REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS

APPLICATION FOR SPECIAL CONSIGNMENT BY A PRODUCT REGISTRANT

Please complete all fields in section 1 to 3, and provide the required confirmation and declarations in section 4 and 5.

1. Registrant Information		
1.1	Name of applicant	
1.2	Designation	
1.3	Company name	
1.4	Company address	
2. Product Information		
2.1	Registration number	
2.2	Product name (as stated in PRISM)	
2.3	Active ingredient	
3. Details of Application		
3.1	Reasons for inability to supply Singapore-registered product	
3.2	Justifications on medical need for the product	
3.3	Availability of registered alternative products (products containing the same active ingredient & strength)	☐ Yes, please specify: ☐ No
3.4	Projected date by which the supply of Singapore-registered product will resume	
3.5	Duration which the requested stock is expected to last (maximum 6 months)	
3.6	Quantity per Container Closure System (CCS) e.g. 10 tablets per blister	
3.7	CCS per Pack e.g. 10 blisters per box	
3.8	Total quantity requested e.g. 100 boxes	

3.9	Justification for requested quantity e.g. historical sales data	*Note: if the consignment is required to fulfil ALPS' tender obligations, please provide tender contract number and duration*
3.10	Batch number	
3.11	Manufacturing date	
3.12	Expiry date	
3.13	Country that the consignment batch was originally intended for	
3.14	Proposed distribution plan for the Singapore approved package insert/patient information leaflet and clarification letter to healthcare professionals e.g. per unit of consignment product, per prescriber	

4. Applicant's Assessment of Product's Quality and Labelling & Undertakings		
4.1	☐ ☐	I confirm that the consignment batch is the same as the Singapore registered product in all quality aspects (including but not limited to formulation, container closure system, manufacturing process, quality and manufacturing controls, storage condition, shelf life, drug substance and drug product manufacturing sites and specifications). OR I confirm that there are differences in the quality aspects between the consignment batch and the Singapore registered product, and that the product's quality complies with current monograph standards or has obtained prior approval by a competent regulatory agency (*please provide details in Annex 1*).
4.2	☐	I confirm that there are no outstanding product quality defect issues or investigations for this product.
4.3	☐	I confirm that the product labels (i.e. outer carton, inner label) of the consignment product will contain the same content (information) as the approved labels of the Singapore-registered product at the point of supply to the healthcare institutions/pharmacies.
4.4	☐	I undertake to supply the consignment product with the Singapore approved package insert and/or patient information leaflet.
4.5	☐	I confirm that all redressing activities will be performed at a facility with a valid manufacturing licence and/or GMP certificate.
4.6	☐	I undertake to provide a clarification letter to healthcare professionals on the differences between the consignment product and the Singapore-registered product (*draft clarification letter to be submitted with this application*).
4.7	☐	I confirm that my company will take full responsibility for ensuring the quality, safety and efficacy of the consignment batch.

5. Declarations

I hereby declare that the information provided by me in this form and the appended Annex is true and accurate. I acknowledge that if any of the information provided by me is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.

_____ _____ _____

(Signature) (Name, designation) (Date)

Annex 1: Quality differences between Singapore-registered product and consignment product

A1. The quality difference(s) are described in the following table (*please complete all columns for each difference*).

Section in Original Dossier Affected by Change	Singapore Registered Product	Consignment Product	Reason for Difference(s) and Impact on Overall Product Quality	Approved by any Reference Agencies [Yes/No] If yes, please specify	Approved by any other competent regulatory agencies [Yes/No] If yes, please specify

A2. Please state if the consignment batches comply with any pharmacopoeia: