

APPENDIX 17 *GUIDELINE ON PRISM SUBMISSION*

This appendix describes the processes for:

- (1) Submitting a new product application
- (2) Submitting a variation product application
- (3) Responding to Input Request (IR)
- (4) Withdrawing a pending application

1 Submitting a New Product Application

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

NOTE: Applicants must have a Client Registration and Identification Service (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/prism/cris/>

1.1 Registration Requirements

Each product registration is specific to a product identified by the following parameters, viz. product name, product formula, dosage form and strength.

Multiple packaging configurations with varying pack size, fill volume, or co-packaged accessories for administration (e.g. empty syringes or needles) can be included in a single product registration provided that the product name, product formula, dosage form and strength remain the same.

A packaging configuration describes how a product is supplied, including:

- the container closure system (e.g., vial, blister or bottle);
- the quantity of product, or fill volume of product in each container closure system (e.g., 30 tablets/ blister or 1 ml/ vial); and

- the number of container closure systems in each pack (e.g., 1 vial/ carton, or 10 blisters/ carton).

Where the container closure system functions as a drug delivery device (e.g. pre-filled syringe or pre-filled pen), and is supplied in multiple packaging configurations, only the same type of container closure system can be considered under the same registration.

Where the above conditions are not met, individual product registration applications must be submitted.

1.2 When to Submit as Individual Applications

When determining whether a product should be submitted as an individual registration, the following should be considered:

a) Specific Dosage Form and Strength

Each product registration application must correspond to one specific dosage form and strength. Where a therapeutic product is available in different dosage forms or strengths, separate applications must be submitted for each product.

b) Product Name Consistency

Each registration must correspond to one product name, which must be used consistently across all packaging configurations of the product. Refer to *Section 4.1 - Product Name* for the recommended format for product name.

c) Single Product Formula

Each product registration is specific to a single product formula. Different product formulae cannot be included under a single registration application.

d) Container Closure Systems as Drug Delivery Devices

Each product registration must correspond to only one type of container closure system when it functions as a drug delivery device. Where a product is supplied in different types of container closure systems that function as drug delivery devices, individual applications must be submitted for each type of container closure system. Refer to Table A below for examples.

Table A: Examples of Container Closure Systems that Function as Drug Delivery Devices and Require Individual Product Registrations
Pre-filled syringe
Pre-filled pen or auto-injector
Inhalation products with delivery mechanisms
Patches with device-controlled release mechanisms
Note: Different pack sizes or fill volume of the same container closure system type (e.g. 1mL and 2mL pre-filled pens) may be submitted under one product registration application as multiple packaging configurations.

Table 1 below illustrates where multiple packaging configurations may be included under a single product registration; and Table 2 illustrates where individual registrations are required.

Table 1 - Products with Multiple Packaging Configurations Under One Registration:

Dosage form	Labelled strength in Product Name	Container closure system	Submit Under One Registration
Tablet	20mg	Bottle	i. 30 tablets in bottle ii. 10 tablets in blister
	20mg	Blister	
Solution for Injection	10mg/mL	Vial containing 1mL solution	i. 1mL vial ii. 2mL vial
	10mg/mL	Vial containing 2mL solution	
Solution for Injection	10mg/mL	Vial containing 5mL solution	i. 5mL vial ii. 5mL ampoule
	10mg/mL	Ampoule containing 5mL solution	
Solution for Injection	2mg/mL	Pre-filled pen containing 1mL solution	i. 1mL pre-filled pen ii. 2mL pre-filled pen
	2mg/mL	Pre-filled pen containing 2mL solution	

Dosage form	Labelled strength in Product Name	Container closure system	Submit Under One Registration
Solution for Injection	2mg/mL	Vial containing 1mL solution	i. 1mL vial ii. 1mL vial with empty syringe and needle Note: An empty syringe or needle packed as an accessory does not constitute a container closure system functioning as a drug delivery device. This is distinct from a pre-filled syringe, where the pre-filled syringe is the container closure system of the drug product.
	2mg/mL	Vial containing 1mL solution supplied with empty syringe and needle	
Concentrate for Solution for Injection	2mg/mL	Vial containing 1mL concentrate	i. 1mL vial ii. 5mL vial
	2mg/mL	Vial containing 5mL concentrate	
Powder for Solution for Injection	2mg/vial	Vial containing 2mg powder, supplied with one 2mL ABC diluent in vial	i. 2mg/vial with one 2 mL diluent ii. 2mg/vial with two 2 mL diluent
		Vial containing 2mg powder, supplied with two 2mL ABC diluent in vial	

Dosage form	Labelled strength in Product Name	Container closure system	Submit Under One Registration
Powder for Solution for Injection	2mg/vial	Vial containing 2mg powder, supplied with 2mL ABC diluent in vial	i. 2mg/vial with 2mL diluent ii. 2mg/vial with 4mL diluent
	2mg/vial	Vial containing 2mg powder, supplied with 4mL ABC diluent in vial	
Patches/Plasters	2%w/w/patch	Pouch containing 5 patches	i. 5 patches per pouch ii. 10 patches per pouch
		Pouch containing 10 patches	

Table 2 - Products Requiring Individual Product Registrations:

Dosage form	Labelled strength in Product Name / Product Details	Application	Reason
Tablet	20mg	Submit as 2 individual applications	Products have different strengths.
	50mg		
Tablet	20mg	Submit as 3 individual applications	Products have different strengths. Note: The starter kit contains more than one strength and therefore cannot be included as a packaging configuration of either single- strength product.
	50mg		
	Starter kit with 20mg and 50mg in a pack		
Powder for Solution for Injection	25mg/vial	Submit as 2 individual applications	Products have different strengths.
	50mg/vial		

Dosage form	Labelled strength in Product Name / Product Details	Application	Reason
Powder for Solution for Injection supplied with or without diluent	Powder supplied with 2mL diluent ABC in vial	Submit as 3 individual applications	Products have different formulae. Note: Diluent is considered as part of the product formula.
	Powder supplied with 2mL diluent XYZ in vial		
	Powder supplied without diluent		
Powder for Solution for Injection supplied with diluent	Powder supplied with 2mL diluent in vial	Submit as 2 individual applications	Diluents are supplied in different container closure systems, one of which functions as a drug delivery device, e.g. pre- filled syringe
	Powder supplied with 2mL diluent in pre-filled syringe		
Solution for Injection	10mg/2mL in a vial containing 2mL of the solution	Submit as 2 individual applications	Products have different strengths.
	10mg/mL in a vial containing 1mL of the solution		

Dosage form	Labelled strength in Product Name / Product Details	Application	Reason
Solution for Injection	10mg/2mL in a vial containing 2mL of the solution	Submit as 2 individual applications	The labelled strengths differ despite equivalent concentration
	5mg/mL in a vial containing 1mL of the solution		
Solution for Injection	2mg/mL in a vial containing 1mL of the solution	Submit as 2 individual applications	Products are supplied in different container closure systems, one of which functions as a drug delivery device, e.g. pre-filled syringe
	2mg/mL in a pre-filled syringe containing 1mL of the solution		
Solution for Injection	2mg/mL in a 1mL pre-filled syringe	Submit as 2 individual applications	Products are supplied in different types of container closure systems that function as drug delivery devices, e.g. pre-filled syringe and pre-filled pen
	2mg/mL in a 1mL pre-filled pen		

Dosage form	Labelled strength in Product Name / Product Details	Application	Reason
Concentrate solution	10mg/5mL	Submit as 2 individual applications	The labelled strengths differ despite equivalent concentration
	2mg/mL		
Solution for Injection in single- use pre-filled syringe labelled with different strengths	100iu/mL	Submit as 2 individual applications	The labelled strengths differ despite equivalent concentration
	400iu/4mL		
Solution for Inhalation	Inhaler with 2mcg cartridge	Submit as 2 individual applications	Products are supplied in different types of container closure systems: one is supplied with a drug delivery device (inhaler) while the other is supplied as a refill cartridge.
	2mcg cartridge for re-fill		

1.3 Sections of a PRISM Application

1.3.1 Section 1 – Company Particulars

A product registration applicant is the local company that applies to register the product. Each application for a product registration is company-specific. The company must be registered in Singapore and must be authorised by the product owner before applying to register the product.

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 required 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 to the company, which will be the Product Registrant.

1.3.2 Section 2 – Applicant Particulars

The product registration applicant company may authorise its 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 section 2.4.5, please enter only ONE email address.

Fields marked with an asterisk * are mandatory.

2. Applicant Particulars			
2.1 Name : *	Peter Tan		(as in NRIC/FIN)
2.2 NRIC/FIN : *	S0123456J		(Example: S1234567A, F1234567B)
2.3 Designation : *	Regulatory Affairs Executive		
2.4 Contact Details			
2.4.1 Tel : *	61234560	2.4.2 Fax :	67654321
2.4.3 Handphone :		2.4.4 Pager :	
2.4.5 Email :	peter@tan.com		
2.5 Preferences			
2.5.1 Preferred Contact Mode : *	☒ Email ☐ SMS (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)		

Direct telephone and fax numbers of the company may be entered. Take note that only company email addresses should be entered.

The local contact details must be 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 are any changes to this PRISM section, especially to the contact details.

1.3.3 Section 3 – Application Details

In this PRISM section, enter specific details of the application, including 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:

3. Application Details	
3.1 Type of Application : *	GDA-1 ▼
3.2 Type of Product : *	Chemical Drug ▼
3.3 Ref. Product Application/Registration No. : *	test Please specify Product Application Number of the reference product that is the basis for the submission. Alternatively, specify reference Therapeutic Product Registration Number.
3.5 Type of Dossier : *	Abridged ▼ HSA reserves the right to request for a specific dossier type for an application
3.6 Type of Format : *	ASEAN CTD ▼

Note: The 3.4 numbering is intentionally skipped.

1.3.3.1 Section 3.1 – Type of Application

Input the type of application to be submitted to HSA.

Note:

Once an application is submitted, if the type of application is selected incorrectly and needs to be changed

- within the same application type (e.g. from NDA-2 to NDA-3): 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): the 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.

1.3.3.2 Section 3.2 – Type of Product

Input either '*Chemical Drug*' for a chemical drug product or '*Biological Drug*' for a biologic drug product. 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 compound, chemical compound 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 compound 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 compound, such as a protein or polypeptide.

1.3.3.3 Section 3.3 – Reference Product

This section applies to all application types except for NDA-1 and NDA-2 applications.

For NDA-3 or 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 NDA-3 or GDA-2 that is submitted separately from the initial registration application, the NDA-1/2 or GDA-1's registration/application number must also be inserted in the reference product field.

1.3.3.4 Section 3.5 – Type of Dossier

This refers to the different evaluation routes stated 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 of the re-categorisation.

1.3.3.5 Section 3.6 – Type of Format

Indicate whether the dossier format is ICH CTD or ACTD. The dossier format selected must be the same as that of the actual submitted dossier. Once the format type has been set in PRISM, it **cannot be changed** throughout the entire life cycle of the product. Explanatory notes on the application dossier format can be found in section 6.2 of the main guidance.

NOTE: Changing the selected Type of Format will result in removal of all uploaded supporting documents in the List of Supporting Documents

1.3.4 Section 4 – Product Information

1.3.4.1 Section 4.1 – Product Name

4. Product Information	
4.1 Product Name : *	ABC Solution for Injection 300mg/ml

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

The term '*product labels*' or '*product labelling*' refers to the inner label, outer carton, package insert (PI) and/or patient information leaflet (PIL) of the product.

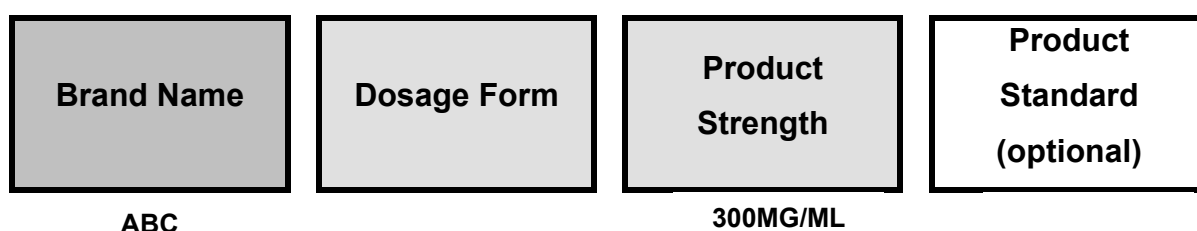
Applicants should ensure that the product name:

- does not suggest greater safety or efficacy than that supported by clinical data;
- does not imply superiority over another product;
- does not imply the presence of any substance(s) not present in the product; and
- must not cause confusion with another product.

In addition, a proposed product name which comprises the international non-proprietary name (INN) must 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 regulatory considerations and will be requested to amend it.

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



The pharmaceutical dosage form should precisely reflect the product's actual dosage form (e.g. "Film-coated Tablet" instead of "Tablet") and include description of any drug delivery devices (e.g. "Solution for Injection in Pre-filled Syringe" instead of "Solution for Injection", or the inclusion of diluent, if applicable).

The product strength represents the amount of the active substance 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).

For products supplied with diluent, the product strength in the product name should refer to the product's strength prior to reconstitution.

Stating the product strength as part of the product name may be optional 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 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

1.3.4.2 Section 4.2 – Product Formula

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

4.2 Product Formula

4.2.1 Name of Substance * (Film Coating) Ingredient Z

4.2.2 Substance Type * Excipient

4.2.3 Grade * NF

4.2.4 Strength * 0.015mg

New Save

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	Active Substance	Active Ingredient	In-house	--
☐	Excipient A	Excipient	USP	--
☐	Excipient B	Excipient	Ph. Eur.	--

Remove

Choose either 'Active Ingredient' or 'Excipient' from the drop-down list

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:

☐ Select All	Name of Substance	Type of Substance	Grade
☐	Active Substance	Active Ingredient	In-house
☐	(Film Coating) Ingredient Z	Excipient	NF
☐	(Printing ink) Black Ink 1	Excipient	JP
☐	Excipient A	Excipient	USP
☐	Excipient B	Excipient	Ph. Eur.
Remove			

Film coating ingredient

Printing ink

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 <u>total</u> amount of the proprietary film coat, Coat Brand D.

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

4.2 Product Formula

4.2.1 Name of Substance *

4.2.2 Substance Type *

4.2.3 Grade *

4.2.4 Strength *

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	Active substance A	Active Ingredient	In-house	--
☐	(Film coat) Ingredient H	Excipient	USP	--
☐	(Film coat, Coat Brand D) Ingredient E	Excipient	In-house	3mg
☐	(Film coat, Coat Brand D) Ingredient F	Excipient	In-house	1mg
☐	(Film coat, Coat Brand D) Ingredient G	Excipient	In-house	1mg
☐	Excipient B	Excipient	USP	--
☐	Excipient C	Excipient	EP	--

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

For ingredients associated with a specific portion of the finished product, such as powder (active substance) and solvent (solution for reconstitution) or different layers of a multi-layered tablet, the relevant portion of the drug product should be identified in parentheses before the ingredient name of the excipients, as shown in Examples 4 and 5:

Example 4. A product with powder and solvent:

Select All	Name of Substance	Type of Substance	Grade
☐	Active Substance	Active Ingredient	In-house
☐	(Powder) Excipient A	Excipient	USP
☐	(Solvent) Excipient B	Excipient	EP
☐	(Solvent) Water for Injection	Excipient	Ph. Eur.

Excipient in powder →

Excipient in solvent →

Example 5. A multi-layered tablet:

☐ Select All	Name of Substance	Type of Substance	Grade
☐	Active Substance Y	Active Ingredient	In-house
☐	Active Substance Z	Active Ingredient	USP
☐	(Y Layer) Excipient A	Excipient	USP
☐	(Y Layer) Excipient B	Excipient	Ph. Eur.
☐	(Z Layer) Excipient C	Excipient	BP
☐	(Z Layer) Excipient D	Excipient	JP
Remove			

Do NOT include layer separation for active ingredients

Excipients in Y layer

Excipients in Z layer

Entering the strength of ingredients

The labelled strength and unit of the active substance must be aligned to the strength reflected in the PRISM product name and should not include over-fill/overage amounts.

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 form of the active substance (see Example 8)	30mg Active Substance potassium dihydrate	Active Substance potassium dihydrate	30mg
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:

4.2 Product Formula

4.2.1 Name of Substance * Active Substance phosphate eqv Active Substance

4.2.2 Substance Type * Active Ingredient ▾

4.2.3 Grade * USP

4.2.4 Strength * 30mg

New Save

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	Active Substance phosphate eqv Active Substance	Active Ingredient	USP	--

Remove

Enter the strength of the active substance **base** here if the strength stated on the product labels refers to the active ingredient in its **base** form.

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

4.2 Product Formula

4.2.1 Name of Substance * Active Substance phosphate

4.2.2 Substance Type * Active Ingredient ▾

4.2.3 Grade * USP

4.2.4 Strength * 30mg

New Save

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	Active Substance phosphate	Active Ingredient	USP	--

Remove

Enter the strength of the active substance **salt** here if the strength stated on the product labels refers to the active ingredient in its **salt** form.

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

4.2 Product Formula

4.2.1 Name of Substance * Active Substance potassium dihydrate

4.2.2 Substance Type * Active Ingredient ▾

4.2.3 Grade * USP

4.2.4 Strength * 30mg

New Save

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	Active Substance potassium dihydrate	Active Ingredient	USP	--

Remove

Enter the strength of the active substance **hydrate** here if the strength stated on the product labels refers to the active ingredient in its **hydrate** form.

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

4.2 Product Formula

4.2.1 Name of Substance * Active Substance sodium

4.2.2 Substance Type * Active Ingredient ▾

4.2.3 Grade * USP

4.2.4 Strength * 30mg

New Save

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	Active Substance sodium	Active Ingredient	USP	--

Remove

Enter the strength of the active substance **as described on the product label** here if the strength stated on the product labels refers to neither the active ingredient in its **base nor salt** form.

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:

4.2 Product Formula

4.2.1 Name of Substance *

4.2.2 Substance Type *

4.2.3 Grade *

4.2.4 Strength *

This strength will actually be entered here

Select All	Name of Substance	Type of Substance	Grade	Strength (Encrypted)
☐	(Residual) Human serum albumin	Excipient	In-house	--
☐	(Residual) Neomycin	Excipient	In-house	--
☐	(Residual) Ovalbumin content	Excipient	In-house	--

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

1.3.4.3 Section 4.3 – Ingredients Derived From Human Blood/Animal Sources

4.3 Please Indicate :

a) Whether any part of the product is derived from human blood *

☒ Yes ☐ No

State Source *

Note: If yes is selected, Country-specific Quality Requirements/Checklist for Human Blood Product documents will be mandatory to attach in the Supporting Attachment Page

b) Whether any part of the product or any raw materials used in the manufacturing process is derived from animal sources *

☒ Yes ☐ No

State Source *

Note: If yes is selected, Country-specific Quality Requirements/TSE Checklist documents will be mandatory to attach in the Supporting Attachment Page

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:

The screenshot shows a PRISM form for section 4.3(a). The title is '4.3 Please Indicate :'. The question is 'a) Whether any part of the product is derived from human blood *'. There are two radio buttons: 'Yes' (selected) and 'No'. Below the radio buttons is a text field labeled 'State Source' with a red asterisk. The text field contains the entry 'Human serum albumin - excipient - USA'. Below the text field is a 'Save' button. At the bottom of the form, there is a note: 'Note: If yes is selected, Country-specific Quality Requirements/Checklist for Human Blood Product documents will be mandatory to attach in the Supporting Attachment Page'.

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:

b) Whether any part of the product or any raw materials used in the manufacturing process is derived from animal sources *

☒ Yes ☐ No

State Source *

Bovine, gelatin – excipient – Germany

Save

Note: If yes is selected, Country-specific Quality Requirements/TSE Checklist documents will be mandatory to attach in the Supporting Attachment Page

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.

1.3.4.4 Section 4.4 – Pharmacotherapeutic Group

4.4 Pharmacotherapeutic group by ATC Code, if available :

WHO ATC Code for the proposed indication(s)

New Save

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.

NOTE: Do not insert spacing in-between the characters entered for the WHO ATC code.

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

1.3.4.5 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.

1.3.4.6 Section 4.6 – Route of Administration

Screenshots of PRISM section 4.6 is given below:

4.4 Pharmacotherapeutic
WHO ATC Code for the p

New Save

4.5 Dosage Form : *

4.6 Route of Administration : *

New Save

Select All List of Route of Administrations

Remove

INTRATUBULAR
INTRATUMOR
INTRATYMPANIC
INTRAUTERINE
INTRAVASCULAR
INTRAVERNOUS
INTRAVERNOUS BOLUS
INTRAVERNOUS DRIP
INTRAVENTRICULAR
Select One

Choose from the dropdown list and 'Save' before adding another option

Include all routes of administration proposed for the product.

4.5 Dosage Form : *

4.6 Route of Administration : *

New Save

Select All List of Route of Administrations

Remove

INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION

Select One

INTRAMUSCULAR

INTRAVERNOUS

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

1.3.4.7 Section 4.7 – Packaging, Shelf Life and Storage Conditions

List all packaging configurations proposed for registration and ensure that they match with those shown on the outer carton label.

4.7 Packaging, Shelf Life & Storage Conditions

4.7.1 Cold Chain *

☒ Yes
☐ No

4.7.2 Container Closure System*

PVC bottle

Description and composition of primary packaging. E.g. Brown type I borosilicate 20ml glass vial with butyl rubber stopper, PVC/PE blisters with alu foil, etc.

4.7.3 Quantity/Container*

50ml/bottle

Units per CCS. E.g. 5.25ml/vial, 7 tablets/blister, etc.

4.7.4 Shelf Life *

12

Months

4.7.5 Storage Condition*

below 5C

4.7.6 Pack Size *

2

Number of CCS in the secondary packaging. E.g. 1 vial/carton should be indicated as "1", 4 blisters/pack indicated as "4", etc.

New

Save

Select	Container Closure System (CCS)	Quantity per CCS	CCS per Pack	Shelf Life	Cold Chain	Storage Condition
☐	PVC bottle	50ml/bottle	2	12 Months	Yes	below 5C
☐	Type I glass ampoule	1ml	10	24 Months	Yes	below 5C

Remove

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 or accessory (e.g. vial adaptor, syringe and needle) is packed together with the drug product, applicants should include information of the medical device or accessory 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'

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 CCS per Pack should be entered as '5'. All pack sizes should be included.

A screenshot with PRISM section 4.7 entries is shown below:

Select	Container Closure System (CCS)	Quantity per CCS	CCS per Pack	Shelf Life	Cold Chain	Storage Condition
All						
☐	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	25mL/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:

4.7.6 Shelf Life (after first opening) :		Select One ▼
	255 characters left	
4.7.7 Shelf Life (after reconstitution) :		Select One ▼
	255 characters left	

1.3.4.8 Section 4.8 – Forensic Classification

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

4.8 Forensic classification in Singapore : *	Prescription Only Medicine ▼
--	------------------------------

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.

1.3.4.9 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:

4.9 Registration Status in Other Countries
Information from benchmark agencies and all rejections/withdrawals are mandatory

4.9.1 State Country :*

4.9.2 Application status : *

4.9.3 Status Date: (dd/mm/yyyy)

4.9.4 Application Details:

Details to be included are as follows:

1. Approved indication(s) and dosing regimen(s) for an approved application.
2. Reason for rejection/withdrawal for a rejected/withdrawn application.
3. Proposed SmPC/PI/PIL for an application pending evaluation by HSA's benchmark regulatory agencies (To be attached as supporting document).
4. Expected date of submission for an application pending submission to HSA's benchmark regulatory agencies.

4.9.5 Approved forensic classification :

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 <u>all</u> 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 must inform HSA of any rejection, withdrawal or deferral of any application and provide details of the reason(s) once it becomes known.

Additional details of the product's registration status in other countries may be submitted in PRISM section 7 (Supporting Attachments). The document should be in the format as seen in Table 8 of the main guidance.

1.3.4.10 Section 4.10 – Product Owner Information

4.10 Product Owner Information	
4.10.1 Name : *	Product Owner Pte Ltd
4.10.2 Product Owner Address	
4.10.2.1 Address Type : *	☐ Local ☒ Overseas
4.10.2.2 Address : *	123 Medicines Lane 1st Avenue
4.10.2.3 Country : *	UNITED STATES ▼
4.10.2.4 City :	New York
4.10.2.5 State :	New York
4.10.2.6 Postal Code :	12345

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

1.3.5 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.

1.3.5.1 *Active Substance Manufacturer*

The manufacturing site details for the final drug substance must be submitted in the product registration application, and it forms an integral part of the product registration.. Additional sites which perform any of the following critical steps in drug substance manufacturing must also be included:

- Production of critical drug substance intermediate
- Micronisation
- Sterilisation

For these additional sites, specify the manufacturing activity after the manufacturer's name in PRISM, e.g., "XYZ Limited (micronisation)".

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:

5. Manufacturer's Particulars

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

5.3 Name of Manufacturer : * Active Subst Manufacturer UVW

5.5 Site Address

5.5.1 Address Type : * ☐ Local ☒ Overseas

5.5.2 Address : * DEF street

5.5.3 Country : * UNITED STATES

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

Please choose active substance(s) for the manufacturer selected above.

5.8 Active Substance : * Select One

New Substance Select One
Active Substance Y
Active Substance Z

☐ Select All ☐ Active Substance Y

Remove Substance

5.9 Active Substance Manufacturer List

☐ Select All	Name of Manufacturer	Manufacturer Type
☐	Active Subst Manufacturer XYZ	Active Substance Manufacturer
☐	Active Subst Manufacturer UVW	Active Substance Manufacturer

Remove Manufacturer

New Manufacturer Save Manufacturer

'Save Substance' button

'Save Manufacturer' button

1.3.5.2 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.

a) 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.

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)
5.2 Regulatory GMP Audit : *	☒ Audited by HSA ☐ Pending Audit by HSA ☐ None of the above Licence No./GMP No. Retrieve
5.3 Name of Manufacturer : *	
5.4 Manufacturing Operation : *	Select One ▼

NOTE: Do not enter the local GMP Certificate No./ GMP Certificate Application No. of the local finished product manufacturer.

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.

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)
5.2 Regulatory GMP Audit : *	☐ Audited by HSA ☒ Pending Audit by HSA ☐ None of the above
Application No. Retrieve	
5.3 Name of Manufacturer : *	
5.4 Manufacturing Operation : *	Select One ▼
New Manufacturer Save Manufacturer	

b) Overseas Finished Product Manufacturer

For an overseas finished product manufacturer, enter both the manufacturing site and office (i.e. headquarters) 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 : *	Manufacturer ABC
5.4 Manufacturing Operation : *	Bulk Production/Primary Packaging/Secondary Packaging ▼
5.5 Site Address	
5.5.1 Address Type : *	☐ Local ☒ Overseas
5.5.2 Address : *	Street AAA
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

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

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 : *

Select All	Name of Manufacturer	Manufacturer Type
☐	Active Subst Manufacturer XYZ	Active Substance Manufacturer
☐	Active Subst Manufacturer UVW	Active Substance Manufacturer
☐	Manufacturer ABC	Finished Product Manufacturer (Overseas)
☐	Manufacturer ABC	Finished Product Manufacturer (Overseas)
☐	Manufacturer POR	Finished Product Manufacturer (Overseas)

Remove Manufacturer

New Manufacturer Save Manufacturer

'Save Manufacturer' button

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:

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 ABC

5.4 Manufacturing Operation : * Select One

5.5 Site Address

5.5.1 Address Type : * ☐ Bulk Production
☐ Bulk Production (Solvent/Diluent)
☐ Bulk Production (Drug Product Intermediate)
☐ Primary Packaging
☐ Secondary Packaging

5.5.2 Postal Code : * # [] - []

5.5.3 Block / House No : []

5.5.5 Street Name : []

5.5.6 Building Name : []

5.5.7 Country : []

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

Select All	Name of Manufacturer	Manufacturer Type
Remove Manufacturer		

New Manufacturer Save 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.

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 : *

5.4 Manufacturing Operation : *

5.5 Site Address

5.5.1 Address Type : * ☐ Local ☒ Overseas

5.5.2 Address : *

5.5.3 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

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.

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 EFG
5.4 Manufacturing Operation : *	Bulk Production (Drug Product Intermediate)
5.5 Site Address	
5.5.1 Address Type : *	☐ Local ☒ Overseas
5.5.2 Address : *	Street EEE
5.5.3 Country : *	ECUADOR
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 “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	

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 : *

☐ Select All	Name of Manufacturer	Manufacturer Type
☐	Active Subst Manufacturer XYZ	Active Substance Manufacturer
☐	Active Subst Manufacturer UVW	Active Substance Manufacturer
☐	Manufacturer JKL	Finished Product Manufacturer (Overseas)
☐	Manufacturer JKL	Finished Product Manufacturer (Overseas)
☐	Manufacturer ABC	Finished Product Manufacturer (Overseas)

Remove Manufacturer

New Manufacturer

Save Manufacturer

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	

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 : *

Select All	Name of Manufacturer	Manufacturer Type
☐	Active Subst Manufacturer XYZ	Active Substance Manufacturer
☐	Active Subst Manufacturer UVW	Active Substance Manufacturer
☐	Manufacturer MNO	Finished Product Manufacturer (Overseas)
☐	Manufacturer MNO	Finished Product Manufacturer (Overseas)
☐	Manufacturer ABC	Finished Product Manufacturer (Overseas)

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.

1.3.6 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.

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 : * ABC 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 : * Select One 'Save Manufacturer' button

Save Manufacturer Select One Manufacturer ABC

☒ Select All Name of Batch

Remove Batch Releaser 'Save Batch Releaser' button

New Batch Releaser Save Batch Releaser

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.

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 : *

6.2 Site Address

6.2.1 Address Type : * ☒ Local ☐ Overseas

6.2.2 Postal Code : *

6.2.3 Block / House No : 6.2.4 Level - Unit : # -

6.2.5 Street Name :

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 ▼

Select All	Name of Batch Releaser
☐	ABC Pte Ltd
☐	DEF Pte Ltd

Two batch releasers for this product

1.3.7 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, or submit via eCTD.

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.

1.3.7.1 Submission via PRISM

Documents must be uploaded correctly under their respective section headers. For example, Certificate of Pharmaceutical Product (CPP) should be attached under “1.8 Proof of Approval” and not under “Other Supporting Documents” section.

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.

Literature References :

7.56 Other Supporting Documents :

Note :
Please fill up the template ([download here](#)) if you are sending the supporting attachment(s) via CD, after which you are required to save a copy and attach it under "CD Submission."

A Dossier Clarification Supplement is required for NDAs and GDAs filed under the abridged evaluation route and for which approval has been obtained from at least one of HSA's reference agencies not more than 5 years before the date of submission to HSA. The document can be uploaded in PRISM under "Other Supporting Documents" (refer to Appendix 18).

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.

Note :
Please fill up the template ([download here](#)) if you are sending the supporting attachment(s) via CD, after which you are required to save a copy and attach it under "CD Submission."

Select All to delete all attachment records

Sn	☐	Attachment Name	Attachment Type	Size (Kb)	Remarks
1	☐	Attachment 1.doc	CD Submission	19	
2	☐	test.txt	Module 1 – Comprehensive Table of Contents	1	

To remove an attachment, click on the checkbox. Then hit the Remove button to remove the attachment from the list.

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.

7.65 Module 3 – List of Literature References : *	Browse...
7.66 Module 5 – Table of Contents : *	Unable to add "test.txt" due to following reason : The same file name exist Browse...
7.67 Module 5 – Tabular Listings of All Clinical Studies : *	Browse...
7.68 Module 5 – Clinical Study Reports / Reports of	Browse...

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.

Select All to delete all attachment records

Sn	☐	Attachment Name	Attachment Type	Size (Kb)	Remarks
1	☐	Attachment 1.doc	CD Submission	19	
2	☒	test.txt	Module 1 – Comprehensive Table of Contents	1	

To remove an attachment, click on the checkbox. Then hit the Remove button to remove the attachment from the list.

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.

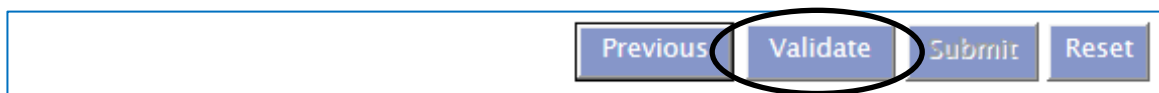
1.3.7.2 Submission via eCTD

For dossier submission in eCTD format, applicants must prepare the dossier according to the current SG-HSA eCTD Specification and submit the eCTD package via the [SG-HSA eCTD portal](#). **Submission of Module 1 to Module 5 documents in PRISM is not required.** Instead, applicants should upload a file titled [eCTD ID] for document 7.1 – *CD Submission* to indicate that the submission is via eCTD.

1.3.8 Section 8 – Confirmation

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

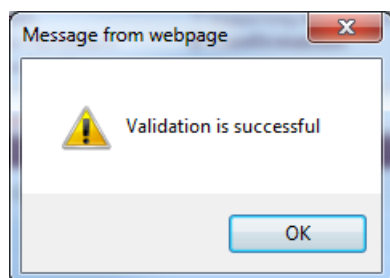
Applicants may click scroll down to the bottom of the page and click the “Validate” button to check if all the mandatory fields had been filled up.



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

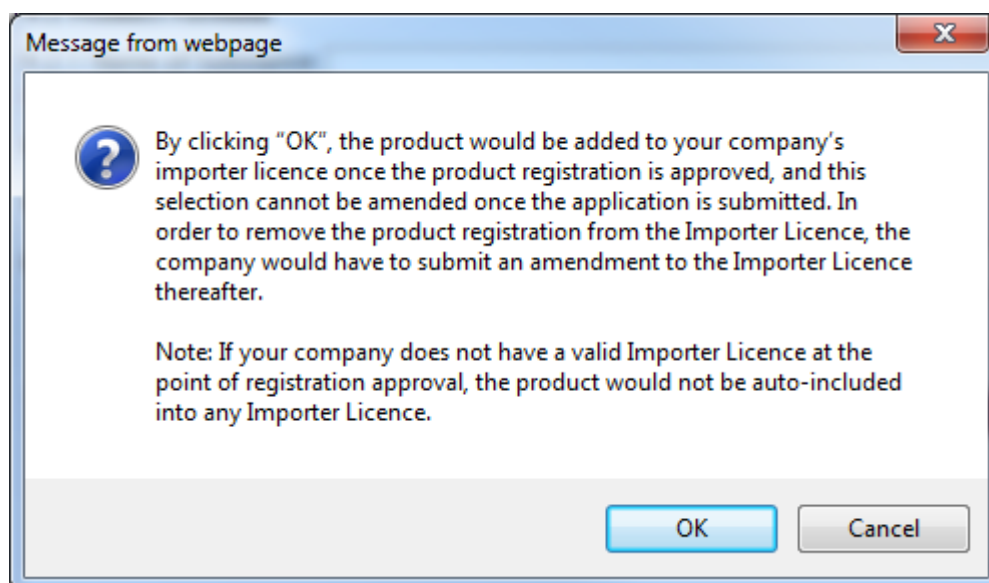
PZ0101 VALIDATION ERROR REPORT	
2. Applicant Particulars	
2.1	Name for applicant is mandatory
2.2	NRIC/FIN for applicant is mandatory
2.3	Designation for applicant is mandatory
2.4.1	Telephone number in applicant is mandatory
2.5.1	Preferred contact mode for applicant is mandatory
4. Product Information	
4.1	Proprietary 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:

Auto-Inclusion to Importer Licence	
☐	Click here to agree that, if this registration is approved and the company is the importer for the product below, the product shall be auto-included into the company's valid importer licence.



Note: This selection cannot 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.

Auto-Inclusion to Importer Licence	
☐	Click here to agree that, if this registration is approved and the company is the importer for the product below, the product shall be auto-included into the company’s valid importer licence.
All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.	
Declaration	
1.	I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
2.	I, on behalf of my company, undertake to notify the Health Sciences Authority of any changes in the particulars submitted in the application and of any new significant safety information during the course of evaluation.
3.	I, on behalf of my company, undertake to notify and provide reasons thereof to the Health Sciences Authority (HSA) of any rejection, deferral of decision, or withdrawal of pending applications/products by any regulatory authorities due to quality, safety or efficacy reasons, during the course of evaluation.
Accept ☐ Decline ☐	

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.

Payment Advice			
Sn	Description	Amount (SGD)	GST
1	CH NDA-1 Abr Dos Scr Fee	550.00	N
2	CH NDA-1 Abr Dos Eva Fee	11000.00	N

The total payment for your application is SGD **11550.00**.

Progressive Payment: ☒ Full payment ☐ Progressive Payment

The amount of SGD **11550.00** will be deducted from your Giro Account.

[Previous](#)
[Validate](#)
[Submit](#)
[Reset](#)

1.3.9 Acknowledgement

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

Logon ID: Client Name: LTD - NEW Application No: 2200170T [Logout](#)

Date of Submission: 29/03/2022

PT0101 THERAPEUTIC PRODUCT REGISTRATION

Acknowledgement	
Your application has been successfully submitted	
Please note that your application number is 2200170T	
Client Code	: C001 X
Registration Name	: SH TD - NEW

[Print Confirmation Page](#)

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

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 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.

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	Special Symbol Attach Save	
1. Company Particulars	4. Product Details	7. Supporting Attachments		
2. Applicant Particulars	5. Manufacturer Particulars	8. Confirmation		

Next

0. Registration/Permit/Certificate/Listing/Registration Summary	
0.1 Registration/Permit/Certificate/Listing/Registration No.:	SIN14381P
0.2 Retention Date:	19/12/2018
0.3 Remarks:	
0.4 Table of Summary of Changes:	Table of Summary of Changes template (attach under section 7 Supporting Attachments).
0.5 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.:	SIN16512P
0.2 Retention Date:	21/09/2018
0.3 MIV Checklist Number (Primary Change):*	Please Select One
0.4 MIV Checklist Number (Secondary Change(s)):	Available MIV Checklist B1 Addn or Repl of Mfr/site of DS [CEP B2 Addn or Repl of Mfr/site of DS [CEP B3 Major Chg of Mfg Proc of DS [CEP nc B4 Major Chg of Mfg Proc of DS [CEP Av B5 Chg of Spec of DS [CEP not Avail] B6 Chg of Spec of DS [CEP Avail] B7 Addn or Repl of Mfg Site of DP B8 Addn or Repl of Mfg Site for PriPac B9 Chg of Release / Shelf-life Spec of C B10 Chg of Batch Size of Sterile DP B11 Chg of Batch Size of Non-sterile D B12 Major Chg in Mfg Proc for DP B13 Qual or Quan Chg of Excipient B14 Quan Chg in Coat W, Cap Shell W/s B15 Chg in PriPac Mtl for Sterile DS or I B16 Chg or Addn Pack Size/Vol/Shape B17 Incl or Repl of Solvent/Diluent for I B18 Chg of Shelf-life of DP B19 Chg of Storage Cond of DP B20 Addn or Chg of Functional Score/B Selected MIV Checklist
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 ☐ N ☒

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.

The screenshot displays the '0. Registration/Permit/Certificate/Listing/Registration Summary' section of the PRISM application form. It includes fields for '0.1 Registration/Permit/Certificate/Listing/Registration No.: SIN16512P', '0.2 Retention Date: 21/09/2018', and '0.3 MIV Checklist Number (Primary Change):*'. The dropdown for 0.3 is set to 'Others', with a text box below it asking for details of MIV changes not specified in Appendices 13 or 14. The '0.4 MIV Checklist Number (Secondary Change(s)):' section features two columns: 'Available MIV Checklist' and 'Selected MIV Checklist'. The available list includes items B1 through B12, such as 'B1 Addn or Repl of Mfr/site of DS [CEP nc]', 'B2 Addn or Repl of Mfr/site of DS [CEP nc]', 'B3 Major Chg of Mfg Proc of DS [CEP nc]', 'B4 Major Chg of Mfg Proc of DS [CEP nc]', 'B5 Chg of Spec of DS [CEP not Avail]', 'B6 Chg of Spec of DS [CEP Avail]', 'B7 Addn or Repl of Mfg Site of DP', 'B8 Addn or Repl of Mfg Site for PriPac', 'B9 Chg of Release / Shelf-life Spec of C', 'B10 Chg of Batch Size of Sterile DP', 'B11 Chg of Batch Size of Non-sterile DI', and 'B12 Major Chg in Mfg Proc for DP'. Navigation arrows are present between the columns.

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 Checklist C26 Addn or Repl of Mfr for PriPac for i 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 M 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 L 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 >><< Selected MIV Checklist
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 Checklist C26 Addn or Repl of Mfr for PriPac for i 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 M 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 L 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 >><< Selected MIV Checklist
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 Checklist 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 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 Checklist
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 ☒ 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.

PQ1001 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
2. Applicant Particulars	5. Manufacturer Particulars	8. Confirmation

Special Symbol Attach Save

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

Fields marked with an asterisk * are mandatory.

3. Application Details

3.1 Type of Application : *	MIV-1
3.2 Type of Product : *	Chemical Drug
3.3 Ref. Therapeutic Product Registration No. : *	123
Ref. Product Application No. :	
3.4 Is the product intended for export only?	Yes
3.5 Type of Dossier : *	Select One Abridged Verification
HSA reserves the right to request for a specific dossier type for an application.	
3.6 Type of Format : *	ASEAN CTD

Once the Format type and Product type are selected and confirmed, they will apply to all the future amendments.

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

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

For changes to company information such as company name, company address, contact details and other related information, please submit the change using the

Change of Business Information e-Service:

<http://eservice.hsa.gov.sg/osc/portal/jsp/AA/process.jsp?eService=201>

For changes to applicant's details and pending applications, please submit the change using the "Amend applicant's details for licences and applications" e-Service:

<http://eservice.hsa.gov.sg/osc/portal/jsp/AA/process.jsp?eService=204>

3 RESPONDING TO INPUT REQUEST (IR)

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 can retrieve the IR and submit response to the IR via Track@PRISM.

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

For submission in eCTD format, applicant should only respond to IR in PRISM after the eCTD package has been submitted and successfully passed validation.

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”.

PZ0951 TRACK@PRISM

Important Notes:

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

General Search

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

Application/Submission Type *

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

Enquiry Type *

Transaction No.

Application/Submission No.

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

Product Name.

Submission Date (dd/mm/yyyy) To

Last Update Date (dd/mm/yyyy) To

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

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

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

New Application/Submission for Therapeutic Products – Product Registration (Input Request)							
S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1400228K	T1400310K	name	Input Request	09/12/2016	28/10/2014	Click here for Primary IR (26/07/2016)

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

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

Note:

Application resubmission is required for Primary IR but not for Secondary IR.

For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

- 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



PZ0951 TRACK@PRISM

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

General Search

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

Application/Submission Type *

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

Enquiry Type *

Transaction No.

Application/Submission No.

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

Product Name.

Submission Date (dd/mm/yyyy) To

Last Update Date (dd/mm/yyyy) To

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

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

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

New Application/Submission for Therapeutic Products – Product Registration (Input Request)							
S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1400228K	T1400310K	name	Input Request	09/12/2016	28/10/2014	Click here for Primary IR (26/07/2016)

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

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

Note:
Application resubmission is required for Primary IR but not for Secondary IR.
For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

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.

When submitting documents in response to IR, the documents must be uploaded under the respective section headers. For example, Certificate of Pharmaceutical Product (CPP) should be attached under “1.8 Proof of Approval” and not under the “Other Supporting Documents” section.

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.

PZ0951 TRACK@PRISM

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

General Search

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

Application/Submission Type *

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

Enquiry Type *

Transaction No.

Application/Submission No.

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

Product Name.

Submission Date (dd/mm/yyyy) To

Last Update Date (dd/mm/yyyy) To

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

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

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

New Application/Submission for Therapeutic Products – Product Registration (Input Request)							
S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1400228K	T1400310K	name	Input Request	26/11/2016	28/10/2014	Click here for Secondary IR (26/07/2016)

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

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

INPUT REQUEST LIST (SECONDARY)

Application No

: 1400228K

Product Name

: name

Please reply with comments for each item in the action list and submit this secondary input request.
Please note that resubmission of the application is not required.

1 Records

Action List

SN	Action	Due Date	Applicant's Response (if any)
1.	Test. Please clarify on xxxxxx.	26/11/2016	

Documents Attached

SN	Attachment Name	Size (Kb)	Remarks
1	test3.txt	4	

Submit

Cancel



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”.

PZ2001 WITHDRAW@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/Registration Type*

Application Type

Application no.

Product Name

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

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

Pending Approval Therapeutic Products – Product Registration Application(s)		
S/No	Application No	Action
1	2200190G	Withdraw

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

For submissions using eCTD format, please refer to the current SG-HSA eCTD Specification on the process of submission withdrawal.

PZ2321 WITHDRAWAL APPLICATION OF THERAPEUTIC PRODUCT REGISTRATION


Special Symbol

1. Application Summary

1.1 Application No.:	2200190G
1.2 Original Application Date:	19/04/2022
1.3 Application Status:	Pending Approval

2. Applicant Particulars

2.1 Name: *

3. Withdrawal Details

3.1 Reason for withdrawal: *

All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

☐ Accept ☐ Decline

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

Date of Submission:
19/04/2022

[Logout](#)

PZ2322 WITHDRAWAL APPLICATION OF THERAPEUTIC PRODUCT REGISTRATION

Acknowledgement

Your withdrawal application has been successfully submitted

Please note that your application number is 2200190G

Client code :

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**.

If the applicant requires the withdrawal request to be processed 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.
