

APPENDIX 1 PATENT DECLARATION FORMS

Form 1 – Declaration on patent related information for application for registration of a therapeutic product under the Health Products Act 2007

Form 2 – Notice to proprietor of patent

REVISION HISTORY

Form Version

TPB-SUB-002-005 (version 6; updated 30 June 2023)

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*)

- | | |
|--------------------------|---|
| <input type="checkbox"/> | <p>Category A1 (Proceed to Section 4)
 Refers to an application where no patent is in force in respect of the therapeutic product to which the application relates.</p> |
| <input type="checkbox"/> | <p>Category A2 (Proceed to Section 5)
 Refers to an application where —</p> <ul style="list-style-type: none"> (a) a 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 patent or, if the applicant is not the proprietor of the patent, the proprietor has consented to or acquiesced in the grant of the registration. |
| <input type="checkbox"/> | <p>Category A3 (Proceed to Section 6)
 Refers to an application where —</p> <ul style="list-style-type: none"> (a) a patent is in force in respect of the therapeutic product to which the application relates; (b) the applicant is not the proprietor of the 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 patent expires. <p>A Category A3 declaration is applicable only to an application that is made within 18 months of the patent expiry from the point of application submission. Such an application may not be made earlier than 18 months before the patent expires.</p> |
| <input type="checkbox"/> | <p>Category B (Proceed to Section 7)
 Refers to an application where —</p> <ul style="list-style-type: none"> (a) a patent is in force in respect of the therapeutic product to which the application relates; (b) the applicant is not the proprietor of the 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 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 —	
<input type="checkbox"/>	There is no patent under the Patents Act 1994 in force 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 — <i>(check one box)</i>	
<input type="checkbox"/>	(a) A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. (b) I am the proprietor of the patent. (c) The Singapore Patent No. for the patent is
<input type="checkbox"/>	(a) A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. (b) I am not the proprietor of the 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 patent or his authorised agent are (d) The Singapore Patent No. for the 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 —	
<input type="checkbox"/>	(a) A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. (b) I am not the proprietor of the 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 patent expires. (d) I am making the application not earlier than 18 months before the patent expiry from the point of application submission. (e) The name and address of the proprietor of the patent or his authorised agent are (f) The Singapore Patent No. for the patent is (g) The 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 —	
<input type="checkbox"/>	(a) A patent under the Patents Act is in force in respect of the product stated in Section 2 on the

	<p>date of this declaration.</p> <p>(b) I am not the proprietor of the 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.</p> <p>(c) In my opinion and to my best belief, the patent is invalid or will not be infringed by the doing of the act for which the registration is sought.</p> <p>(d) The name and address of the proprietor of the patent or his authorised agent are</p> <p>(e) The Singapore Patent No. for the patent is</p> <p>(f) The patent will expire on _____ (dd/mm/yyyy).</p>
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SECTION 8: DECLARATION

<p>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[#].</p> <p>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.</p> <p>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.</p> <p>4. I am aware that a false declaration is an offence under the Health Products Act 2007.</p> <p>5. I further undertake to notify the Health Sciences Authority of any change in the information furnished in this form.</p>		
_____ Signature	_____ Name, designation	_____ Date

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

FORM 2

REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY
HEALTH PRODUCTS (THERAPEUTIC PRODUCTS)
REGULATIONS 2016

NOTICE TO PROPRIETOR OF PATENT

Date:

Name and Address of Proprietor of Patent:

Dear Sir

Notice under regulation 23(5) of the Health Products (Therapeutic Products) Regulations 2016

According to regulation 23(5) of the Health Products (Therapeutic Products) Regulations 2016 and as required by the Health Sciences Authority (HSA), I notify you that the following application to register a therapeutic product under the Health Products Act 2007 has been made to the HSA:

Registration Application Number:

Product Name:

Active Substance(s) and Strength:

Dosage Form:

Date of Filing of Registration Application:

Patent Number and Expiry Date of the Relevant Patent:

2. In my opinion and to the best of my belief, the abovementioned patent is invalid or will not be infringed by the doing of the act for which the registration is sought.

Name of applicant or his authorised agent

Signature

Name and address of applicant company

Copy to:

Health Sciences Authority

[Acknowledgement and date of receipt by proprietor of patent]