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. 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.

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

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 labelling requirements, including: a) Inner label b) Outer label / carton (if any) c) Package insert (if any)	✓	✓
Photograph of the product's contents (e.g. capsules, tablets) Physical sample of product to be sold/supplied in Singapore, only upon request	✓	✓
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)	✓	
Manufacturer's Licence or certificate	✓	
Good Manufacturing Practice (GMP) certificate (if any)	✓	
Product registration certificate (if applicable)[#]	✓	
Free sale certificate or equivalent from country of manufacture	✓	
Test results of toxic heavy metals and microbial contamination	✓	✓
Storage condition / containers	✓	✓
Quality parameters for CPM products	✓	✓
Endorsement of product formula by overseas manufacturer and undertaking by overseas manufacturer that product does not contain any Western drugs or active synthetic substances	✓	
Information on legal classifications of product in countries of sales	✓	
Website undertaking – for products with website stated on label(s)	✓	✓

TSE undertaking – for products containing materials (including those used for making capsule shells) derived from ruminants (e.g. cattle, buffalo, sheep, goat, deer, antelope)	✓	✓
Info for Fermented Substance – for products containing fermented substance(s) (e.g. Cordyceps, Red Yeast Rice)	✓	✓

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

Please ensure that the submitted documents are signed by the correct signatories.

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

All draft applications will be saved in the system for only 7 days after the latest update. To save a draft application in the system for another 7 days, please extenddraft@prism.

申请中成药产品登记

在线填写申请中成药产品登记的电子表格平均约需20-30分钟。

所需时间依据附加文件的大小、数量，申请人的电脑及网络系统的运行情况等。请注意上述时间不包括填写电子表格所需要的准备工作（如扫描附加文件）。

在填写表格前请注意以下事项：

1. 对于首次使用电子呈报系统的公司，请预先注册CRIS。

2. 登录电子呈报系统需要CorpPass (自2017年5月2日起) 或卫生科学局的个人识别号码（仅适用于居住于海外的申请人）。

3. 申请开始时，要求申请人输入CorpPass号码及其密码，接着，需要输入个人身份证号码，即公司在注册CRIS时所指定的身份证号码。

4. 在接受使用电子表格的条款后，申请人即可进入申请表格的主体。

申请表

请仔细阅读申请表格指南。申请人或许需要在电脑里安装必要的中文软件，才能在表格的特定区域输入中文。

第一部分：公司详情

在此部分，申请人需要核实/输入以下信息：
1) 公司名称
2) 公司地址、邮编、门牌号码（在ACRA注册时所使用的地址）
3) 公司电话/传真号码
4) 公司的注册号码 （UEN）

如上述的公司信息有所更改，请通过CRIS申请更新

第二部分：申请人详情

在此部分，申请人需完成以下信息：
1) 申请人姓名（申请人必须为CRIS注册者）
2) 申请人身份证号码（申请人必须为CRIS注册者）
3) 职务
4) 申请人的详细联络方式，如电话/传真/传呼号码/电子邮件地址
5) 选择的通讯方式

第三部分：产品一般资料

在此部分，申请人需完成以下信息：
1) 选择以下产品登记类型的其中之一：
   (i) 产品进口将以原包装在本地销售
   (ii) 产品进口将在本地分装或包装后，以不同包装销售
   (iii) 产品在本地制造后以原包装在本地销售
   (iv) 产品在本地制造后将交给其它工厂分装或包装
   (v) 产品为本地分装或包装，以供本地销售
2) 产品的英文名称及商标名
3) 产品的中文名称及商标名（如有）
4) 产品分装前的申请或登记号（仅适用于本地分装产品）
5) 剂型
6) 有效期
7) 包装规格
8) 批号排列系统
9) 产品在原产国的名称（仅适用于进口产品）

第四部分：成份资料

在此部分，申请人需完成以下信息：
1) 产品的单位重量或容量
2) 成份的中英文名称
3) 产品单位重量/容量中的成分的量（不允许以百分率表达）
4) 存在特定成份

第五部分：制造商资料

在此部分，申请人将选择：制造商的中英文名称（如有）

第六部分：-海外分装商资料

（注：此部分仅适用于在海外由另一工厂分装的产品）

在此部分申请人将选择：分装商的中英文名称（如有）

第七部分：-在本地制造的产品之原料资料

（注：此部分仅适用于本地制造的产品）

在此部分，申请人将填写以下信息：
1) 原料的类型
2) 本地制造的产品的原料来源
3) 供应商名称
4) 供应商国家

第八部分：附加的支持文件

依据选择的产品登记类型（参照第三部分），以下文件需要扫描并附加至申请：

文件	进口产品	本地制造产品
将在本地销售的产品标签(需符合标签要求), 包括: a) 内标签 b) 外标签(若有) c) 说明书(若有)	✓	✓
以照片展示产品样本（如胶囊，片剂等） 新加坡销售的产品样本在有需要时会要求提交	✓	✓
在原产国销售的产品标签, 包括: a) 内标签 b) 外标签(若有) c) 说明书(若有)	✓	
制造商执照或证书	✓	
GMP 证书(若有)	✓	
产品注册证书(若有)#	✓	
原产国所签发的自由销售证书或同等文件	✓	
有毒重金属及卫生学检验报告	✓	✓
贮存条件/容器	✓	✓
产品质控指标资料	✓	✓
外地制造商确认的产品成份表(包括活性和非活性成份), 和产品不含任何西药或活性合成物质的书面声明	✓	
产品在其它销售国家的分类	✓	
网站的书面声明 – 限于网址标注于产品标签上的产品	✓	✓
传染性海绵状脑病的书面声明 – 限于产品含有来源于反刍动物（如牛、羊、鹿、羚羊等）的成份（包括制作胶囊壳的成份）	✓	✓

发酵物质的信息 – 限于产品含有发酵成分如冬虫夏草菌粉，红曲米	✓	✓

在没有产品注册证书的情况下，则应提交自由销售证书、药品证书或其他的类似文件

请确保所提交的文件签名正确。

除了以上要求，执照签发当局也可能要求申请人提供其它的资料或文件。

第九部分：确认

在此部分，申请人需检查输入的信息及附加的文件是否正确。检查后，申请人必须接受此申请要求的声明。然后确证并提交申请。

其它有用的信息

所有的申请草稿只能在系统中保存7天，如果要将草稿再存7天, 请在extenddraft@prism申请延长。