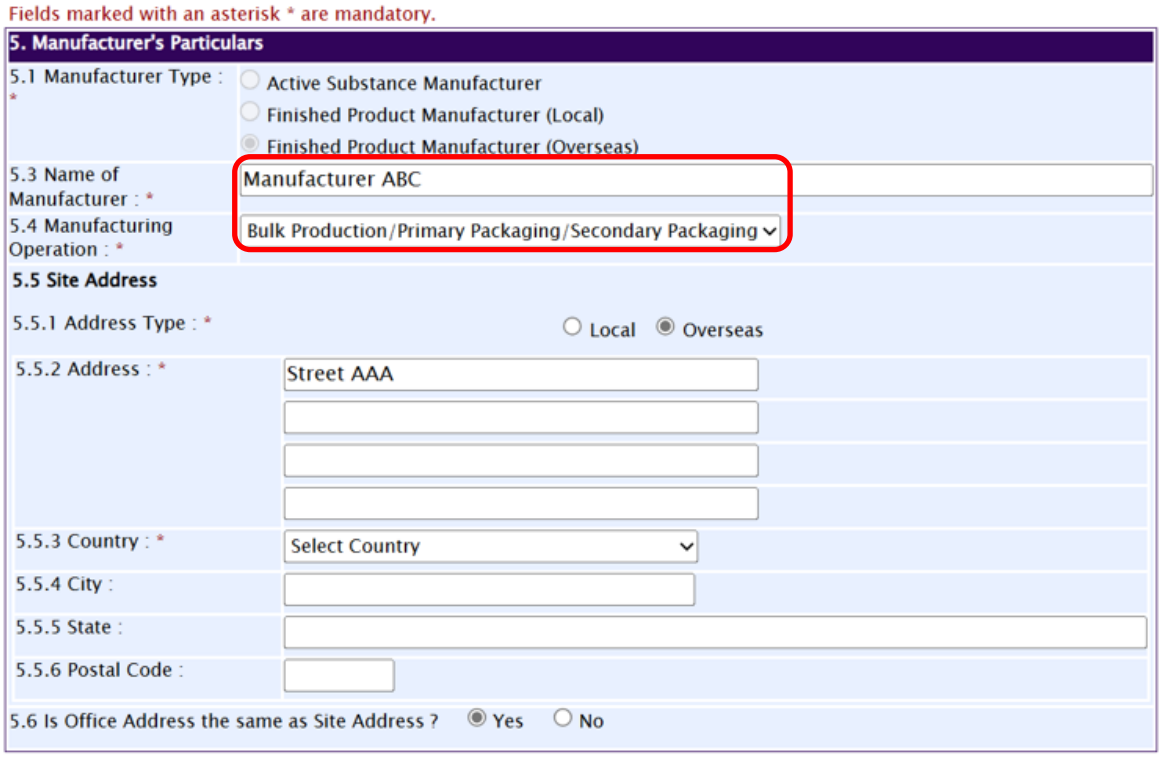
Select one of the following options from the manufacturing operation dropdown list for each manufacturer:



Manufacturing sites performing multiple manufacturing operations such as "Bulk Production", "Primary Packaging" and "Secondary Packaging" will only need to be entered once in Section 5 of the application form, with one of the following manufacturing operations combinations selected:

- Bulk Production/Primary Packaging
- Bulk Production/Secondary Packaging
- Bulk Production/ Primary Packaging/Secondary Packaging
- Primary Packaging/Secondary Packaging

Example 11. Manufacturer ABC performs bulk production, primary packaging and secondary packaging activities.

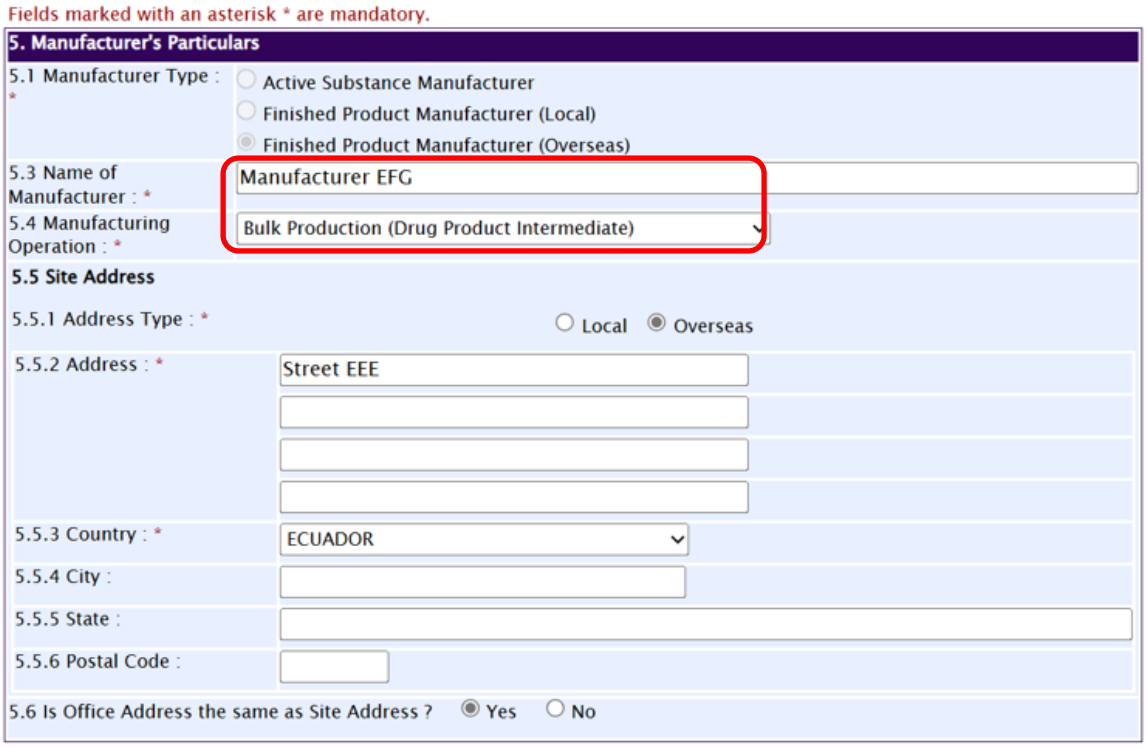


The following tabulation provides some examples of multiple manufacturing operations involving bulk production, primary and/or secondary packaging activities:

Manufacturing Operation	**Examples of activities**
Bulk Production / Primary Packaging	• Production of tablets packaged in blister packs or unlabelled bottles. • Production of vials without labelling.
Bulk Production / Primary Packaging / Secondary Packaging	• Production of tablets packaged in blister packs or labelled bottles and enclosing in an outer carton. • Production of vials with labelling. • Production of vials with labelling and enclosing in an outer carton.

For manufacturing sites that only perform "Bulk Production (Drug Product Intermediate)" and are not involved in the main bulk production of the finished product, the sites should be entered in the PRISM application form as shown in Example 12.

Example 12. Manufacturer EFG only manufactures the drug product intermediate. This manufacturer is not involved in the main bulk production of the finished product.



Manufacturing sites performing "Bulk Production" and "Bulk Production (Solvent/Diluents)" are to be **entered separately** in the PRISM application form, each with the respective manufacturing operation selected as shown in Example 13.

Example 13. Manufacturer JKL performs bulk production as well as manufactures the diluent for the finished product. Hence the site is entered twice in the application form, with "Bulk Production" selected as the first entry, and "Bulk Production (Solvent/Diluent)" selected for the second entry:

Fields marked with an asterisk * are mandatory.

5. Manufacturer's Particulars

5.1 Manufacturer Type : *
- Active Substance Manufacturer
- Finished Product Manufacturer (Local)
- Finished Product Manufacturer (Overseas)

5.3 Name of Manufacturer : * Manufacturer JKL

5.4 Manufacturing Operation : * Bulk Production

5.5 Site Address

5.5.1 Address Type : * Local / Overseas

5.5.2 Address : * Street JJJ

5.5.3 Country : * Select Country

5.5.4 City :

5.5.5 State :

5.5.6 Postal Code :

5.6 Is Office Address the same as Site Address ? Yes / No

Fields marked with an asterisk * are mandatory.

5. Manufacturer's Particulars

5.1 Manufacturer Type : *
- Active Substance Manufacturer
- Finished Product Manufacturer (Local)
- Finished Product Manufacturer (Overseas)

5.3 Name of Manufacturer : * Manufacturer JKL

5.4 Manufacturing Operation : * Bulk Production (Solvent/Diluent)

5.5 Site Address

5.5.1 Address Type : * Local / Overseas

5.5.2 Address : * Street JJJ

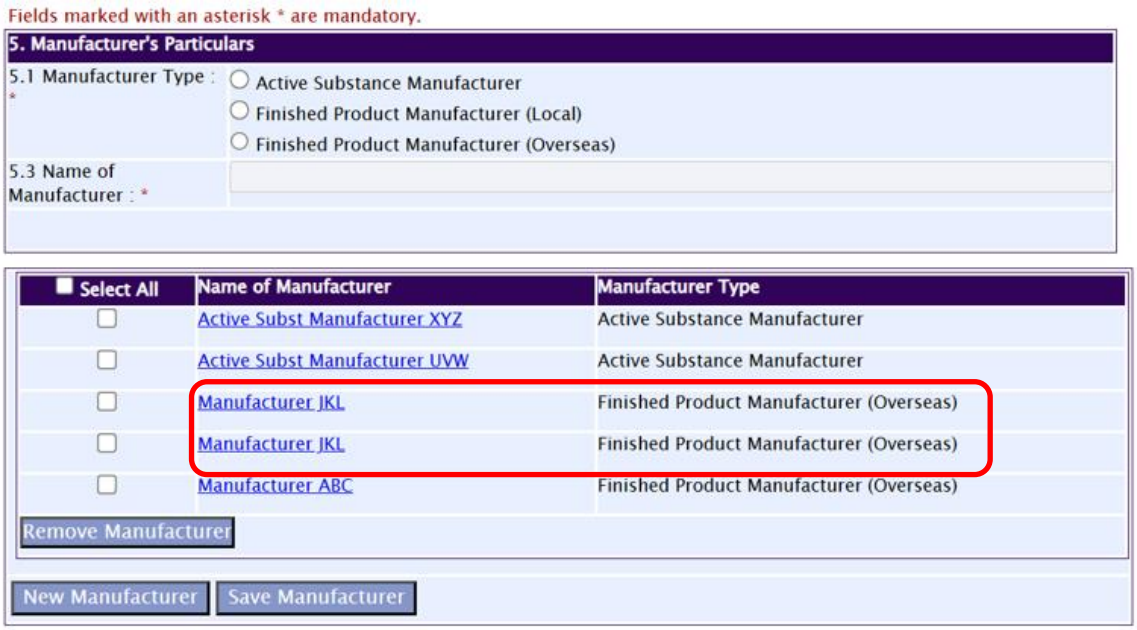
5.5.3 Country : * Select Country

5.5.4 City :

5.5.5 State :

5.5.6 Postal Code :

5.6 Is Office Address the same as Site Address ? Yes / No



Manufacturing sites performing “Bulk Production” and “Quality Control Testing” are to be **entered separately** in the PRISM application form, each with the respective manufacturing operation selected as shown in Example 14.

Example 14. Manufacturer MNO performs bulk production as well as quality control testing for the finished product. Hence the site is entered twice in the application form, with “Bulk Production” selected the first entry, and “Quality Control Testing” selected for the second entry:

Fields marked with an asterisk * are mandatory.

5. Manufacturer's Particulars

5.1 Manufacturer Type : *
- ○ Active Substance Manufacturer
- ○ Finished Product Manufacturer (Local)
- ◉ Finished Product Manufacturer (Overseas)

5.3 Name of Manufacturer : * Manufacturer MNO

5.4 Manufacturing Operation : * Bulk Production

5.5 Site Address

5.5.1 Address Type : * ○ Local ◉ Overseas

5.5.2 Address : * Street MMM

5.5.3 Country : * Select Country

5.5.4 City :

5.5.5 State :

5.5.6 Postal Code :

5.6 Is Office Address the same as Site Address ? ◉ Yes ○ No

Fields marked with an asterisk * are mandatory.

5. Manufacturer's Particulars

5.1 Manufacturer Type : *
- ○ Active Substance Manufacturer
- ○ Finished Product Manufacturer (Local)
- ◉ Finished Product Manufacturer (Overseas)

5.3 Name of Manufacturer : * Manufacturer MNO

5.4 Manufacturing Operation : * Quality Control Testing

5.5 Site Address

5.5.1 Address Type : * ○ Local ◉ Overseas

5.5.2 Address : * Street MMM

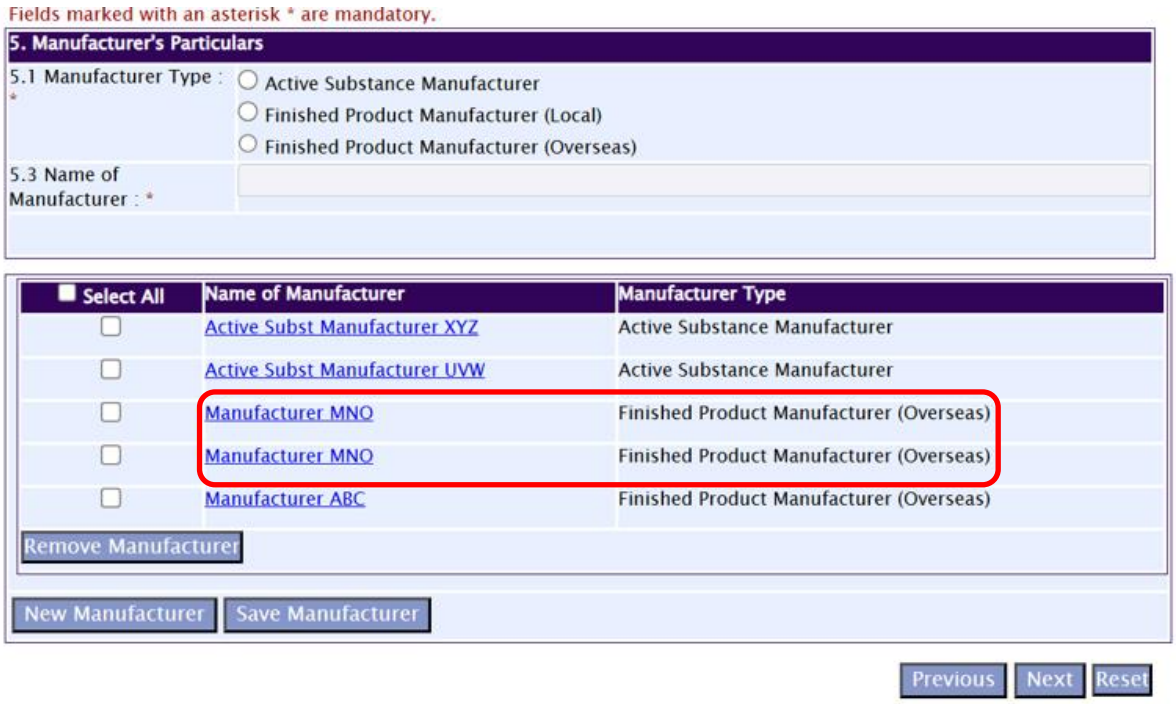
5.5.3 Country : * Select Country

5.5.4 City :

5.5.5 State :

5.5.6 Postal Code :

5.6 Is Office Address the same as Site Address ? ◉ Yes ○ No



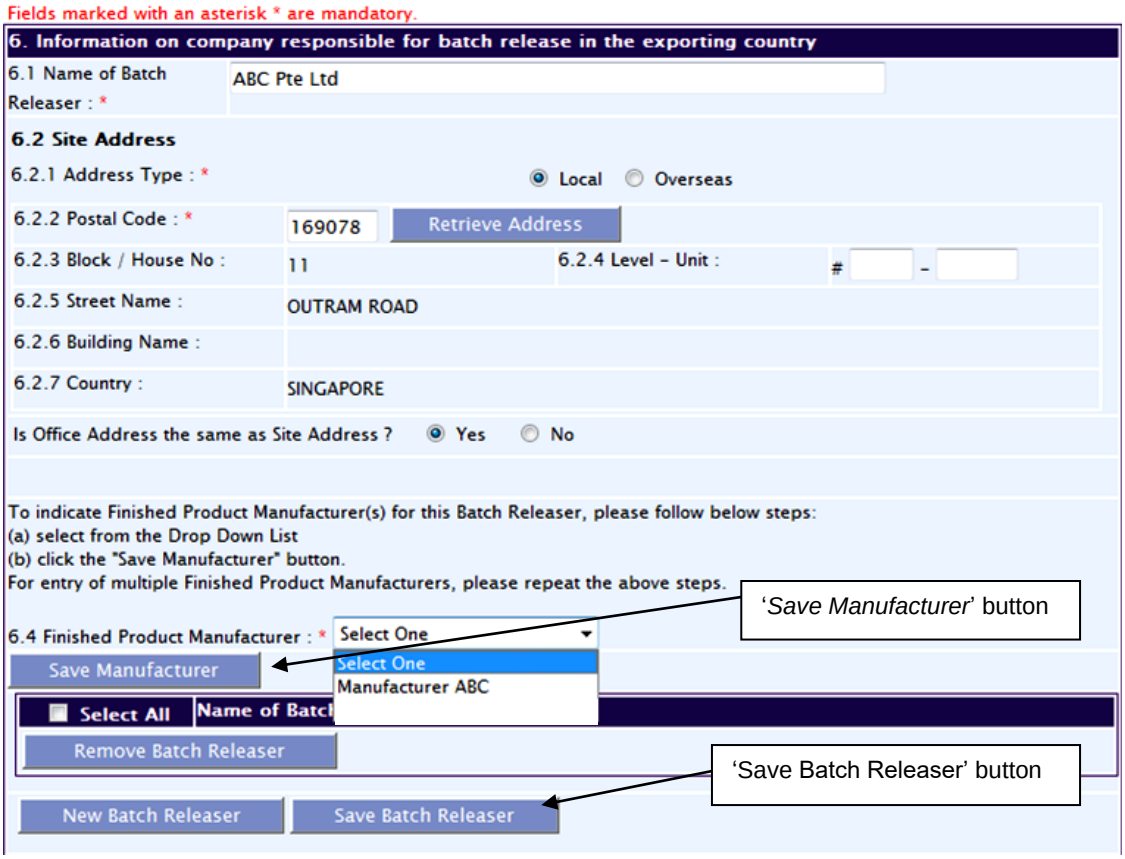
Additional points to note:

- For sites (different from the proposed bulk production site) that perform activities such as contract sterilisation, enter "(Contract steriliser)" after the name of the site;
- For sites which only purify, crystallise or micronise the drug substance or produce the crude drug substance, enter the activity e.g. "(micronisation)" after the name of the manufacturer.

1.1.6 Section 6 – Information on Company Responsible for Batch Release

Enter the name, site/plant address and office address of the company responsible for batch release of the drug product in the exporting country. The Finished Product Manufacturer(s), which the Batch Releaser is releasing the product from, must also be specified.

This screenshot is an example of an entry into PRISM section 6.

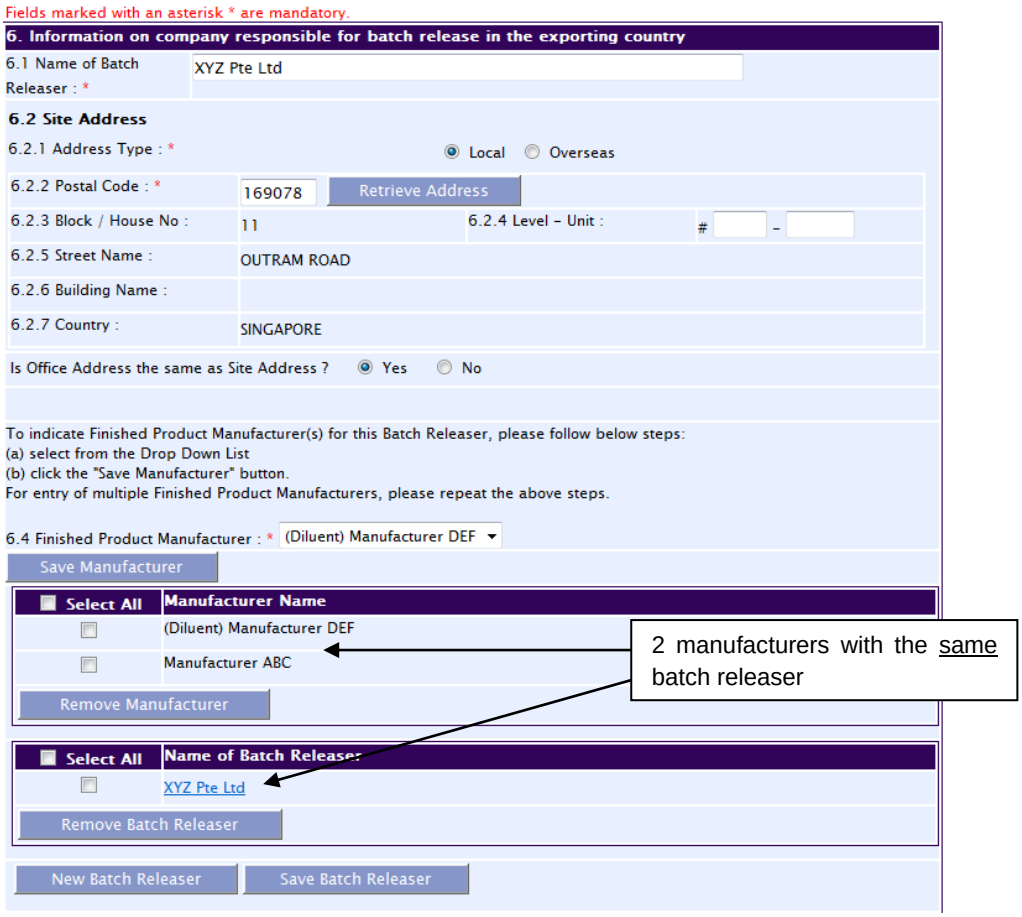


After selecting the Finished Product Manufacturer that this particular Batch Releaser is releasing the products from (PRISM section 6.4), click the '*Save Manufacturer*' button to save that manufacturer to that batch releaser.

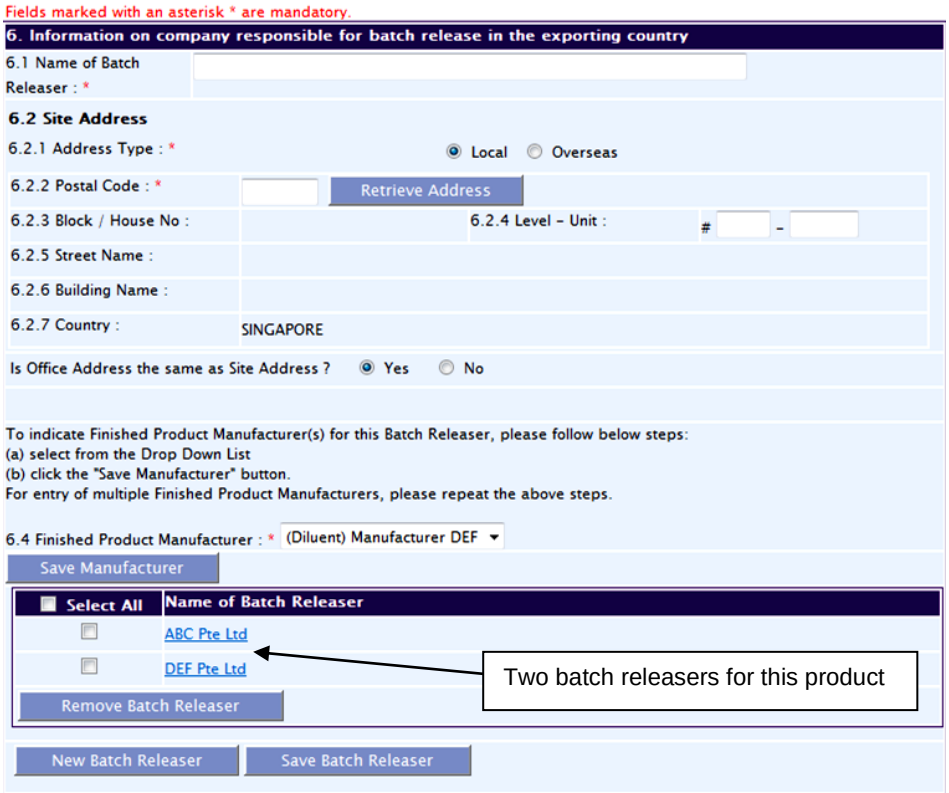
Click the '*Save Batch Releaser*' button to save the entire section for that Batch Releaser.

It is also possible to have one Batch Releaser releasing products from two finished product manufacturers as well as multiple Batch Releasers – see Examples 15 and 16:

Example 15. One Batch Releaser responsible for multiple Finished Product Manufacturers.


Fields marked with an asterisk * are mandatory.
6. Information on company responsible for batch release in the exporting country
6.1 Name of Batch Releaser : *
XYZ Pte Ltd
6.2 Site Address
6.2.1 Address Type : *
Local
Overseas
6.2.2 Postal Code : *
169078
Retrieve Address
6.2.3 Block / House No :
11
6.2.4 Level - Unit :
6.2.5 Street Name :
OUTRAM ROAD
6.2.6 Building Name :
6.2.7 Country :
SINGAPORE
Is Office Address the same as Site Address ?
Yes
No
To indicate Finished Product Manufacturer(s) for this Batch Releaser, please follow below steps:
(a) select from the Drop Down List
(b) click the "Save Manufacturer" button.
For entry of multiple Finished Product Manufacturers, please repeat the above steps.
6.4 Finished Product Manufacturer : *
(Diluent) Manufacturer DEF
Save Manufacturer
Select All
Manufacturer Name
(Diluent) Manufacturer DEF
Manufacturer ABC
Remove Manufacturer
Select All
Name of Batch Releaser
XYZ Pte Ltd
Remove Batch Releaser
New Batch Releaser
Save Batch Releaser
2 manufacturers with the same batch releaser

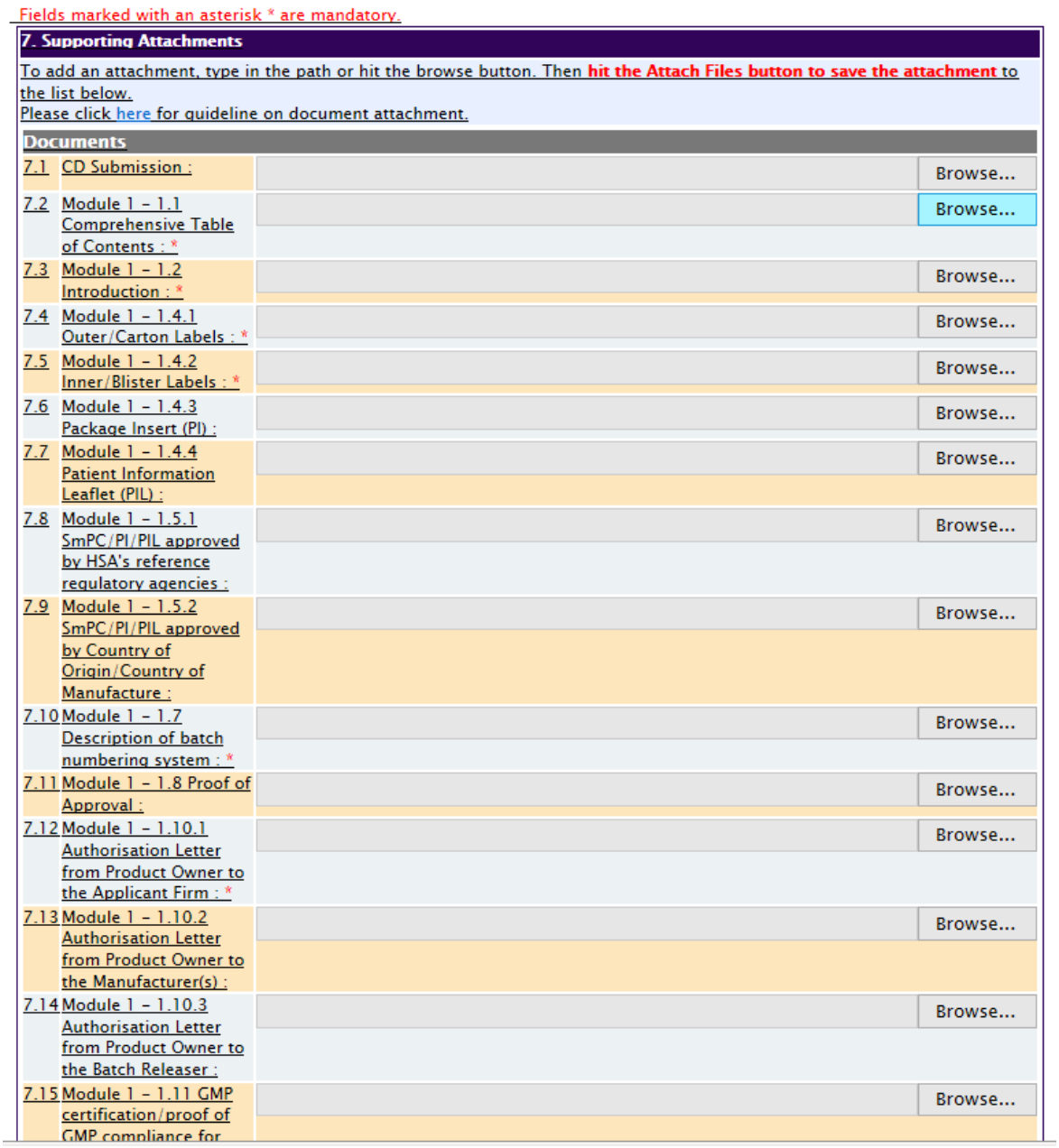
Example 16. Multiple Batch Releasers responsible for batch release of the final product.



1.1.7 Section 7 – Supporting Attachments

Before the online application can be completed, applicants must attach all documents relating to Module 1/Part I of the CTD into this PRISM section.

NOTE: Acceptance of the dossier for evaluation does not constitute acceptability of the data provided in the dossier. Acceptability of the data can only be determined during evaluation of the application.



Fields marked with an asterisk * are mandatory.

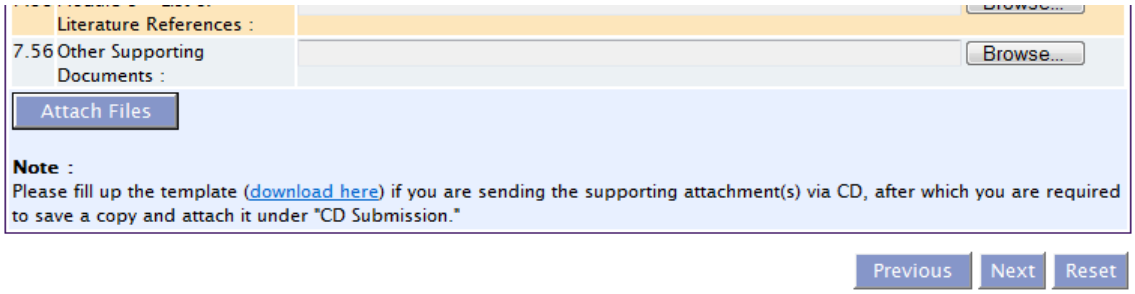
7. Supporting Attachments

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

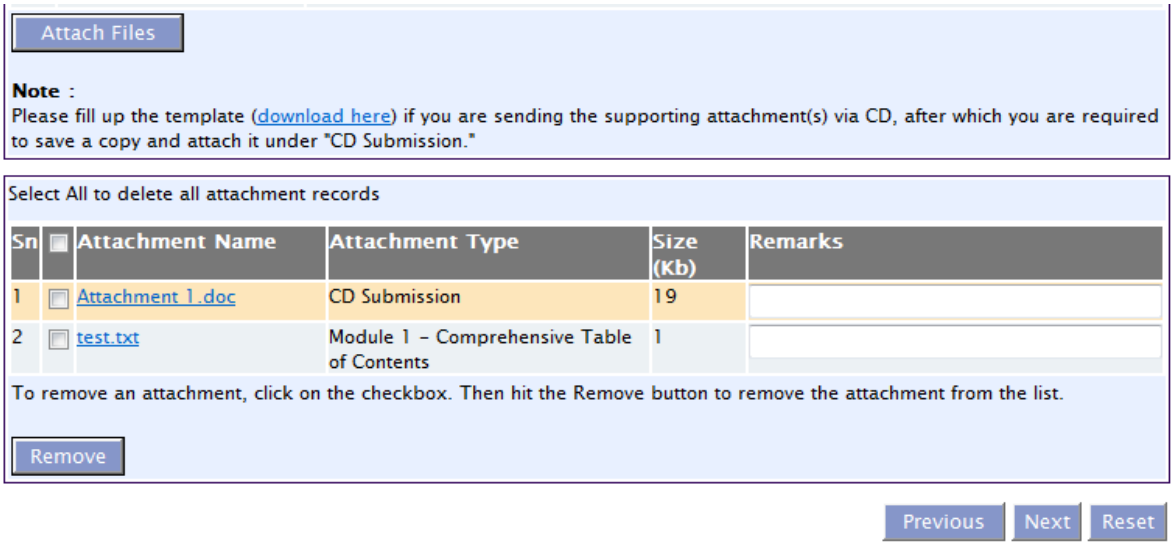
7.1	CD Submission :	Browse...
7.2	Module 1 – 1.1 Comprehensive Table of Contents : *	Browse...
7.3	Module 1 – 1.2 Introduction : *	Browse...
7.4	Module 1 – 1.4.1 Outer/Carton Labels : *	Browse...
7.5	Module 1 – 1.4.2 Inner/Blister Labels : *	Browse...
7.6	Module 1 – 1.4.3 Package Insert (PI) :	Browse...
7.7	Module 1 – 1.4.4 Patient Information Leaflet (PIL) :	Browse...
7.8	Module 1 – 1.5.1 SmPC/PI/PIL approved by HSA's reference regulatory agencies :	Browse...
7.9	Module 1 – 1.5.2 SmPC/PI/PIL approved by Country of Origin/Country of Manufacture :	Browse...
7.10	Module 1 – 1.7 Description of batch numbering system : *	Browse...
7.11	Module 1 – 1.8 Proof of Approval :	Browse...
7.12	Module 1 – 1.10.1 Authorisation Letter from Product Owner to the Applicant Firm : *	Browse...
7.13	Module 1 – 1.10.2 Authorisation Letter from Product Owner to the Manufacturer(s) :	Browse...
7.14	Module 1 – 1.10.3 Authorisation Letter from Product Owner to the Batch Releaser :	Browse...
7.15	Module 1 – 1.11 GMP certification/proof of GMP compliance for	Browse...

For the remaining Modules/Parts, if they are not attached in PRISM, applicant should upload a file for document 7.1 – *CD Submission*. This would render the rest of the online attachments non-mandatory in PRISM system. Applicants may wish to download a CD submission template document for attaching in 7.1.



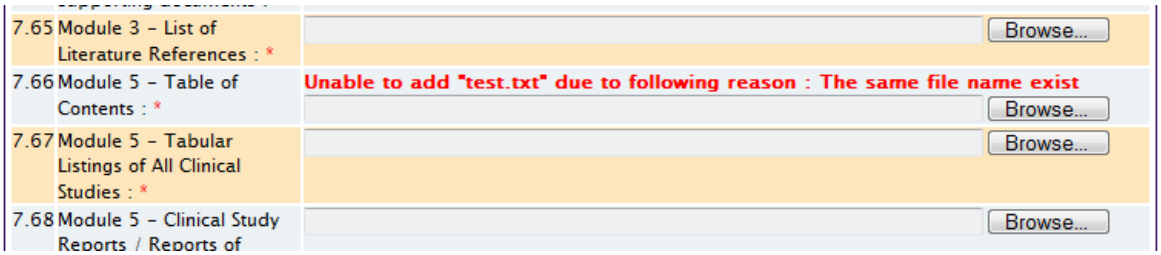
To add attachments:

1. Click on the “browse” button of the document section in which the document is to be attached (e.g. to attach the Table of Contents of the submission, click on the browse button under “Module 1 – Comprehensive Table of Contents”.
2. Select the document to be attached.
3. Click “Open”.
4. Scroll down and click “Attach Files”.
5. Verify that the document has been attached in the Attachment Records table, as illustrated below.



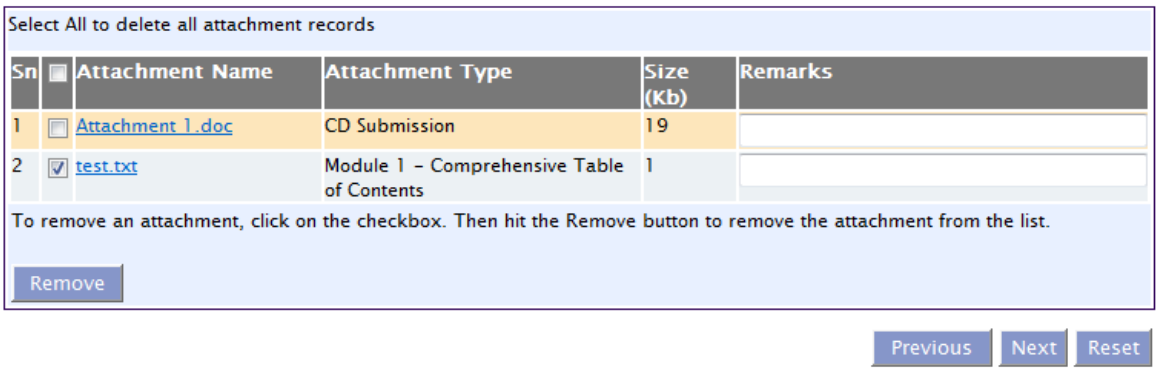
Tips:

- Only one document can be selected for attachment per document section at any one time.
- Multiple documents in different document sections can be attached at the same time.
- Files with the same filename cannot be attached in the same application more than once even if the files are to be attached in different document sections.



To delete attachments:

1. Select the document to be removed from the Attachment Records.
2. Click “Remove”.
3. Scroll down and click “Attach Files”.
4. Verify that the document has been removed from the Attachment Records table.



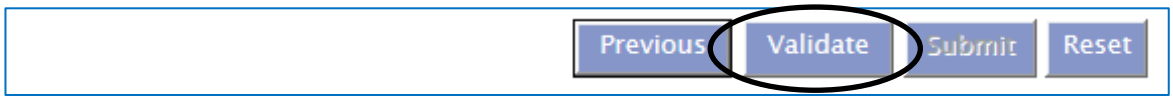
The following additional points should also be noted:

- Documents should be submitted in PDF format whenever possible;
- Do not combine documents if the content is unrelated – for example, do not submit a GMP certificate with Letters of Authorisation as a single PDF;
- Ensure that the documents are appropriately named to facilitate screening – more detail in the file name will help us to identify its contents;
- When scanning documents, applicants are advised not to break seals of authenticated documents as this will render them invalid;
- When attaching new documents in response to an Input Request, do not delete or override the existing documents in PRISM. Instead, attach them as new documents; and
- Documents attached and submitted in PRISM can only be removed when HSA sends a primary input request to the applicant.

1.1.8 Section 8 – Confirmation

Applicants should review the completed form to ensure that all entered details are accurate and complete.

Applicants may click scroll down to the bottom of the page and click the “Validate” button to check if all the mandatory fields had been filled up.



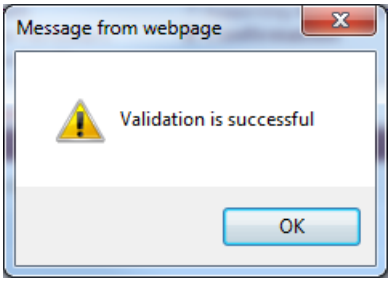
This is an example of an unsuccessful validation, indicating the fields which needed to be entered in order for the application to be submitted:

PZ0101 VALIDATION ERROR REPORT

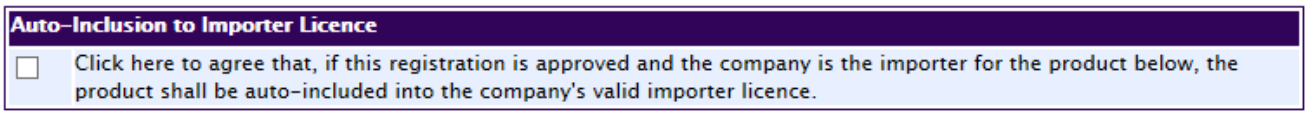
2. Applicant Particulars	
2.1	Name for applicant is mandatory
2.2	NRIC/FIN for applicant is mandatory
2.3	Designation for applicant is mandatory
2.4.1	Telephone number in applicant is mandatory
2.5.1	Preferred contact mode for applicant is mandatory

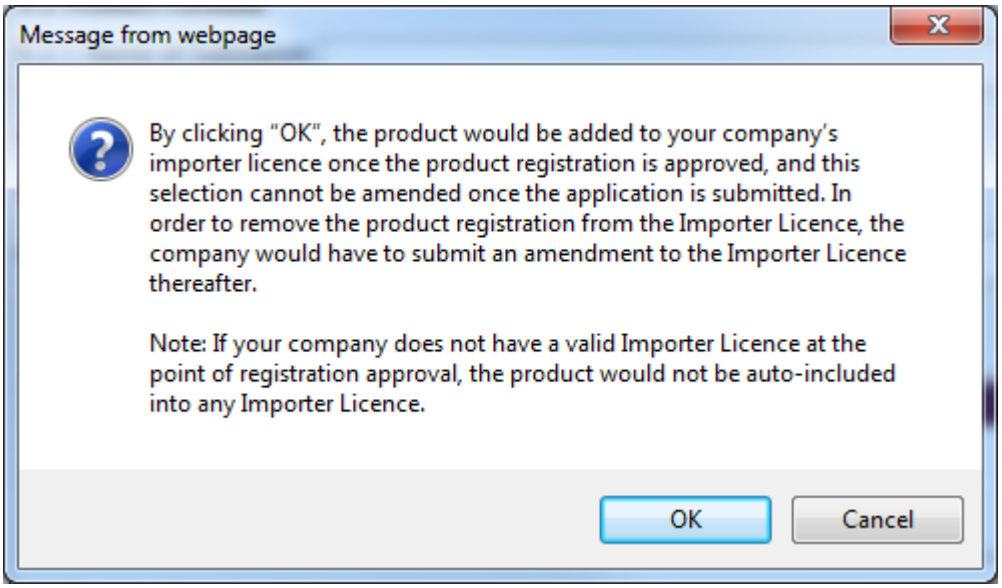
4. Product Information	
4.1	Propietary Name is mandatory
4.2	Please provide substance information of the product
4.3 (a)	Please indicate whether any part of the product is derived from human blood
4.3 (b)	Please indicate whether any part of the product or any raw materials used in the manufacturing process is derived from animal sources

This is an example of a successful validation:



Applicants can request for the product registration to be auto-included to their own Importer's Licence upon the approval of the product by clicking on the checkbox, followed by "OK" in the pop-up message box, as seen below:





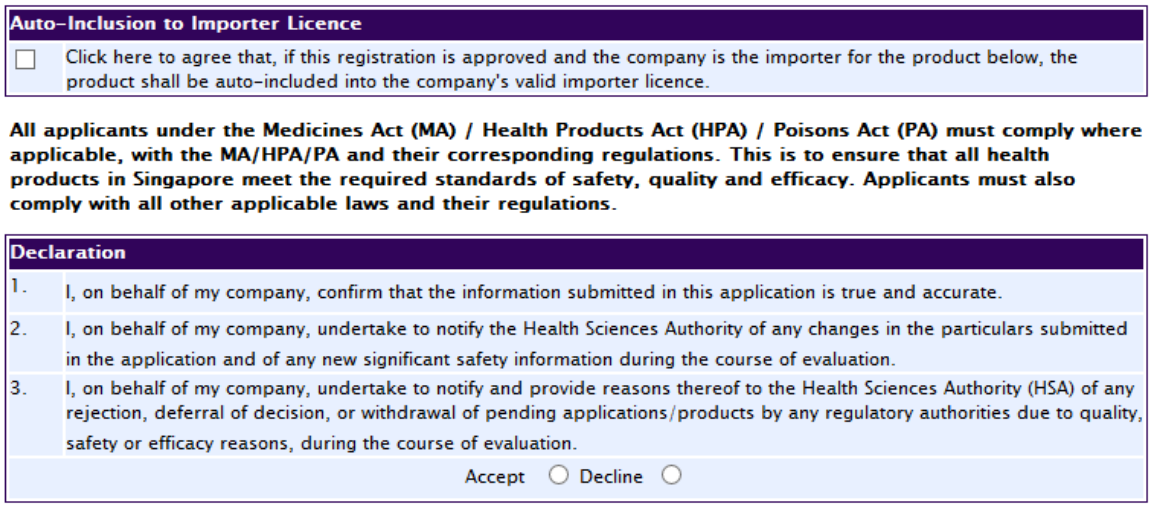
Note: This selection <u>cannot</u> be amended via input request or post-approval once the product application is submitted.

If selected, the product registration will be auto-included to the active and valid Importer's Licence upon the approval of the product. An active and valid Importer's Licence is one that fulfils all the following criteria:

- Held by the same company (same UEN and HSA client code); and
- Approved as a “Full Scope” Importer; and
- Approved with “Registered therapeutic products” as an importation activity; and
- Importer’s Licence Status is “Active” at the point of product registration.

Once the product registration is auto-added to the Importer’s Licence, applicants must submit amendment applications to the Importer’s Licence in order to remove the product registration from the Importer’s Licence.

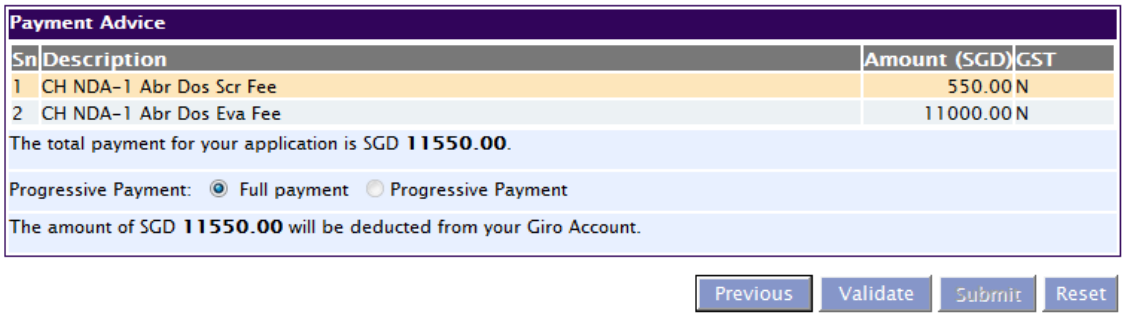
When the applicant is ready to submit the application, ensure that the “Accept” radio button under Declaration is selected before the “Submit” button becomes clickable.



For companies who are making payment via GIRO, applicants should select the preferred payment scheme for the evaluation fee, “Full payment” or “Progressive payment” (if applicable).

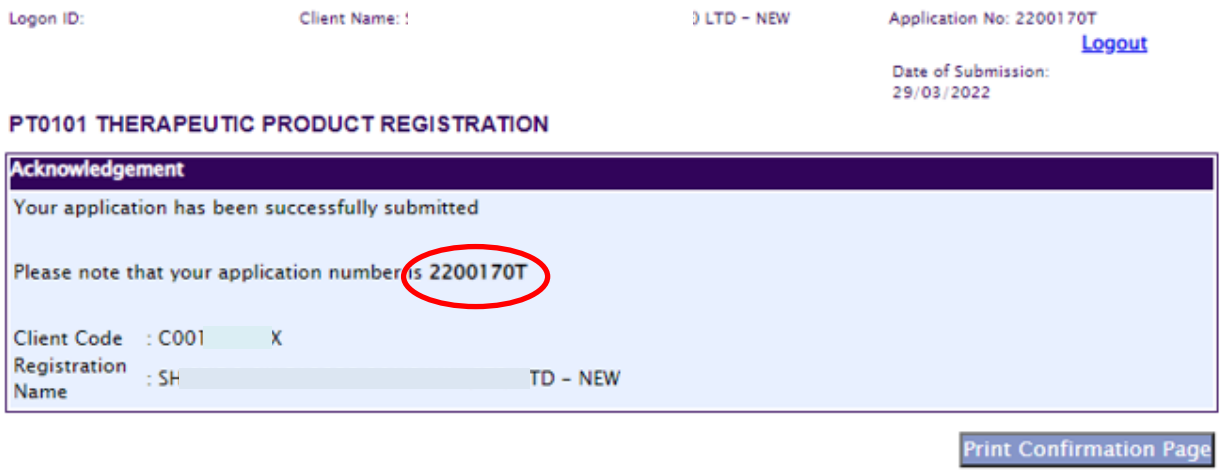
Once submitted, the selected payment scheme (“full payment” or “progressive payment”) **cannot** be amended. Applicants who wish to change their selected payment scheme would have to withdraw and re-submit the application, and any upfront payment made is non-refundable.

For companies who are making e-Payment, selection of payment scheme ("full payment" or "progressive payment") is not applicable.



1.1.9 Acknowledgement

Upon successful submission of the application, applicant should be able to see the acknowledge page with the **application number** provided.



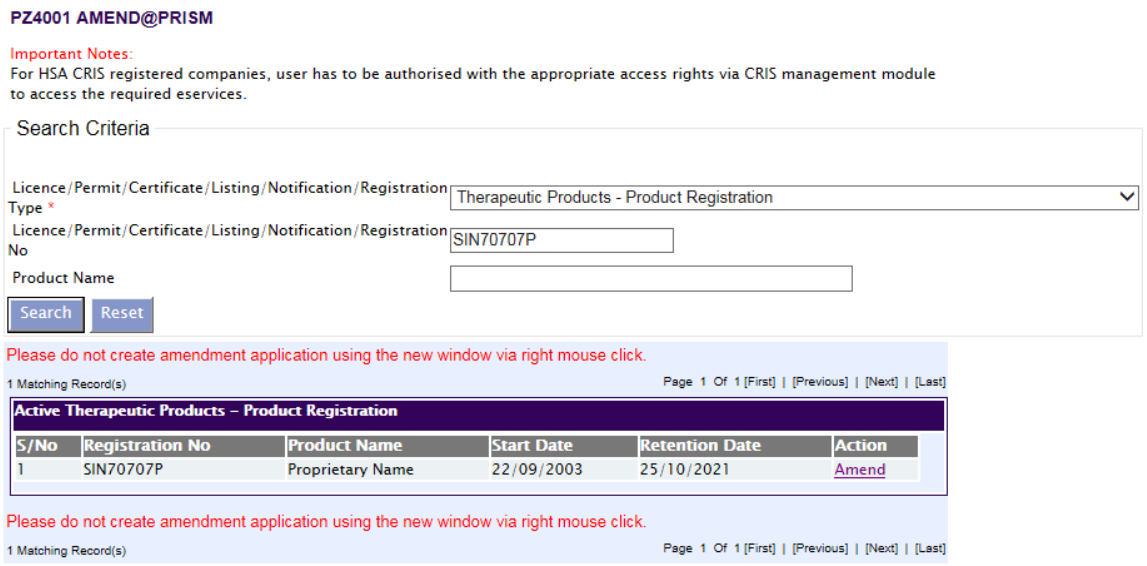
Please refer to this application number for any correspondence with us with regards to your application.

NOTE: Acceptance of the dossier for evaluation does not constitute acceptability of the data provided in the dossier. Acceptability of the data can only be determined during evaluation of the application.

2 SUBMITTING A VARIATION PRODUCT APPLICATION

Variation applications are to be submitted online via Amend@PRISM, and an application is to be submitted for every product registration for which the variation is applicable to.

The application form for a variation application is similar to that of a new application, except that there is an additional section (Registration Summary). In addition, not all the form fields are amendable, depending on the variation type that was selected.



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: SIN70707P

Product Name:

Search | Reset

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

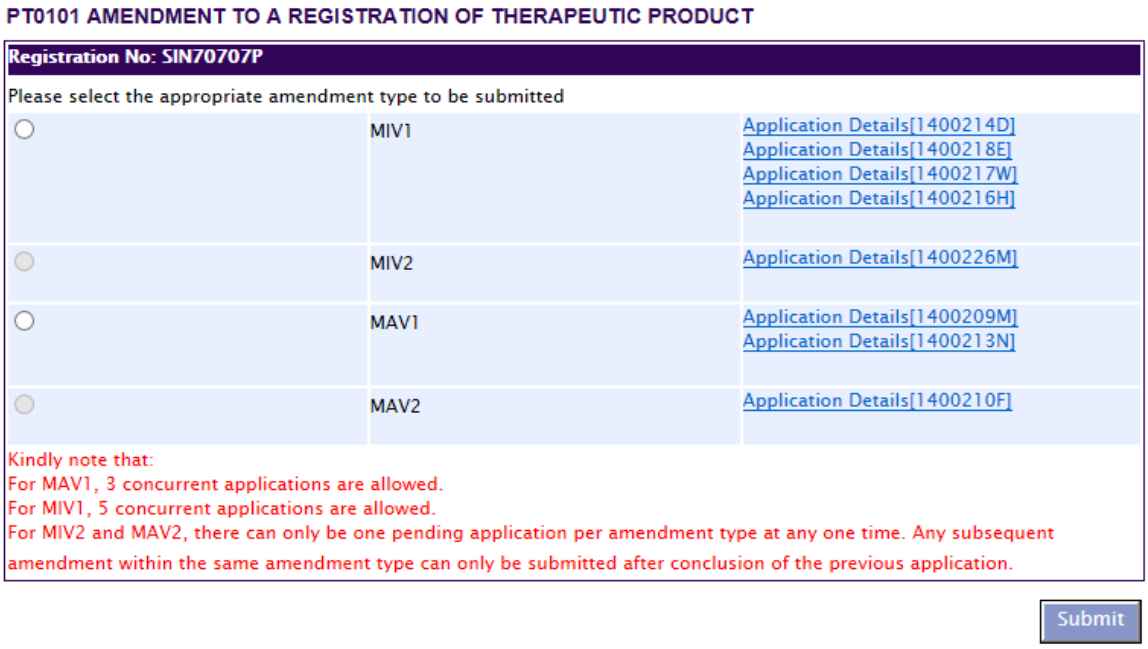
1 Matching Record(s) — Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Active Therapeutic Products – Product Registration

S/No	Registration No	Product Name	Start Date	Retention Date	Action
1	SIN70707P	Proprietary Name	22/09/2003	25/10/2021	Amend

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

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



PT0101 AMENDMENT TO A REGISTRATION OF THERAPEUTIC PRODUCT

Registration No: SIN70707P

Please select the appropriate amendment type to be submitted

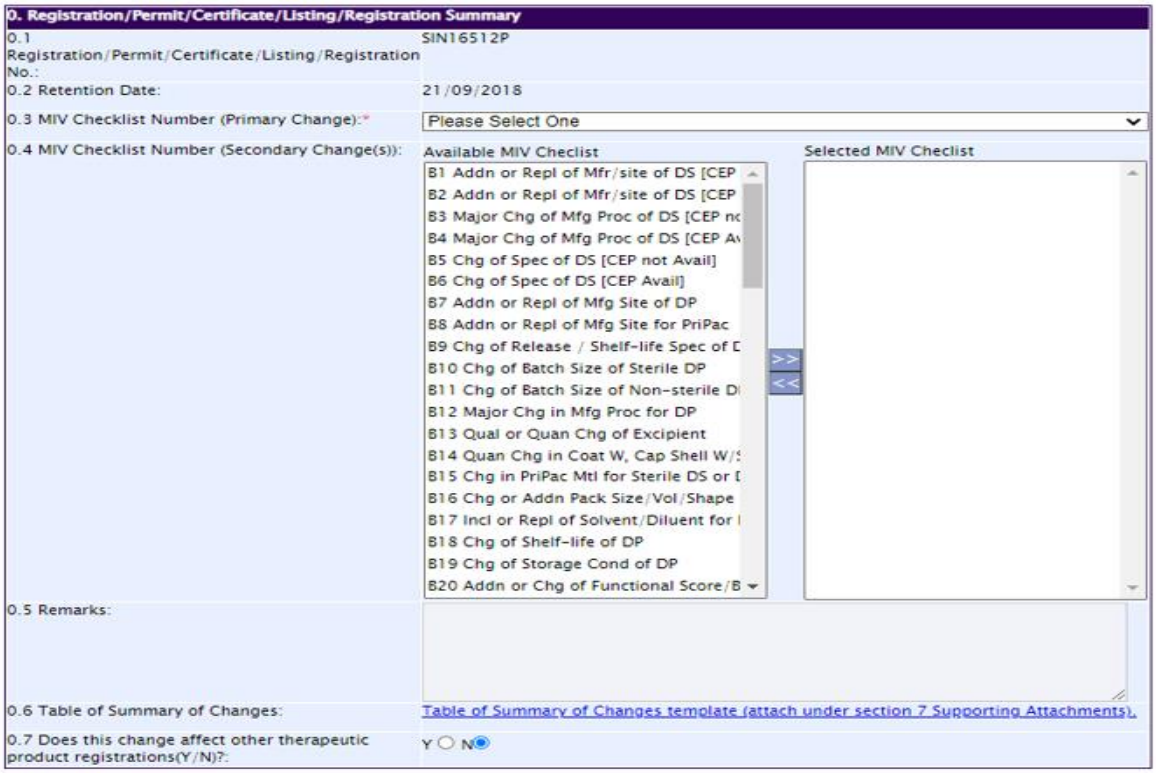
○	MIV1	Application Details[1400214D] Application Details[1400218E] Application Details[1400217W] Application Details[1400216H]
○	MIV2	Application Details[1400226M]
○	MAV1	Application Details[1400209M] Application Details[1400213N]
○	MAV2	Application Details[1400210F]

Kindly note that:
For MAV1, 3 concurrent applications are allowed.
For MIV1, 5 concurrent applications are allowed.
For MIV2 and MAV2, there can only be one pending application per amendment type at any one time. Any subsequent amendment within the same amendment type can only be submitted after conclusion of the previous application.

Submit

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

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).

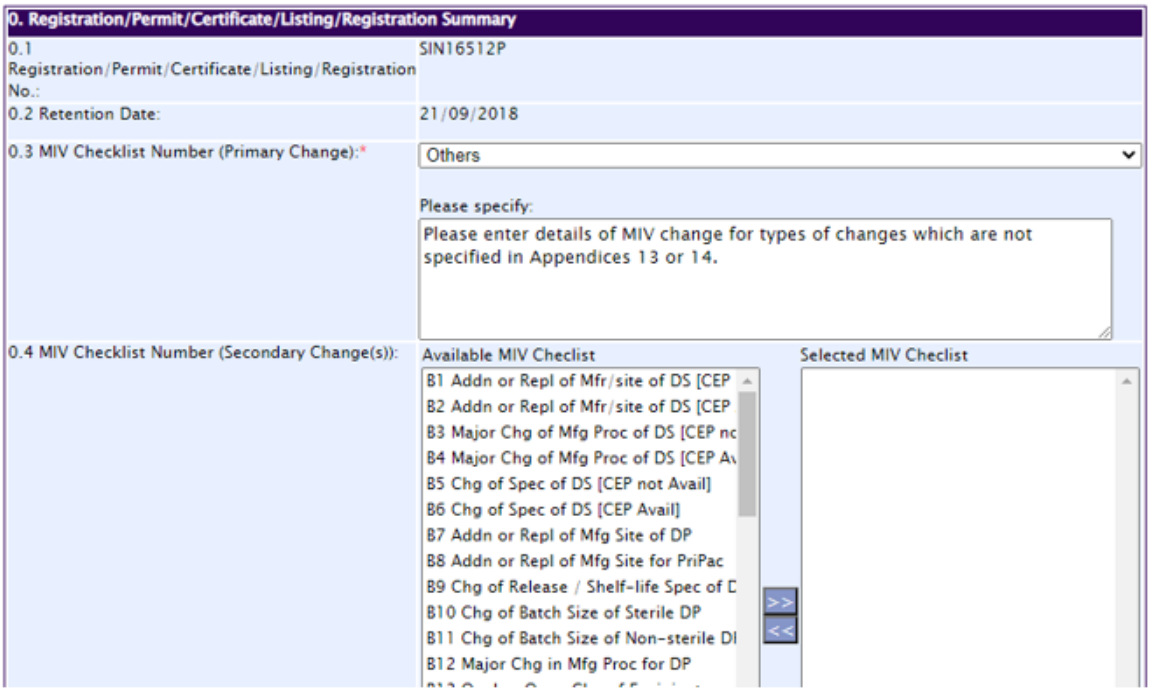


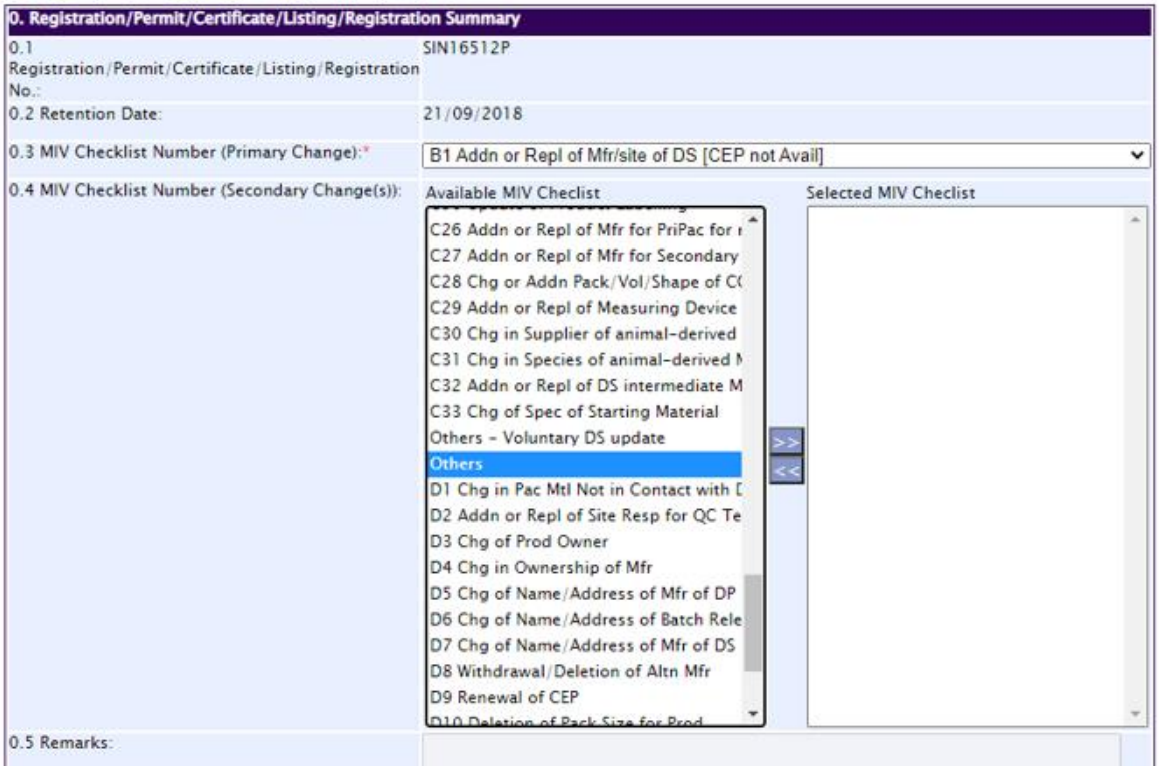
For MIV applications, applicants should select the applicable MIV-1 or 2 checklist title from the drop-down list under “0.3 MIV Checklist Number (Primary change)” based on the variation changes described in Appendix 13 and Appendix 14 of the main guidance document. Note that there should only be one MIV Checklist (Primary Change) per application.

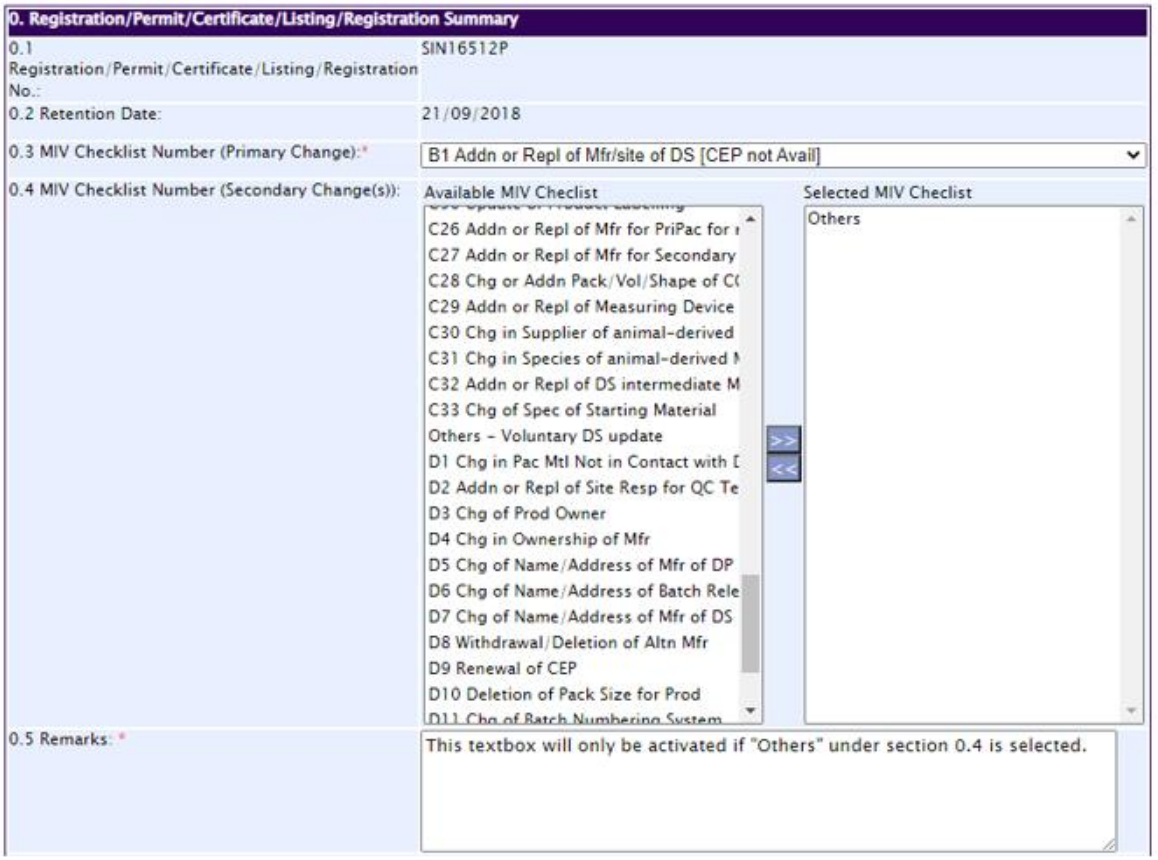
In situations when an application contains consequential changes, the main change is to be reflected as the primary change in “0.3 MIV Checklist Number (Primary Change)” and each consequential change should be entered in “0.4 MIV Checklist Number (Secondary Change[s])”.

For the Secondary Change, to select multiple changes at one go, hold down the Ctrl button while mouse-clicking on all the applicable changes, then release the Ctrl button and click the right arrow. To de-select, the same steps can be followed to select all the applicable changes on the right, then click on the left arrow to remove.

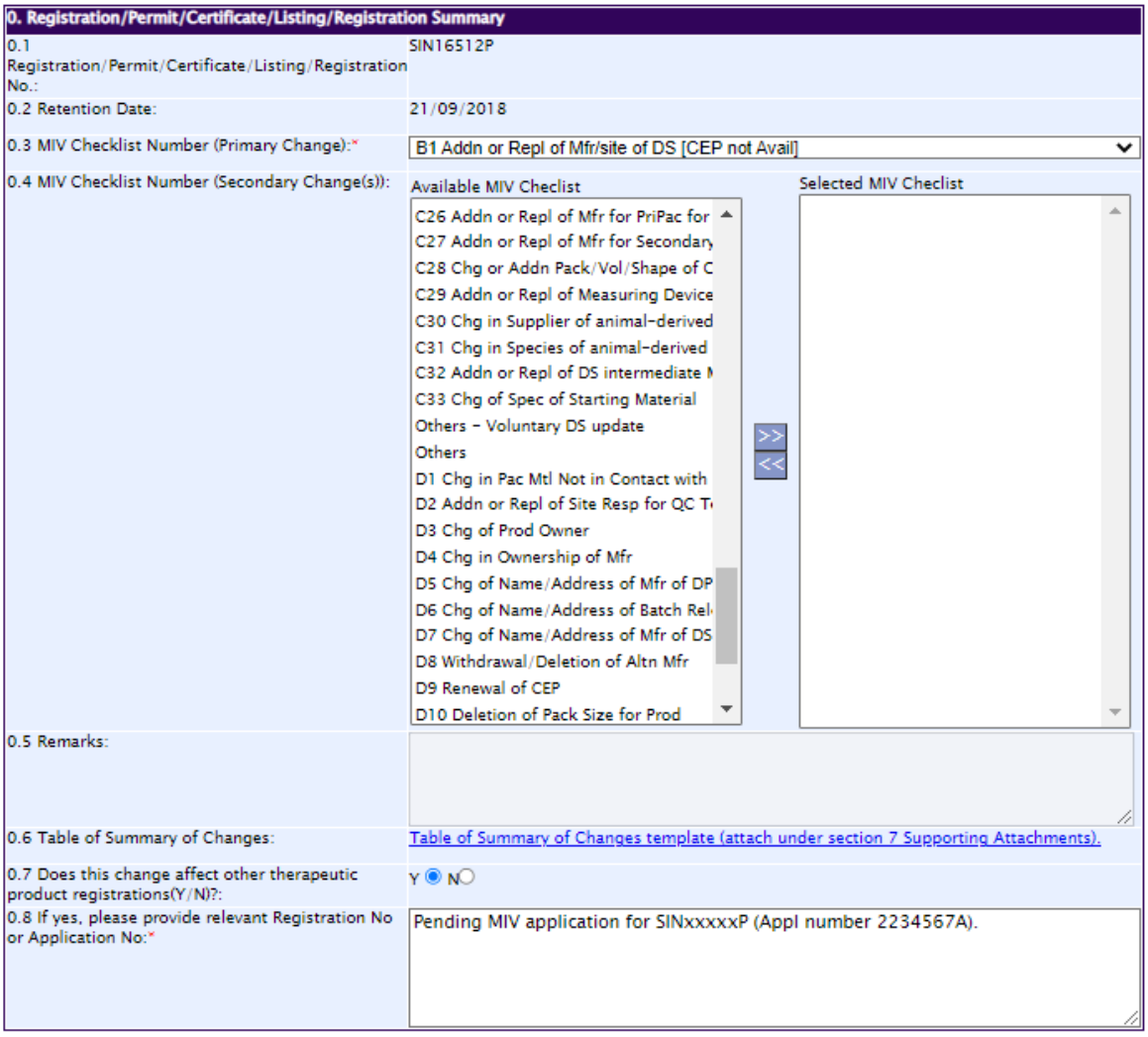
For variation changes that are not specified under Appendix 13 and Appendix 14 of the main guidance document (e.g. those provided as a result of MIV Inquiries), applicants are to select “Others” from the drop-down list and indicate the relevant details in the text box provided.




0. Registration/Permit/Certificate/Listing/Registration Summary
0.1 Registration/Permit/Certificate/Listing/Registration No.:
SIN16512P
0.2 Retention Date:
21/09/2018
0.3 MIV Checklist Number (Primary Change):*
B1 Addn or Repl of Mfr/site of DS [CEP not Avail]
0.4 MIV Checklist Number (Secondary Change(s)):
Available MIV Checlist
Selected MIV Checlist
C26 Addn or Repl of Mfr for PriPac for
C27 Addn or Repl of Mfr for Secondary
C28 Chg or Addn Pack/Vol/Shape of C
C29 Addn or Repl of Measuring Device
C30 Chg in Supplier of animal-derived
C31 Chg in Species of animal-derived
C32 Addn or Repl of DS intermediate M
C33 Chg of Spec of Starting Material
Others - Voluntary DS update
Others
D1 Chg in Pac Mtl Not in Contact with
D2 Addn or Repl of Site Resp for QC Te
D3 Chg of Prod Owner
D4 Chg in Ownership of Mfr
D5 Chg of Name/Address of Mfr of DP
D6 Chg of Name/Address of Batch Rele
D7 Chg of Name/Address of Mfr of DS
D8 Withdrawal/Deletion of Altn Mfr
D9 Renewal of CEP
>>
<<
0.5 Remarks:

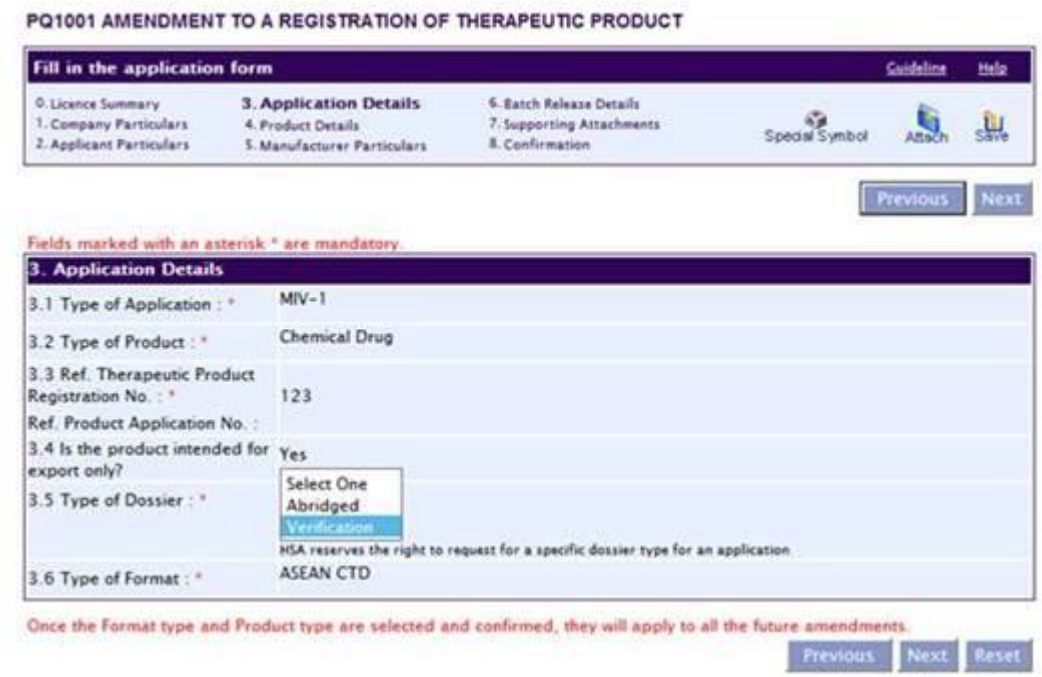

0. Registration/Permit/Certificate/Listing/Registration Summary
0.1 Registration/Permit/Certificate/Listing/Registration No.:
SIN16512P
0.2 Retention Date:
21/09/2018
0.3 MIV Checklist Number (Primary Change):*
B1 Addn or Repl of Mfr/site of DS [CEP not Avail]
0.4 MIV Checklist Number (Secondary Change(s)):
Available MIV Checlist
Selected MIV Checlist
Others
C26 Addn or Repl of Mfr for PriPac for
C27 Addn or Repl of Mfr for Secondary
C28 Chg or Addn Pack/Vol/Shape of C
C29 Addn or Repl of Measuring Device
C30 Chg in Supplier of animal-derived
C31 Chg in Species of animal-derived
C32 Addn or Repl of DS intermediate M
C33 Chg of Spec of Starting Material
Others - Voluntary DS update
D1 Chg in Pac Mtl Not in Contact with
D2 Addn or Repl of Site Resp for QC Te
D3 Chg of Prod Owner
D4 Chg in Ownership of Mfr
D5 Chg of Name/Address of Mfr of DP
D6 Chg of Name/Address of Batch Rele
D7 Chg of Name/Address of Mfr of DS
D8 Withdrawal/Deletion of Altn Mfr
D9 Renewal of CEP
D10 Deletion of Pack Size for Prod
D11 Chg of Batch Numbering System
>>
<<
0.5 Remarks: *
This textbox will only be activated if "Others" under section 0.4 is selected.

If the change(s) in the variation application affect other product registrations, or if there are pending related applications which the applicant would like to bring to HSA's attention, select radio button "Y" for section 0.7, and enter relevant details in Section 0.8:



0. Registration/Permit/Certificate/Listing/Registration Summary	
0.1 Registration/Permit/Certificate/Listing/Registration No.:	SIN16512P
0.2 Retention Date:	21/09/2018
0.3 MIV Checklist Number (Primary Change):*	B1 Addn or Repl of Mfr/site of DS [CEP not Avail]
0.4 MIV Checklist Number (Secondary Change(s)):	Available MIV Checlist: C26 Addn or Repl of Mfr for PriPac for; C27 Addn or Repl of Mfr for Secondary; C28 Chg or Addn Pack/Vol/Shape of C; C29 Addn or Repl of Measuring Device; C30 Chg in Supplier of animal-derived; C31 Chg in Species of animal-derived; C32 Addn or Repl of DS intermediate M; C33 Chg of Spec of Starting Material; Others - Voluntary DS update; Others; D1 Chg in Pac Mtl Not in Contact with; D2 Addn or Repl of Site Resp for QC T; D3 Chg of Prod Owner; D4 Chg in Ownership of Mfr; D5 Chg of Name/Address of Mfr of DP; D6 Chg of Name/Address of Batch Rel; D7 Chg of Name/Address of Mfr of DS; D8 Withdrawal/Deletion of Altn Mfr; D9 Renewal of CEP; D10 Deletion of Pack Size for Prod. Selected MIV Checlist:
0.5 Remarks:	
0.6 Table of Summary of Changes:	Table of Summary of Changes template (attach under section 7 Supporting Attachments).
0.7 Does this change affect other therapeutic product registrations(Y/N)?:	Y (selected) N
0.8 If yes, please provide relevant Registration No or Application No:*	Pending MIV application for SINxxxxxP (Appl number 2234567A).

For submission of an MAV-1 or MIV-1 application via the Verification route, please select “Verification” under Section 3.5 of the PRISM application form.



Upon the completion of this page, click “Next” to proceed to the next sections of the form, which are identical to those described in Section 1 of this appendix (Submitting a New Product Application):

1. Amend Company particulars
2. Amend Applicant particulars
3. Amend Application details
4. Amend Product information
5. Amend Manufacturer particulars
6. Amend Information on Company Responsible for Batch Release
7. Attach Supporting documents
8. Confirmation
9. Acknowledgement

3 RESPONDING TO INPUT REQUEST (IR) FROM HSA

During the course of screening or evaluating the product application, HSA may send applicants Input Request (IR) to seek clarification or request for more information on the application.

There are 2 types of IRs:

- Primary IR – input request whereby HSA returns the PRISM application form to the applicant for editing of the information in the form, or to request for documents to be attached into the form.
- Secondary IR – input request whereby HSA is seeking clarification without the need for the applicant to change the PRISM application form or to attach any documents in PRISM.

An application can only have one pending primary IR at any one time, but can have multiple concurrent secondary IRs.

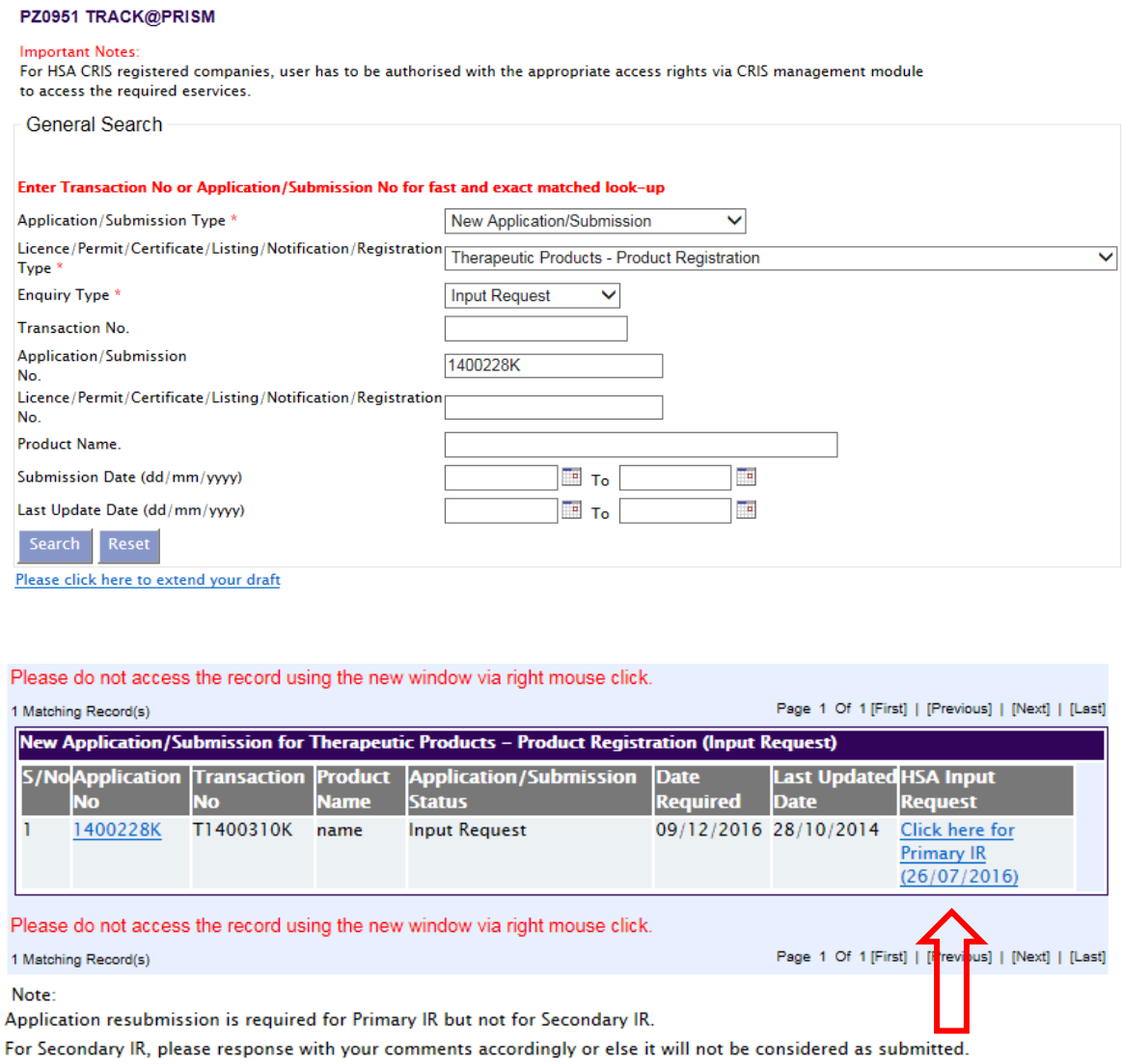
When an IR is sent to the applicant, the applicant will receive an email/fax/sms notification (depending on the preferred mode of contact selected in the PRISM application form). Applicants are able to retrieve the IR and submit response to the IR via Track@PRISM.

Note: Any attachment sent together with the IR can only be retrieved and viewed via Track@PRISM.

3.1 Responding to a Primary IR

i. Select the application type (New Application/ Amendment), registration type (Therapeutic Products – Product Registration) and enquiry type (Input Request).

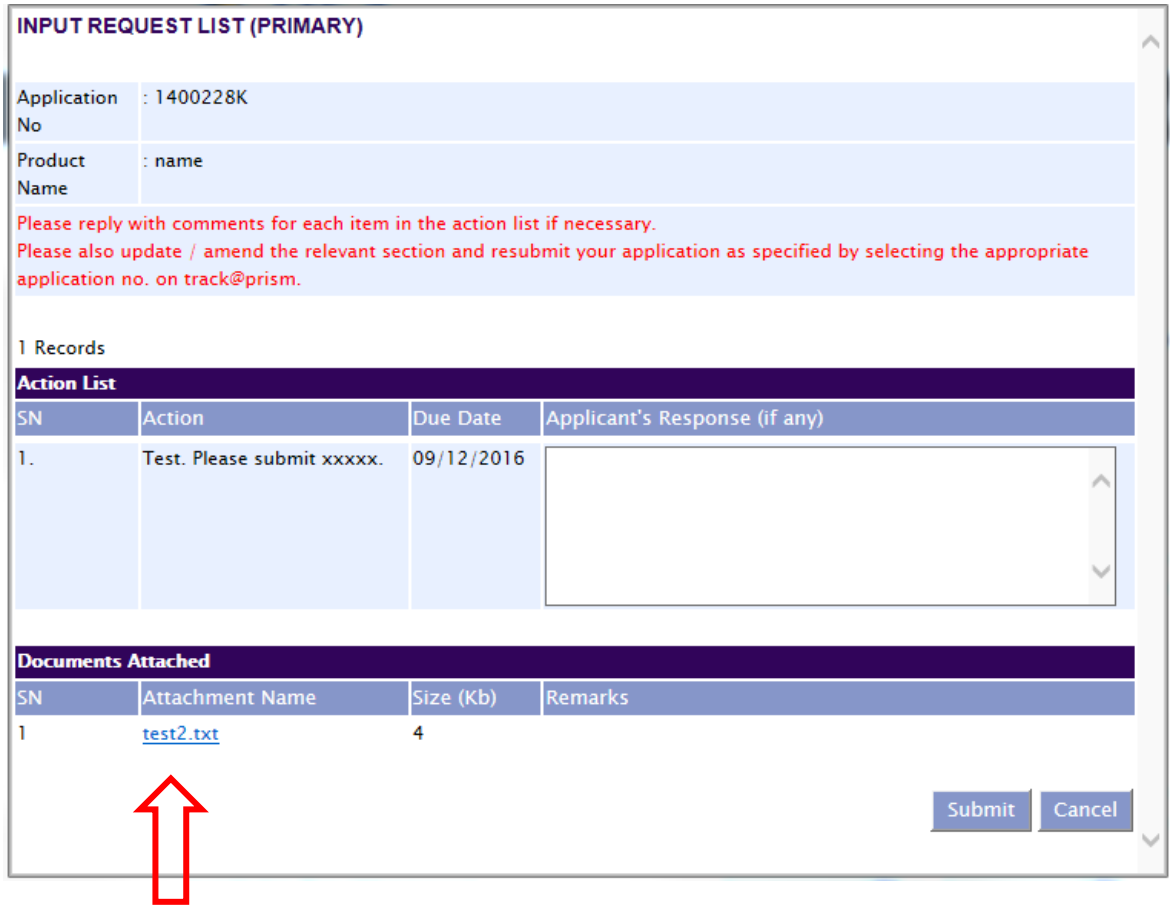
ii. The Input request from HSA will be displayed in the column “HSA Input Request”.

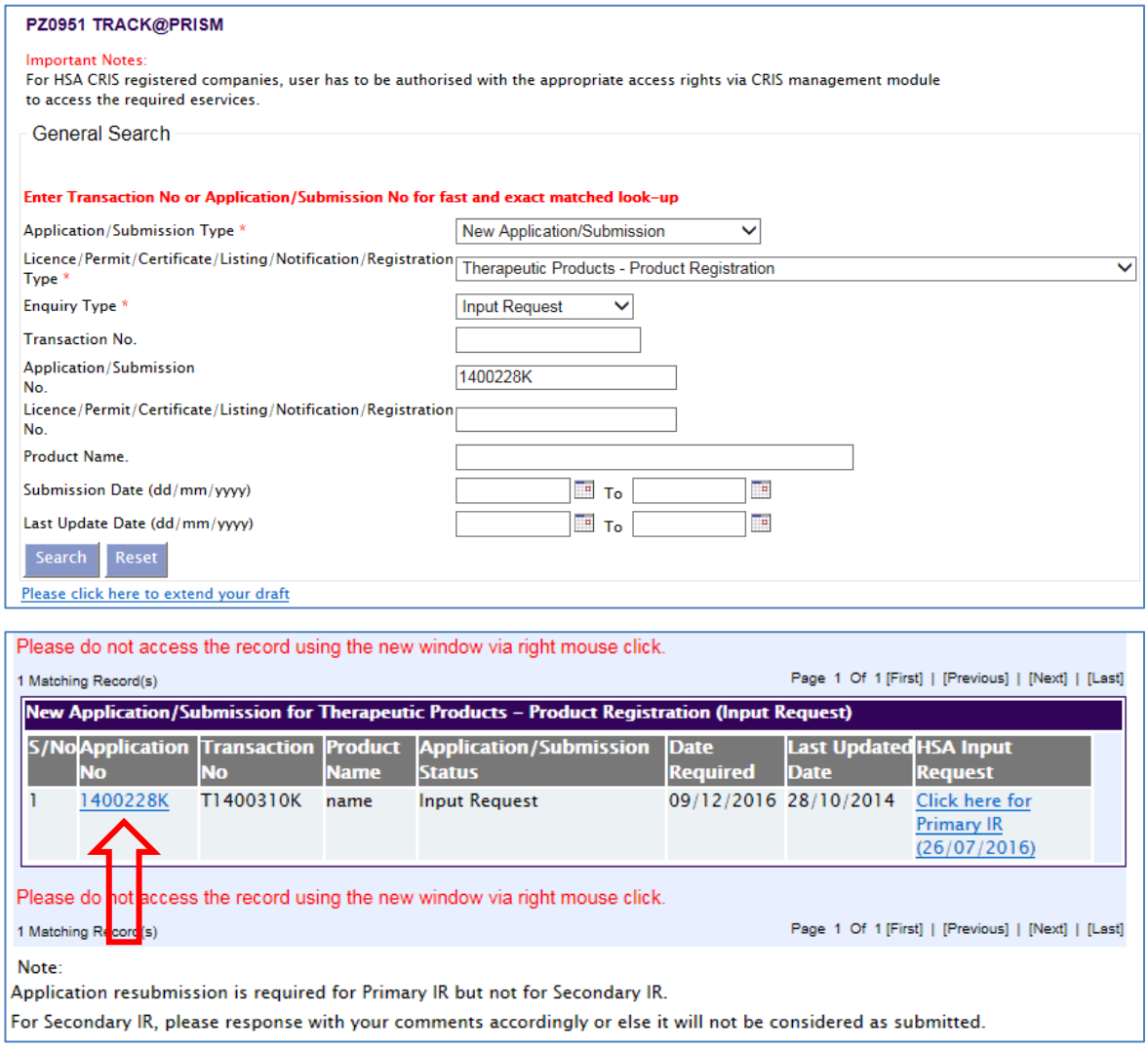


iii. Click on the hyperlink under the "HSA Input Request" column to see the document attached by HSA officers.

iv. Under "Applicant's Response", include information on the mode of submission of response, e.g. "attached in PRISM", "Sent via CD-ROM" etc.

v. To access the application form in order to edit the information in the form, click on the application number hyperlink.


INPUT REQUEST LIST (PRIMARY)
Application No : 1400228K
Product Name : name
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.
Test. Please submit xxxxx.
09/12/2016
Documents Attached
SN
Attachment Name
Size (Kb)
Remarks
1
test2.txt
4
Submit
Cancel



Note: the resubmission of the application form is not considered as a new application (the application number does not change), and fees will not be charged when submitting the form.

3.2 Responding to a Secondary IR

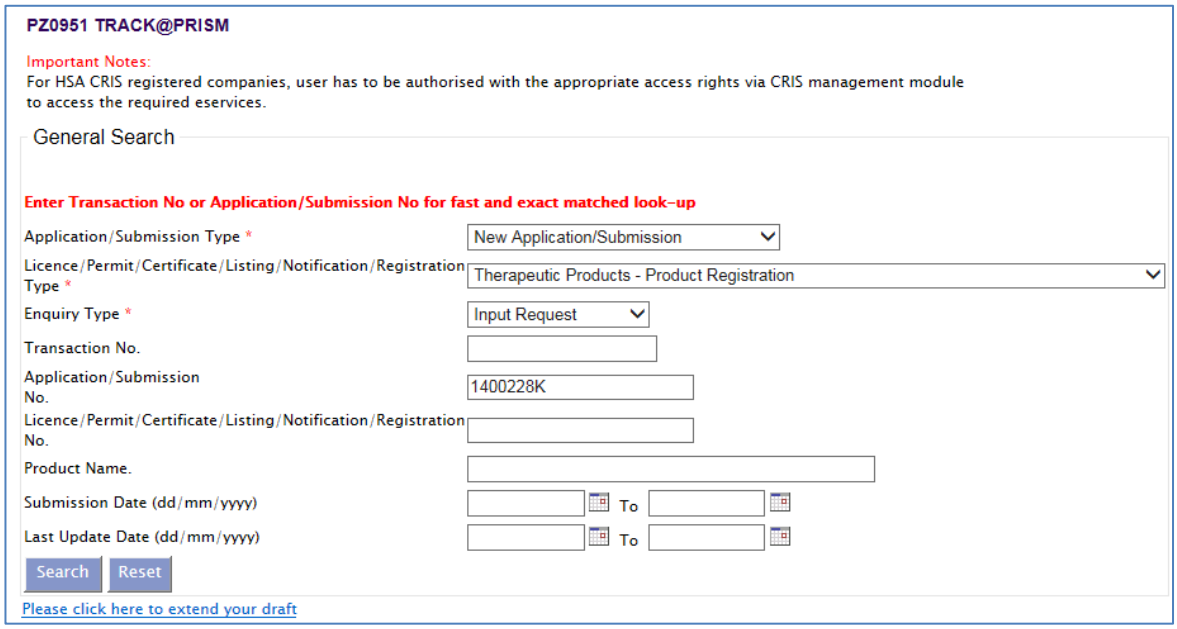
i. Select the application type (New Application/ Amendment), registration type (Therapeutic Products – Product Registration) and enquiry type (Input Request).

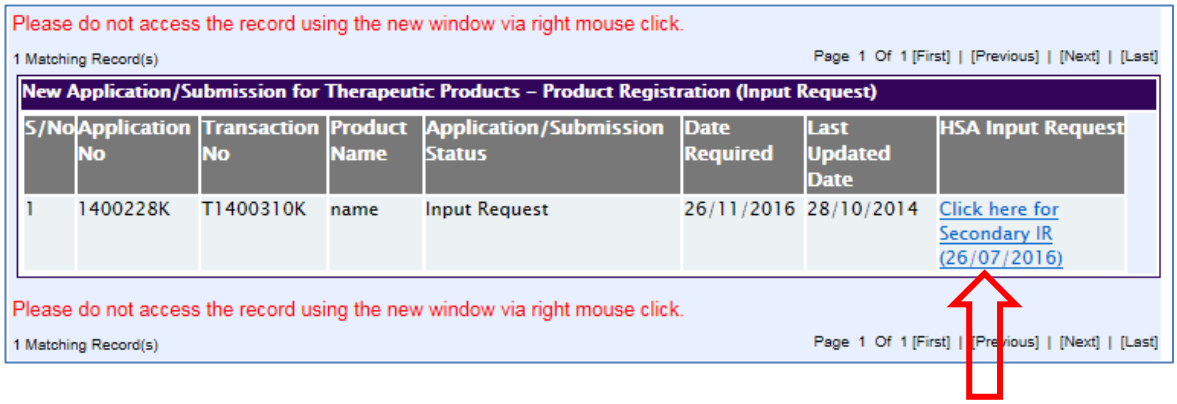
ii. The Input request from HSA will be displayed in the column “HSA Input Request”.

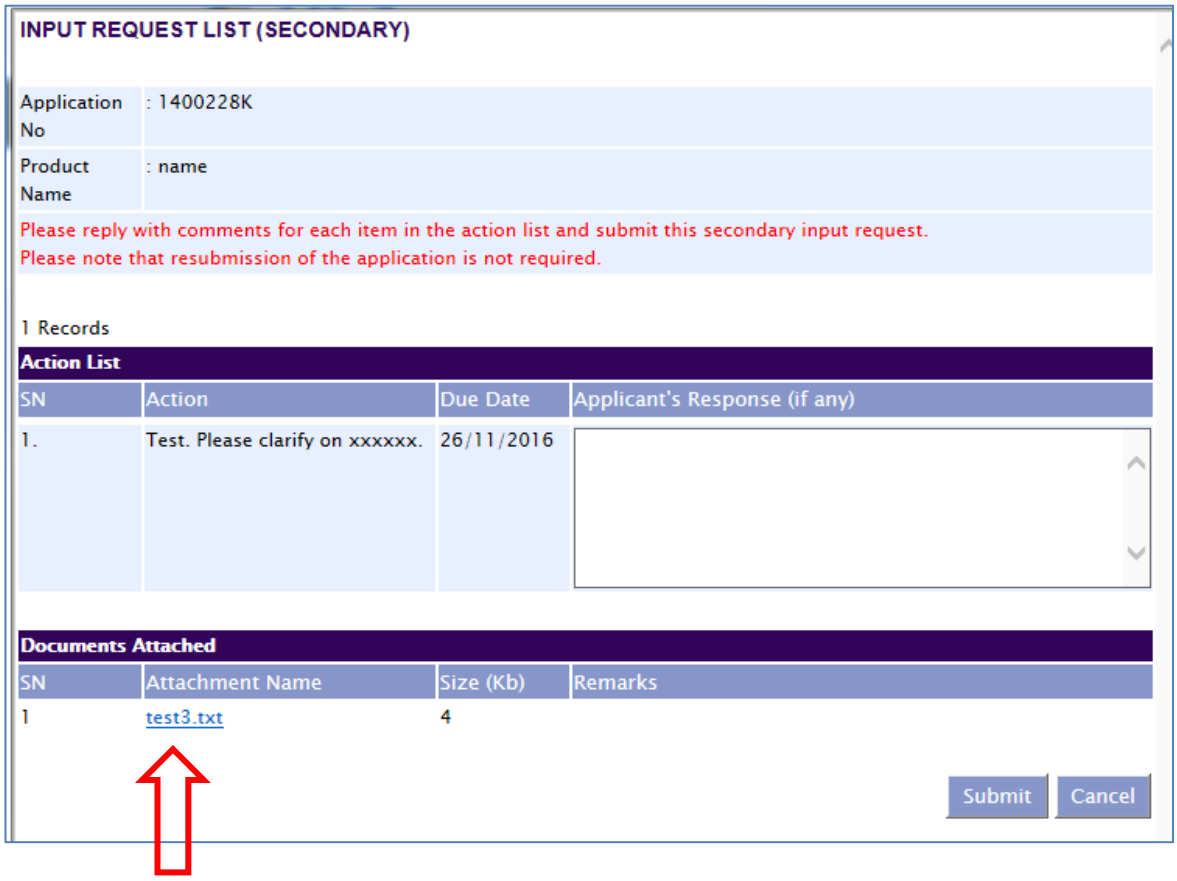
iii. Click on the hyperlink under the “HSA Input Request” column to see the document attached by HSA officers.

iv. Under “Applicant’s Response”, include information on the mode of submission of response, e.g. “attached in PRISM”, “Sent via CD-ROM” etc.

v. For a secondary input request, the resubmission of the application form is not required.



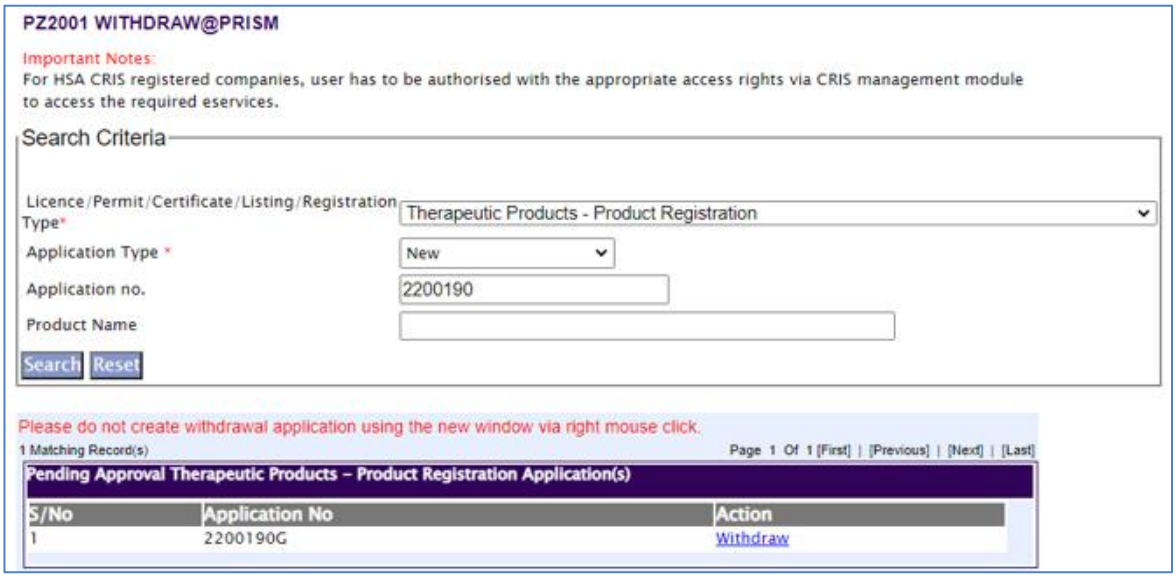




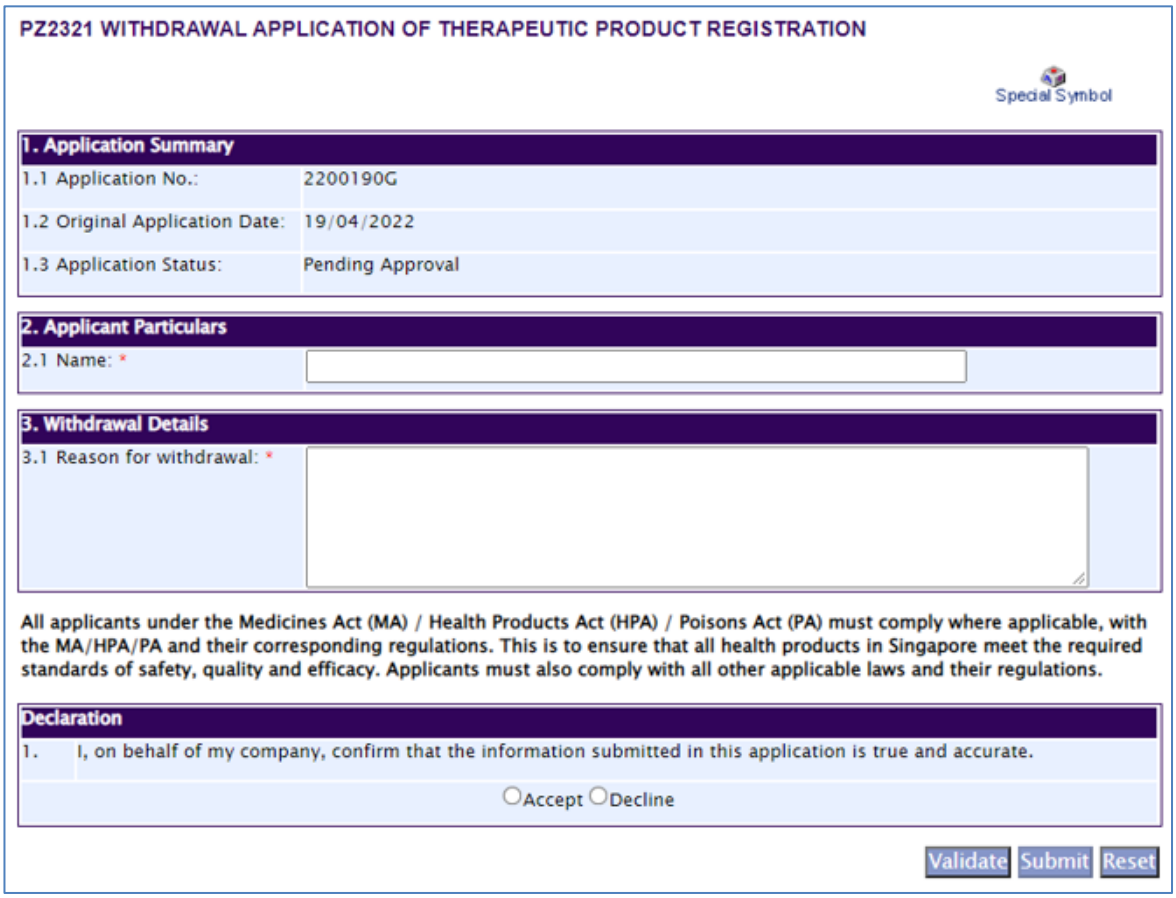
4 WITHDRAWING A PENDING APPLICATION

The applicant may withdraw a pending application at any point in time via Withdraw@PRISM. Once submitted, a withdrawal request cannot be reversed.

Select the application number that is to be withdrawn, and click on “Withdraw”.



In the subsequent screen, enter the applicant name and reason for withdrawal, complete the declaration section and click “Submit”.



The following acknowledgement view indicates that the withdrawal had been successfully submitted.

HSA will need to process your withdrawal request before the application is considered withdrawn in PRISM. However, please note that even if HSA has yet to process the withdrawal request, a **withdrawal request cannot be "cancelled" or reversed**.

In the event that the applicant requires the withdrawal request to be processed so as to submit another of the same application type (e.g. MIV-2 application), the applicant may contact HSA to request for the withdrawal request to be processed promptly.

REVISION HISTORY

Guidance Version (Publish Date)

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