

# 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	CPMF6.4_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	CPMF11.5_Info for Fermented Substance	CMM Supplier and Manufacturer 原料生产商及本地生产商
5	CPMF13.3b_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	CPMF5.3_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	CPMF6.4_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	CPMF11.5_Info for Fermented Substance	CMM Manufacturer and Importer 原料生产商和进口商
7	CPMF13.4a_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）

	<b>Name of Form / Undertaking</b> 表格/书面声明名称	<b>Acceptable Signatory</b> 要求的签名者
1	CPMF5.3_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	CPMF6.4_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	CPMF13.3b_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）

	<b>Name of Form / Undertaking</b> 表格/书面声明名称	<b>Acceptable Signatory</b> 要求的签名者
1	CPMF5.3_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	CPMF6.4_Website Undertaking	Secondary Assembler 分装商
3	CPMF8.3_Advertisement Undertaking	Secondary Assembler 分装商
4	CPMF13.3b_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