

Guideline on Signatory of Forms and Undertaking for CPM

中成药申请中所使用的表格及书面声明的签名要求

This document is meant to provide general guidance on the acceptable signatory for the forms and undertakings submitted during the application of Chinese Proprietary Medicines (CPM) through PRISM:

呈交中成药产品申请时，需填写相应的表格及书面声明，其所要求的签名如下：

1. For CPM Manufactured for Local Sale / Manufactured for Local Assembly

本地生产供销售/本地分装的产品

	Name of Form / Undertaking 表格/书面声明名称	Acceptable Signatory 要求的签名者
1	FORM(GL)-CHPB-4-001C_Website Undertaking	Manufacturer 生产商
2	CPMF8.3_Advertisement Undertaking	Manufacturer 生产商
3	CPMF9.6_TSE Undertaking	Manufacturer 生产商
4	FORM(GL)-CHPB-4-001D_Info for Fermented Substance	CMM Supplier and Manufacturer 原料生产商及本地生产商
5	FORM(GL)-CHPB-4-001A_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Manufacturer 生产商
6	Undertaking to test products at accredited labs	Manufacturer 生产商

2. For CPM Imported for Local Sale / Imported for Local Assembly

进口供本地销售/分装

	Name of Form / Undertaking 表格/书面声明名称	Acceptable Signatory 要求的签名者
1	FORM(GL)-CHPB-4-001B_Forensic Classification	Importer or Overseas Manufacturer or Product Owner 进口商或海外生产商或产品所有人
2	FORM(GL)-CHPB-4-001C_Website Undertaking	Importer 进口商
3	CPMF8.3_Advertisement Undertaking	Importer 进口商
4	CPMF9.6_TSE Undertaking	Importer 进口商
5	CPMF10.3_Undertaking Form for Amended Formula	Overseas Manufacturer 海外生产商
6	FORM(GL)-CHPB-4-001D_Info for Fermented Substance	CMM Manufacturer and Importer 原料生产商和进口商
7	FORM(GL)-CHPB-4-001A_Storage Condition of CPM - Imported Products	Importer 进口商
8	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer 海外生产商
9	Undertaking to test products at accredited labs	Importer 进口商

3. For CPM Assembled for Local Sale (Primary Assembly)

分装后供本地销售（一级分装）

	Name of Form / Undertaking 表格/书面声明名称	Acceptable Signatory 要求的签名者
1	FORM(GL)-CHPB-4-001B_Forensic Classification	Primary Assembler or Overseas Manufacturer or Product Owner 分装商或海外生产商或产品所有人
2	FORM(GL)-CHPB-4-001C_Website Undertaking	Primary Assembler 分装商
3	CPMF8.3_Advertisement Undertaking	Primary Assembler 分装商
4	CPMF9.6_TSE Undertaking	Primary Assembler 分装商
5	FORM(GL)-CHPB-4-001A_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Primary Assembler 分装商
6	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer 海外生产商
7	Undertaking to test products at accredited labs	Primary Assembler 分装商

4. For CPM Assembled for Local Sale (Secondary Assembly)

分装后供本地销售（二级分装）

	Name of Form / Undertaking 表格/书面声明名称	Acceptable Signatory 要求的签名者
1	FORM(GL)-CHPB-4-001B_Forensic Classification	Secondary Assembler or Overseas Manufacturer or Product Owner 分装商或海外生产商或产品所有人
2	FORM(GL)-CHPB-4-001C_Website Undertaking	Secondary Assembler 分装商
3	CPMF8.3_Advertisement Undertaking	Secondary Assembler 分装商
4	FORM(GL)-CHPB-4-001A_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Secondary Assembler 分装商
5	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer 海外生产商
6	Undertaking to test products at accredited labs	Secondary Assembler 分装商