

## APPLY FOR CHINESE PROPRIETARY MEDICINES PRODUCT LISTING

The online form to apply for Chinese Proprietary Medicines Listing may take an average of 20 to 30 minutes to fill in.

The time taken varies depending on the number and sizes of the file attachments, configurations of applicant's computer and network system, internet performance etc. The recommended computer and network configurations are at [http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/PRISM\\_e\\_services/system-requirements-for-prism.html](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e_services/system-requirements-for-prism.html). Please note that the time stated above excludes time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

Please note the following before filling up the form:

1. For a company which is using PRISM for the first time, [CRIS](#) registration is required beforehand.
2. A CorpPass (from 2 May 2017) or HSA PIN (which is applicable for foreigners residing overseas only) is required for applicant to login the system for authentication and authorization.  
For more information on CorpPass, please visit <https://www.corppass.gov.sg/>.  
For more information on HSA Pin, please visit [http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/HSA\\_PIN.html](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/HSA_PIN.html).
3. At the start of the application, applicant is required to key in the CorpPass ID followed by CorpPass password. Next the applicant needs to key in the applicant ID i.e. the NRIC of the person from the company which is registered with CRIS.
4. After accepting the Terms and Conditions of Use of the online form, applicant then proceeds to the main part of the form.

### **Application Form**

Please read the instructions on the application form carefully. A Chinese software may be necessary to be installed in applicant's computer to key specific fields in Chinese.

### **Part One – Company Particulars**

In this section, applicant will verify/fill in the following information:

- 1) Company Name
- 2) Company Address, Postal Code, Level and Unit number (based on ACRA registered address)
- 3) Company Telephone / Fax number
- 4) Unique Entity No. (UEN)

If there is a change in company particulars, please apply (through CRIS) to update the particulars at [Amend Company Information](#)

## **Part Two – Applicant Particulars**

In this section, applicant will complete the following information

- 1) Applicant Name (applicant must be CRIS registered)
- 2) Applicant NRIC/Fin (applicant must be CRIS registered)
- 3) Designation
- 4) Contact Details like Telephone/Fax/Handphone/Pager number and E-mail address
- 5) Preferred Contact mode

## **Part Three – General Product Details**

In this section, applicant will complete the following:

- 1) Select one of the following product listing types:
  - (i) Product is imported as the final product ready for local sale
  - (ii) Product is imported for local assembly, to be sold under different packaging
  - (iii) Product is manufactured locally as the final product ready for local sale
  - (iv) Product is manufactured locally for assembly by another company
  - (v) Product is assembled locally for local sale
- 2) Product Name & Brand Name in English
- 3) Product Name & Brand Name in Chinese, if any
- 4) Application number or product reference number of product before assembly (for locally assembled products)
- 5) Dosage form
- 6) Shelf Life
- 7) Pack Sizes
- 8) Batch numbering system
- 9) Product name in country of origin (for imported products)

## **Part Four – Ingredient Details**

In this section, applicant will complete the following:

- 1) Weight or volume per unit measure of product
- 2) Ingredient Name in English & Chinese
- 3) Quantity of ingredient per unit measure of product (use of weight in % is not allowed)
- 4) Presence of specified compounds

## **Part Five – Manufacturer Details**

In this section, applicant will select the following:

- 1) Manufacturer name in English & Chinese, if any

## **Part Six – Overseas Assembler(s) Details**

(Note: This section is only applicable to products that have undergone overseas assembly by another factory)

In this section, applicant will select the following:

- 1) Assembler name in English & Chinese, if any

### **Part Seven – Details of Starting Material(s) For Locally Manufactured Product**

(Note: This section is only applicable to locally manufactured products)

In this section, applicant will fill up the following

- 1) Type of starting material(s)
- 2) Source(s) of starting materials for the locally manufactured product.
- 3) Supplier's Name
- 4) Supplier's Country

### **Part Eight – Supporting Attachments**

The following documents are to be scanned and attached to the application. The type of documents required depend on the product listing type selected (see Part Three):

Document	For imported product	For locally manufactured product
Labels of product to be sold/supplied in Singapore which meet <a href="#">labelling requirements</a> , including: a) Inner label b) Outer label / carton (if any) c) Package insert (if any)	YES	YES
Photograph of the product's contents (e.g. capsules, tablets) – <a href="#">Examples</a> Physical sample of product to be sold/supplied in Singapore, only upon request	YES	YES
Labels of product to be sold/supplied in country of manufacture, including: a) Inner label b) Outer label / carton (if any) c) Package insert (if any)	YES	
Manufacturer's Licence or certificate	YES	
Good Manufacturing Practice (GMP) certificate (if any)	YES	
Product registration certificate (if applicable)#	YES	
Free sale certificate or equivalent from country of manufacture	YES	
<a href="#">Test results of toxic heavy metals and microbial contamination</a>	YES	YES
Storage condition / containers [ <a href="#">Imported products</a> ] [ <a href="#">Locally manufactured / Primary Assembled products</a> ]	YES	YES
<a href="#">Quality parameters for CPM products</a>	YES	YES

Endorsement of product formula by overseas manufacturer and undertaking by overseas manufacturer that product does not contain any Western drugs or active synthetic substances	YES	
<a href="#">Information on legal classifications of product in countries of sales</a>	YES	
<a href="#">Website undertaking</a> – for products with website stated on label(s)	YES	YES
<a href="#">TSE undertaking</a> – for products containing materials (including those used for making capsule shells) derived from ruminants (e.g. cattle, buffalo, sheep, goat, deer, antelope)	YES	YES
<a href="#">Info for Fermented Substance</a> – for products containing fermented substance(s) (e.g. Cordyceps, Red Yeast Rice)	YES	YES

# If product registration certificate is not available, a FSC, CPP or similar documents would be required

For the guideline on signatory of forms and undertaking for CPM, please visit the following website: [http://www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary\\_Health\\_Products/Chinese\\_Proprietary\\_Medicines/Guidelines\\_on\\_CPM\\_Product\\_Listing/Submission\\_of\\_Application/Signatory.pdf](http://www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary_Health_Products/Chinese_Proprietary_Medicines/Guidelines_on_CPM_Product_Listing/Submission_of_Application/Signatory.pdf)

In addition to the above items, dealers may be required to furnish any other information as requested by the Licensing Authority.

### **Part Nine – Confirmation**

In this section, user should check whether the information keyed and the documents attached are correct. After checking, user must then accept the declarations required for this application. Next is to validate and then submit the application.

### **Other Useful Information**

For more details on the guidelines and requirements on the application of Chinese Proprietary Medicines product listing and dealer's licences, please visit the following website : [http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Complementary\\_Health\\_Products/Chinese\\_Proprietary\\_Medicines.html](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/Chinese_Proprietary_Medicines.html)