

Note to Applicant:

- a. Please download the latest version of the form at <http://www.hsa.gov.sg>.
- b. The form should be completed in English except if the product contains Chinese herbs and is intended to be a CPM.
(除产品含有中药成分并欲作为中成药外，此表格需以英文填写。)
- c. Please ensure that all mandatory fields (indicated by red boxes) are completed, including the declaration in Section **D. Incomplete forms will not be processed and will be rejected.**
- d. After completion of the form, click on the "Save" button on the first page or last page of the form to validate (check that all mandatory fields are completed) and save the form.
- e. Please send the completed form and related attachments (copy of product label, packaging and package insert) to:
Email: **HSA_Prod_Class@hsa.gov.sg**, Fax: **(65) 6478 9076** or
Address: **11 Biopolis Way #11-01 Helios Singapore 138667**

Please use **UP ARROW KEY / DOWN ARROW KEY** to navigate line by line.

And **PAGE UP and PAGE DOWN** key to navigate page by page.

(注意：请用↑键或↓键逐行浏览，用PgUp键或PgDn键逐页浏览。)

SECTION A - PARTICULARS OF ENQUIRER (询问人资料)			
Salutation 称呼			
Name 姓名			
Designation 职位			
Company Name 公司名称			
Company Address 公司地址			
Block / House No. 门牌号码		City 市	
Street Name 街道名称		State / Province 州 / 省	
Level 楼层		Country 国家	
Unit 单位号码		Postal Code 邮政编码	
Building 大厦			
Contact Information 联络信息			
Telephone Country Code 国家电话代码		Office Tel 办公电话	
Mobile 手机号码		Fax No. 传真号码	
Home Tel 住宅电话		Email Address 电邮地址	

SECTION B - PURPOSE & HISTORY OF ENQUIRY (询问目的及询问历史)
<p>(i) Enquiry on this product in relation to (询问内容涉及):</p> <p> <input type="checkbox"/> Import 进口 <input type="checkbox"/> Wholesale / Retail 批发/零售 <input type="checkbox"/> Manufacture 制造 <input type="checkbox"/> Assembly 分装 <input type="checkbox"/> Advertisement 广告 <input type="checkbox"/> Developmental product with incomplete information on formulation / concentration / label * 研发中的产品其成分/浓度/标签* 的资料不完整 <input type="checkbox"/> Others (specify) 其它 (请注明): <small>* Delete as appropriate (请删除不适用项)</small> </p> <p>(ii) Have you enquired on this product previously (以前是否曾咨询过该产品)?</p> <p><input type="checkbox"/> No 无 <input type="checkbox"/> Yes 有</p> <p>If yes (如有):</p> <p>a) Please state the date of the previous enquiry (请注明上次询问的时间):</p> <p>b) Please state the agency / unit where the enquiry was sent to (请注明曾向哪个机构/部门提交过咨询):</p>

SECTION C - PRODUCT DETAILS (产品资料)

SECTION C1 - BASIC PRODUCT DETAILS (基本资料)

(i) Brand Name 商标名称	
(ii) Product Name 产品名称	
(iii) Name of Manufacturer 制造商名称	
(iv) Country of Manufacture 制造商国家	
(v) Classification in Country of Manufacture 产品在原产国的分类	<input type="checkbox"/> Medicinal Product 西药 <input type="checkbox"/> Medical Device 医疗器械 <input type="checkbox"/> Health Supplement 保健品 <input type="checkbox"/> Cosmetic Product 化妆品 <input type="checkbox"/> Chinese Proprietary Medicine (CPM) 中成药 <input type="checkbox"/> Traditional Medicine (TM) 传统药 <input type="checkbox"/> Others (specify) 其它 (请注明):
(vi) Intended use / Indications of use in Singapore (i.e. functions / claims) 产品在新加坡的适应症 (如: 功能/宣称)	

SECTION C2 - STATUS OF PRODUCT IN OTHER COUNTRIES (产品在其它国家的情况) [Please attach a separate sheet if space is insufficient (如表中位置不够, 请另附一页).]

Country 国家	Marketed? 已上市?		Product Classification in the Country 产品在该国的分类
	Yes 是	No 否	
Australia 澳洲	<input type="checkbox"/>	<input type="checkbox"/>	
Canada 加拿大	<input type="checkbox"/>	<input type="checkbox"/>	
European Union (EU) 欧盟	<input type="checkbox"/>	<input type="checkbox"/>	
United States 美国	<input type="checkbox"/>	<input type="checkbox"/>	
Japan 日本	<input type="checkbox"/>	<input type="checkbox"/>	
China 中国	<input type="checkbox"/>	<input type="checkbox"/>	
Hong Kong 香港	<input type="checkbox"/>	<input type="checkbox"/>	
India 印度	<input type="checkbox"/>	<input type="checkbox"/>	
Malaysia 马来西亚	<input type="checkbox"/>	<input type="checkbox"/>	
South Korea 韩国	<input type="checkbox"/>	<input type="checkbox"/>	
Taiwan 台湾	<input type="checkbox"/>	<input type="checkbox"/>	
Others 其它 -	<input type="checkbox"/>	<input type="checkbox"/>	
Others 其它 -	<input type="checkbox"/>	<input type="checkbox"/>	
Others 其它 -	<input type="checkbox"/>	<input type="checkbox"/>	
Others 其它 -	<input type="checkbox"/>	<input type="checkbox"/>	

SECTION C3 - DESCRIPTION OF FINISHED PRODUCT (产品资料) [For Medical Devices, please fill in only where applicable (医疗器械产品仅填写相关部分).]

(i) Dosage form 剂型 <i>(e.g. tablet, syrup, injection, powder, etc)</i> (如片剂, 糖浆剂, 注射剂, 散剂等)	Others (specify) 其它 (请注明):		
(ii) Route of Administration 用法 <i>(e.g. oral, topical, intravenous, inhalation, etc)</i> (如口服, 外用, 静脉给药, 吸入等等)	Others (specify) 其它 (请注明):		
(iii) Ingredients – herbs should be specified by botanical names and Chinese name, where applicable (<i>成份-草药成份需注明植物拉丁名和中文名 [如有]</i>)	(iv) Strength* <i>含量(e.g. IU, mg, mcg, %, etc)</i>	(v) To select 请选择	
		Active 活性	Inactive 非活性
* Based on the product classification in the country of manufacture (根据产品在原产国的分类): ~ For <u>Chinese Proprietary Medicines (CPMs), Traditional Medicines (TMs) & Health Supplements</u> , state the actual quantity of the ingredient (IU, mg, mcg, etc) in the product per unit measure (e.g. per capsule, per 5ml dose, per scoop, etc) [对于中成药, 传统药和保健品: 请注明单位重量 (如每粒胶囊, 每 5ml, 每匙等) 中含有的成份量 (国际单位 (IU), 毫克, 微克等)]. ~ For <u>Cosmetic products</u> , state the percentage (%) of the ingredient in the product [对于化妆品, 请注明产品中成份的百分含量 (%)]. ~ For <u>Medicinal Products & Medical Devices (if applicable)</u> , state the strength of the ingredient in the product as reflected in the product label [对于西药和医疗器械 (如适用), 请根据产品标签填写成份含量].			
1.		<input type="checkbox"/>	<input type="checkbox"/>
2.		<input type="checkbox"/>	<input type="checkbox"/>
3.		<input type="checkbox"/>	<input type="checkbox"/>
4.		<input type="checkbox"/>	<input type="checkbox"/>
5.		<input type="checkbox"/>	<input type="checkbox"/>
6.		<input type="checkbox"/>	<input type="checkbox"/>
7.		<input type="checkbox"/>	<input type="checkbox"/>
8.		<input type="checkbox"/>	<input type="checkbox"/>
9.		<input type="checkbox"/>	<input type="checkbox"/>
10.		<input type="checkbox"/>	<input type="checkbox"/>
11.		<input type="checkbox"/>	<input type="checkbox"/>
12.		<input type="checkbox"/>	<input type="checkbox"/>
13.		<input type="checkbox"/>	<input type="checkbox"/>
14.		<input type="checkbox"/>	<input type="checkbox"/>
15.		<input type="checkbox"/>	<input type="checkbox"/>
16.		<input type="checkbox"/>	<input type="checkbox"/>
17.		<input type="checkbox"/>	<input type="checkbox"/>
18.		<input type="checkbox"/>	<input type="checkbox"/>
19.		<input type="checkbox"/>	<input type="checkbox"/>
20.		<input type="checkbox"/>	<input type="checkbox"/>
21.		<input type="checkbox"/>	<input type="checkbox"/>
22.		<input type="checkbox"/>	<input type="checkbox"/>
23.		<input type="checkbox"/>	<input type="checkbox"/>

HEALTH PRODUCTS REGULATION GROUP HEALTH PRODUCT ENQUIRY FORM (FOR INDUSTRY)

E-Form ID:

Version No:

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(iii) Ingredients – herbs should be specified by botanical names and Chinese name, where applicable (成份-草药成份需注明植物拉丁名和中文名 [如有])	(iv) Strength* 含量(e.g. IU, mg, mcg, %, etc)	(v) To select 请选择	
		Active 活性	Inactive 非活性
24.		<input type="checkbox"/>	<input type="checkbox"/>
25.		<input type="checkbox"/>	<input type="checkbox"/>
26.		<input type="checkbox"/>	<input type="checkbox"/>
27.		<input type="checkbox"/>	<input type="checkbox"/>
28.		<input type="checkbox"/>	<input type="checkbox"/>
29.		<input type="checkbox"/>	<input type="checkbox"/>
30.		<input type="checkbox"/>	<input type="checkbox"/>
31.		<input type="checkbox"/>	<input type="checkbox"/>
32.		<input type="checkbox"/>	<input type="checkbox"/>
33.		<input type="checkbox"/>	<input type="checkbox"/>
34.		<input type="checkbox"/>	<input type="checkbox"/>
35.		<input type="checkbox"/>	<input type="checkbox"/>
36.		<input type="checkbox"/>	<input type="checkbox"/>
37.		<input type="checkbox"/>	<input type="checkbox"/>
38.		<input type="checkbox"/>	<input type="checkbox"/>
39.		<input type="checkbox"/>	<input type="checkbox"/>
40.		<input type="checkbox"/>	<input type="checkbox"/>
41.		<input type="checkbox"/>	<input type="checkbox"/>
42.		<input type="checkbox"/>	<input type="checkbox"/>
43.		<input type="checkbox"/>	<input type="checkbox"/>
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49.		<input type="checkbox"/>	<input type="checkbox"/>
50.		<input type="checkbox"/>	<input type="checkbox"/>
51.		<input type="checkbox"/>	<input type="checkbox"/>
52.		<input type="checkbox"/>	<input type="checkbox"/>
53.		<input type="checkbox"/>	<input type="checkbox"/>
54.		<input type="checkbox"/>	<input type="checkbox"/>
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56.		<input type="checkbox"/>	<input type="checkbox"/>
57.		<input type="checkbox"/>	<input type="checkbox"/>
58.		<input type="checkbox"/>	<input type="checkbox"/>
59.		<input type="checkbox"/>	<input type="checkbox"/>
60.		<input type="checkbox"/>	<input type="checkbox"/>
61.		<input type="checkbox"/>	<input type="checkbox"/>

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	(iii) Ingredients – herbs should be specified by botanical names and Chinese name, where applicable (成份-草药成份需注明植物拉丁名和中文名 [如有])	(iv) Strength* 含量(e.g. IU, mg, mcg, %, etc)	(v) To select 请选择	
			Active 活性	Inactive 非活性
62.			<input type="checkbox"/>	<input type="checkbox"/>
63.			<input type="checkbox"/>	<input type="checkbox"/>
64.			<input type="checkbox"/>	<input type="checkbox"/>
65.			<input type="checkbox"/>	<input type="checkbox"/>
66.			<input type="checkbox"/>	<input type="checkbox"/>
67.			<input type="checkbox"/>	<input type="checkbox"/>
68.			<input type="checkbox"/>	<input type="checkbox"/>
69.			<input type="checkbox"/>	<input type="checkbox"/>
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77.			<input type="checkbox"/>	<input type="checkbox"/>
78.			<input type="checkbox"/>	<input type="checkbox"/>
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91.			<input type="checkbox"/>	<input type="checkbox"/>
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94.			<input type="checkbox"/>	<input type="checkbox"/>
95.			<input type="checkbox"/>	<input type="checkbox"/>
96.			<input type="checkbox"/>	<input type="checkbox"/>
97.			<input type="checkbox"/>	<input type="checkbox"/>
98.			<input type="checkbox"/>	<input type="checkbox"/>
99.			<input type="checkbox"/>	<input type="checkbox"/>
100.			<input type="checkbox"/>	<input type="checkbox"/>



**HEALTH PRODUCTS REGULATION GROUP
HEALTH PRODUCT ENQUIRY FORM
(FOR INDUSTRY)**

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SECTION D – DECLARATION

I declare that the particulars given in this application are true and that the supporting documents enclosed are authentic or true copies.

Reminder:

- a. Please ensure that all mandatory fields (**indicated by red boxes**) are completed, including the declaration in Section D. **Incomplete forms will not be processed and will be rejected.**
- b. **Click on the "Save" button** on the first page or last page of the form to validate (check that all mandatory fields are completed) and save the form.