AMEND CHINESE PROPRIETARY MEDICINES PRODUCT LISTING APPLICATION

The online form to apply for Amendment Application for Chinese Proprietary Medicines Listing may take an average of 30 to 40 minutes to fill in.

The time taken varies depending on the type of amendment involved, 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 or HSA PIN (which is applicable for foreigners residing overseas only) is required for applicant to login the system for authentication and authorization.

   Note: *From 11 April 2021, the login process for Corppass has been changed to verify the user's identity via Singpass first before accessing and transacting with government digital services. While Singpass is used for logins, Corppass will continue to be the authorisation system for access to government digital services.*

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.

Under the Search Criteria, applicant will need to select the Licence/Permit/Certificate/Listing Type as "Chinese Proprietary Medicine - Product Listing". Next, applicant can either key in the Licence/Permit/Certificate/Listing Number or Product Name to perform a search and select the relevant product listing(s) to amend.

Following that, under the Licence/Permit/Certificate/Listing Summary, applicant is required to furnish the amendment details (i.e. which are the portions to be amended).

Kindly note that the approval of the amendment is subject to the evaluation by the Licensing Authority.

Part One – Company Particulars

In this section, applicant will verify the following pre-populated 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 verify 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

If there is a change in applicant particulars, please apply (through CRIS) to update the particulars

Part Three – General Product Details

In this section, applicant can choose to amend any of the following:
1) Product Name & Brand Name in English
2) Product Name & Brand Name in Chinese, if any
3) Shelf Life
4) Pack Sizes
5) Batch numbering system
6) Product name in country of origin (for imported products)

Part Four – Ingredient Details

In this section, applicant can choose to amend any of the following:
1) Weight or volume per unit measure of product
2) Inactive ingredient Name in English & Chinese
3) Quantity of inactive ingredient per unit measure of product

Part Five – Manufacturer Particulars

(Note: This section is only applicable to changing or adding manufacturing site of the existing overseas manufacturer)

In this section, applicant can amend the following:
1) Manufacturer name in English & Chinese(only applicable to amending an existing entry, not for changing to another manufacturer)
2) Manufacturer's address (only applicable to amending/adding to an existing entry)

Part Six – Overseas Assembler(s) Particulars

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

In this section, applicant can re-choose 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 can choose to amend any of the following:
1) Source(s) of starting materials for the locally manufactured product.
2) Supplier's Name

Part Eight – Supporting Attachments

Depending on the product listing type selected and the type of amendment involved, applicant would have to scan and attach the relevant documents. The Licensing Authority may also request for further documents or information while processing the amendment application.

Part Nine – Confirmation

In this section, applicant should check whether the information keyed and the documents attached are correct. After checking, applicant 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.

已经登记的中成药产品的变更申请

在线填写已经登记的中成药产品的变更申请的电子表格平均约需30-40分钟。

所需时间依变更的种类，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而有不同。请注意上述时间不包括填写电子表格所需要的相关准备工作（如扫描附加文件）。

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）。

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。

在搜索条件下，申请人需要选择中成药产品登记。接着，申请人可以输入执照/许可/证书/登记号码或产品名称以选择需要变更的产品。

然后，要求申请人填写所变更的详细信息（如对哪部分进行变更）。

请注意此变更是否批准需经执照签发当局审评。

第一部分：公司详情

在此部分，申请人需核实以下信息：
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）

如以上的公司信息有更改，请通过CRIS申请更新

第二部分：申请人详情

在此部分，申请人需核实以下信息：
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

如以上的个人信息有更改，请通过CRIS申请更新

第三部分：产品一般资料

在此部分，申请人可选择变更：
1) 产品的英文名称及商标名
2) 产品的中文名称及商标名（如果有）
3) 有效期
4) 包装规格
5) 批号排列系统
6) 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，申请人可选择变更：
1) 产品的单位重量或容量
2) 非活性成分的中英文名称
3) 产品单位重量/容量中的非活性成分的量

第五部分：海外制造商资料

在此部分，申请人可选择变更：
1) 制造商的中文或英文名称（仅适用于更改现存制造商名称，不允许变更制造商）
2) 制造商的地址（仅适用于改变或增加现存制造商的地址）

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进行二级分装的产品）

在此部分，申请人能重新选择：
1) 分装商的中英文名称（如果有）

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，申请人能选择变更：
1) 本地制造的产品的原料来源
2) 供应商名称

第八部分：附加的支持文件

根据产品登记的类型及所变更的内容，申请人需要扫描并附上相关文件。执照当局在处理变更申请时，还可能还会要求更多的文件或信息。

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.