FORM 1

REPUBLIC OF SINGAPORE

HEALTH SCIENCES AUTHORITY

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS 2016

DECLARATION ON PATENT RELATED INFORMATION FOR APPLICATION FOR REGISTRATION OF A THERAPEUTIC PRODUCT UNDER THE HEALTH PRODUCTS ACT 2007

Application No (for HSA use only): ☐

SECTION 1: APPLICANT PARTICULARS

Company Name	
Company Address	

SECTION 2: PRODUCT PARTICULARS

Proprietary Name	
Active Substance(s) and Strength	
Dosage Form	

SECTION 3: APPLICATION CATEGORY

Application Category *(check one box)*

☐ Category A1 (Proceed to Section 4)

Refers to an application where no restraining patent[1] is in force in respect of the therapeutic product to which the application relates.

☐ Category A2 (Proceed to Section 5)

Refers to an application where —

(*a*) a restraining patent is in force in respect of the therapeutic product to which the application relates; and

(*b*) the applicant is either the proprietor of the restraining patent or, if the applicant is not the proprietor of the restraining patent, the proprietor has consented to or acquiesced in the grant of the registration.

☐ Category A3 (Proceed to Section 6)

Refers to an application where —

(*a*) a restraining patent is in force in respect of the therapeutic product to which the application relates;

(*b*) the applicant is not the proprietor of the restraining patent;

(*c*) the proprietor has not consented to nor acquiesced in the grant of the registration; and

(*d*) the applicant is requesting for registration to be granted after the restraining patent expires.

A Category A3 declaration is applicable only to an application that is made within 18 months of the expiry of the restraining patent from the point of application submission. Such an application may not be made earlier than 18 months before the restraining patent expires.

☐ Category B (Proceed to Section 7)

Refers to an application where —

(*a*) a restraining patent is in force in respect of the therapeutic product to which the

	application relates; (*b*) the applicant is not the proprietor of the restraining patent; (*c*) the proprietor has not consented to nor acquiesced in the grant of the registration; and (*d*) in the opinion and to the best belief of the applicant, the restraining patent is invalid or will not be infringed by the doing of the act for which the registration is sought.
SECTION 4: INFORMATION FOR CATEGORY A1 APPLICATIONS	
I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —	
☐	There is no patent in force under the Patents Act 1994 which relates to a restraining patent in respect of the product stated in Section 2 on the date of this declaration.
SECTION 5: INFORMATION FOR CATEGORY A2 APPLICATIONS	
I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that — *(check one box)*	
☐	(*a*) A patent is in force under the Patents Act which relates to a restraining patent in respect of the product stated in Section 2 on the date of this declaration. (*b*) I am the proprietor of the restraining patent. (*c*) The Singapore Patent No. for the restraining patent is ☐
☐	(*a*) A patent is in force under the Patents Act which relates to a restraining patent in respect of the product stated in Section 2 on the date of this declaration. (*b*) I am not the proprietor of the restraining patent but the proprietor has consented to or acquiesced in the grant of the registration for the product stated in Section 2 to me. (*c*) The name and address of the proprietor of the restraining patent or his authorised agent are ☐ (*d*) The Singapore Patent No. for the restraining patent is ☐
SECTION 6: INFORMATION FOR CATEGORY A3 APPLICATIONS	
I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —	
☐	(*a*) A patent is in force under the Patents Act which relates to a restraining patent in respect of the product stated in Section 2 on the date of this declaration. (*b*) I am not the proprietor of the restraining patent and the proprietor has not consented to nor acquiesced in the grant of the registration for the product stated in Section 2 to me. (*c*) I am requesting for the grant of the registration after the restraining patent expires. (*d*) I am making the application not earlier than 18 months before the expiry of the restraining patent from the point of application submission. (*e*) The name and address of the proprietor of the restraining patent or his authorised agent are ☐ (*f*) The Singapore Patent No. for the restraining patent is ☐ (*g*) The restraining patent will expire on ☐ (dd/mm/yyyy), which is ☐ months from the date of my registration application.

SECTION 7: INFORMATION FOR CATEGORY B APPLICATIONS	
I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —	
☐	(*a*) A patent is in force under the Patents Act which relates to a restraining patent in respect of the product stated in Section 2 on the date of this declaration. (*b*) I am not the proprietor of the restraining patent and the proprietor has not consented to nor acquiesced in the grant of the registration for the product stated in Section 2 to me. (*c*) In my opinion and to my best belief, the restraining patent is invalid or will not be infringed by the doing of the act for which the registration is sought. (*d*) The name and address of the proprietor of the restraining patent or his authorised agent are (*e*) The Singapore Patent No. for the restraining patent is (*f*) The restraining patent will expire on (dd/mm/yyyy).

SECTION 8: DECLARATION

1. I am duly authorised by the applicant to make this declaration on behalf of the applicant, and enclose with this declaration form evidence of such authorisation[2].
2. I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that all information furnished in this form is true.
3. I am aware that the Health Sciences Authority may rely on, and need not be concerned to enquire into the truth of, any statement made in this declaration form.
4. I am aware that a false declaration is an offence under regulation 25 of the Health Products (Therapeutic Products) Regulations 2016.
5. I further undertake to notify the Health Sciences Authority of any change in the information furnished in this form.

Signature	Name, designation	Date

[1] A "restraining patent" refers to a patent mentioned in regulation 23(1)(a) of the Health Products (Therapeutic Products) Regulations 2016.

[2] Please enclose appropriate evidence of authorisation. Delete this statement if applicant is a natural person making the application personally.