HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

JANUARY 2025

GUIDELINES ON CHINESE PROPRIETARY MEDICINES PRODUCT LISTING

GL-CHPB-4-001 Rev. No. 020

The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at www.hsa.gov.sg.

HSA
Health Sciences Authority

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1. Introduction

1.1 These guidelines provide regulatory information for companies dealing with Chinese Proprietary Medicines (CPM) in Singapore. The information provided in these guidelines is not meant to supersede or replace any of the legislation. Other national legislative controls may apply where applicable.

2. Legislation

2.1 The current legislative control that may apply to CPM may be found in the following legislation:

A. Medicines Act 1975 & its Subsidiary Legislation especially:

i. Medicines (Prohibition of Sale, Supply and Importation) Order;
ii. Medicines (Traditional Medicines, Homoeopathic Medicines and Other Substances) (Exemption) Order;
iii. Medicines (Labelling of Chinese Proprietary Medicines) Regulations;
iv. Medicines (Medical Advertisements) Regulations;
v. Medicines (Licensing, Standard Provisions & Fees) Regulations

B. Medicines (Advertisement & Sale) Act 1955

C. Poisons Act 1938 & Poisons Rules

3. Definition

3.1 CPM refers to a medicinal product that:

a. Is in the form of a finished product, such as a capsule or tablet, and
b. Contains one or more active ingredients from any plant, animal or mineral, or any combination of sources. All of the active ingredients have to be documented for use in traditional Chinese medicine.

3.2 The following are not considered as CPM:

a. Products to be injected into the human body.
b. Products containing any chemically-defined isolated constituents as an active ingredient.

3.3 Notwithstanding the above, the HSA reserves the right in determining the final product classification.

4. Submission of Application

4.1 In additional to dealer's licences, CPM importers, manufacturers and assemblers are also required to obtain product listing approvals for the CPM products dealt by them.

4.2 The following items must be submitted during applications for CPM product listing approvals:

Item	For imported product	For locally manufactured product
1. 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)	✓	✓
2. Labels of product sold/supplied in country of manufacture, including: a) Inner label b) Outer label / carton (if any) c) Package insert (if any)	✓	
3. Photograph of the product's contents (e.g. capsules, tablets) Physical sample of product to be sold/supplied in Singapore, only upon request	✓	✓
4. Manufacturer's Licence or certificate	✓	
5. Good Manufacturing Practice (GMP) certificate (if any)	✓	
6. Product registration certificate #	✓	
7. Test results of toxic heavy metals and microbial contamination	✓	✓
8. Test results of DEG and EG in starting material – for oral liquid products with glycerin, propylene glycol, or sorbitol solution	✓	✓

9. Description of manufacturing process	✓	✓
10. General quality parameters information for CPM products, including: • Storage conditions* • Physical characteristics of the product such as colour, taste, smell, shape, size of capsule, and can be included in the product's Certificate of Analysis (COA) or as a separate document • Physical specifications of the product. This can be included in the product's COA or as a separate document	✓	✓
11. Finished product specifications	✓	✓
12. Endorsement of product formula (including all active and inactive ingredients) by overseas manufacturer	✓	
13. Undertaking by overseas manufacturer that product does not contain any western drugs or active synthetic substances	✓	
14. Information on legal classifications of product in countries of sales*	✓	
15. Website undertaking* – *for products with website or QR code stated on label(s)*	✓	✓
16. TSE undertaking* – *for products containing materials (including those used for making capsule shells) derived from ruminants (e.g. cattle, buffalo, sheep, goat, deer, antelope)*	✓	✓
17. Info for Fermented Substance* – *for products containing fermented substance(s) (e.g. Cordyceps, Red Yeast Rice)*	✓	✓

* Forms are available at Annexes 1-7

[#] If product registration certificate is not available, a valid Certificate for Exporter of CPM (Free Sale Certificate), Certificate of Pharmaceutical Product, or similar documents would be required.

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

4.4 Before submitting the application, please ensure that the product does not contain:

- Any synthetic drugs； and
- Any other substances listed in the Poisons Act, except for the list of allowable naturally occurring substances within limits (see section under “Limits for Naturally Occurring Substances and Contaminants”),

4.5 If the CPM contains substances listed under the Endangered Species (Import & Export) Act, dealers should contact the Wildlife Management Group of the NParks to obtain the necessary Convention on the International Trade in Endangered Species of Wild Fauna and Flora (CITES) import and export permits.

Apply online

5. Labelling Requirements and Prohibited Claims

5.1 Full labelling in English is required for all CPM. Chinese or other languages, if any, may be used in addition to English. The information in languages other than Chinese and English, if applicable, should be the same as the English version of the approved labels. The details required are as follows:

5.2 Inner label must state:

a. Trade / brand name
b. Product name
c. Batch number
d. Expiry date
e. Names and quantities of ingredients *

* *If inner label is too small, the information may be stated on the outer label.*

5.3 Outer label must state:

a. Trade / Brand name
b. Product name
c. Batch number
d. Expiry date
e. Importer's or wholesaler's name and address **
f. Manufacturer's name and address **
g. Assembler's name and address (if any) **
h. "Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority. Consumer discretion is advised. 根据向当局提呈的资料允许作为中成药销售。谨慎选用。" ** (Please see below for more details)

** *If there is no outer label, the information must be stated in the inner label.*

Additional label:

"Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority. Consumer discretion is advised. 根据向当局提呈的资料允许作为中成药销售。谨慎选用。"

a. The words must be clearly legible and printed in an indelible manner.
b. The English words should not be less than 1.5 mm in height and the Chinese characters not less than 2 mm in height.
c. It is the responsibility of the applicant/company to measure the height of the words and characters before printing/submission of labels.
d. The words must be enclosed in a boxed area which is clearly visible. Nothing else should appear in the boxed area other than the words of the label.
e. The label must appear conspicuously in a prominent position.

5.4 Package insert must state:

a. Trade / Brand Name
b. Product Name
c. Manufacturer's name and address
d. Names & quantities of ingredients
e. Dosage ***
f. Indication ***
g. Contraindication ***
h. Side effects ***
i. The frequency and method of administration ***

*** *If there is no package insert, the information must be stated on either the inner or outer label.*

5.5 Guidelines on Electronic Labelling (E-labelling)

E-labelling refers to product information which is distributed via electronic means, such as through a machine-readable code (e.g. QR code) or URL on the product packaging, linking to product information in digital format. Presently, e-labelling for CPM is applicable to the product leaflet only.

Dealers who are interested to use e-labelling for their CPM have to inform HSA. For more details, please refer to this guideline.

5.6 The labels, packaging and package inserts of CPM shall not make references to any of the 19 diseases/conditions specified in the First Schedule to the Medicines Act:

1. Blindness	11. Leprosy
2. Cancer	12. Menstrual disorders
3. Cataract	13. Paralysis
4. Drug addiction	14. Tuberculosis
5. Deafness	15. Sexual function
6. Diabetes	16. Infertility
7. Epilepsy or fits	17. Impotency
8. Hypertension	18. Frigidity
9. Insanity	19. Conception and pregnancy
10. Kidney diseases	

6. Photograph of Product's Content

Examples of Pictures Showing Product Contents
产品样本的图片范例

Sample of Granules & Powders 颗粒剂和散剂的样本

Sample of Capsules胶囊的样本

Sample of see-through teabags 茶袋的样本

Sample of Tablets片剂的样本

Sample of Pills丸剂的样本

POINTS TO NOTE注意事项:

a) All samples are to be taken against a **contrasting** background.
所有的样本图片必须摄于可产生对比的背景

b) For capsules and sachets, the contents must be poured out to show the details.
对于胶囊和袋装品，应将其内含物倒出，以显示细节。

c) Tablets are to be cut into halves to display cross-sections.
片剂应切割成大小相似的两半，显示其横切面的细部

7. Limits for Specific Naturally Occurring Substances and Contaminants

7.1 CPM must not exceed the limits for specific naturally occurring substances, heavy metals, microbial, diethylene glycol and ethylene glycol as specified in **Tables 1, 2, 3 and 4**.

Table 1: Specific Naturally Occurring Substances Limits

Substances	Acceptable limit
Ephedra alkaloids	< 1%
Lovastatin	< 1%
Boric acid, sodium borate	Not more than 5% boric acid or 5% sodium borate or 5% of a combination of both
Lobelia alkaloids	< 0.1%
Aconite alkaloids	Dosing of ≤ 60 mcg/day
Tetrahydropalmatine	Dosing of ≤ 19 mg/day

7.2 Test reports for CPM containing herbs with specific naturally occurring substances have to be tested at laboratories with accredited testing methods, and the test results must be quantified in the test reports to be within the stipulated limits.

Table 2: Heavy Metal Limits

Heavy metal	Quantity (by weight)
Arsenic	5 ppm
Cadmium	0.3 ppm
Lead	10 ppm
Mercury	0.5 ppm

7.3 Dealers may wish to take note of the following suggestions in controlling the heavy metal contents of their products:

a. Identify starting materials (e.g. certain herbs, minerals) that may contribute to higher heavy metal content in their product;
b. Source for starting materials which have been tested to contain heavy metals below stipulated limits;

c. Ensure that herbal materials are free from soil particles before use (e.g. by washing thoroughly, if applicable); and
d. Incorporate relevant extraction processes in the manufacturing workflow to remove heavy metals in the product, if necessary.

Table 3: Microbial Limits

For oral CPM	**Quantity (colony-forming units (CFU))**
Total aerobic microbial count	Not more than 10^5 per g or ml
Yeast and mould count	Not more than 5 X 10^2 per g or ml
Escherichia coli Salmonellae *Staphyloccocus aureus*	Absent in 1g or ml
For topical CPM	**Microbial limits**
Total aerobic microbial count	Not more than 10^4 per g or ml
Yeast and mould count	Not more than 5 X 10^2 per g or ml
Pseudomonas aeruginosa *Staphyloccocus aureus*	Absent in 1g or ml

7.4 Toxic heavy metals and microbial contamination tests should be conducted using methods that are in accordance with the latest edition of one of the following pharmacopoeias: British Pharmacopeia, Chinese Pharmacopeia, European Pharmacopeia, United States Pharmacopeia, etc.

Table 4: Diethylene Glycol and Ethylene Glycol Limits

Substance	**Quantity (by weight)**
Diethylene glycol (DEG)	1000ppm
Ethylene glycol (EG)	1000ppm

7.5 The above limits are applicable to oral liquid products.

7.6 Manufacturers of oral liquid products which contain starting materials which are at risk of contamination by DEG or EG (e.g., glycerin (also known as glycerol), propylene glycol, sorbitol solution) should perform routine testing on the starting material or finished product for DEG and EG.

7.7 Refer to the test report requirements for more details.

8. Description of Manufacturing Process

8.1 A description of the manufacturing process must be submitted in a CPM listing application. Description of manufacturing process is a structured sequence of steps and processes used to manufacture raw materials into finished products. It can be presented as a flowchart or description of the process.

9. General Quality Parameters

9.1 It is mandatory for CPM applications to include the following general quality parameters information:

a. storage condition for imported products (see Annex 7a); or
b. storage condition and container(s) for locally manufactured/assembled products (see Annex 7b);
c. physical characteristics of the product such as colour, taste, smell, shape, size of capsule; and
d. physical specifications of the product (see Annex 8).

9.2 Refer to our guide on storage conditions for more details.

10. Finished Product Specifications

10.1 The finished product specifications must be submitted in a CPM listing application. The finished product specifications are a set of tests and limits that are applied to the product to ensure product safety and that every batch is of satisfactory and consistent quality throughout its shelf life. The product specifications should include the parameters that are likely to affect the safety and quality of the product such as parameters relating to dosage forms, acceptance limits for batch release of the finished products.

11. Turn-Around-Time

11.1 Following a CPM Listing Application made via PRISM, the information provided will be screened to ensure the completeness of the documents.

11.2 If deficiencies are identified in the submitted documents, a query stating the deficiencies i.e., Input Request, will be issued to the company.

11.3 In situations where the company is unable to provide a complete response by the due date, the company should inform HSA as soon as possible after receiving HSA's Input Request. The application will be closed without further notice if the company fails to observe the specified response deadline.

11.4 If the company fails to address the deficiencies raised, the submission will not be accepted. If the product is subsequently re-submitted for CPM Listing, it will be processed as a new application.

11.5 The turn-around-time for new product listing applications is 60 working days, excluding the time taken by the company to respond to our request for clarification or additional information (applicant's stop-clock).

11.6 We strive to meet the turn-around-time for all submitted applications. The company should ensure that the applications and replies to Input Requests are complete before submission, to prevent unnecessary delays to the processing due to incomplete information and untimely responses.

12. Responsibilities of Applicant

12.1 The applicant for the CPM product listing is responsible for the safety and quality of the CPM in the market. The applicant should ensure that the product meets all the legal requirements, conforms to the standards and specifications of the product that have been submitted and approved by the HSA and the product remains stable and safe for use during the period of proposed shelf-life. The shelf-life of a product is determined by the product formulation, packaging and storage conditions and the proposed shelf-life should be supported by evidence. In addition, the applicant should ensure that the levels of pesticides and/or other environmental contaminants that could be present in the product have been scientifically assessed not to pose any dangers to the intended users.

12.2 The applicant shall take full responsibility should the CPM product be found adulterated with substances listed under the Poisons Act and/or active synthetic substances.

12.3 After a company has been licensed, any subsequent change(s) in the particulars relating to the CPM or company will render the licence invalid unless prior approval of such change(s) has been obtained from the Health Sciences Authority. This includes any changes to the legal status of the product in the country of origin e.g. registration status, free sale status, classification.
Make CPM licence/product amendments online

12.4 Licence holders shall report to the Vigilance and Compliance Branch, Health Products Regulation Group, Health Sciences Authority, 11 Biopolis Way #11-01 Helios Singapore 138667, as soon as possible (within 7 days) upon receipt of any information of adverse drug reactions arising from the CPM which they are dealing.

The Adverse Drug Reaction Report Form and more details can be found in the Report Adverse Events section.

12.5 All licence holders must keep records of their transaction for a period of 2 years from the date of last entry.

12.6 It is the responsibility of the licence holders to recall any product manufactured / assembled / imported / distributed by them when directed by the Health Sciences Authority for reasons of safety or poor quality.

12.7 The advertisement and sales promotion of CPM require a permit from the Health Sciences Authority under the Medicines (Medical Advertisements) Regulations. Please note that the product listing approval of a CPM does not imply that the product name and/or its claims will be allowed for advertising purposes.

12.8 It is the responsibility of the applicant to refrain from using the CPM product listing approval as a marketing tool to advertise or promote the product.
Please refer to the advertisements and promotions guidelines section for more details.

12.9 The Health Sciences Authority may suspend, revoke or amend the details in any licence or certificate. The Licensing Authority shall serve on the licence or certificate holder a notice giving particulars and reasons for such suspensions, revocation or variation. Any person who is aggrieved by such a decision may appeal to the Minister for Health whose decision shall be final.

12.10 Any person who contravenes any provision of the legislation on CPM is liable, to a fine of not more than $5000 or to an imprisonment of not more than 2 years or both.

13. Submission of Documents for Every Consignment at Point of Import

13.1 All CPM import licence holders are reminded that the following documents are required to be submitted to the Complementary Health Products Branch (CHPB) for the import of every consignment of the CPM:

a. Supplier's invoice with the following (either in print or legible handwriting):
   i. the CPM import licence number (at the top right hand corner of the invoice) and
   ii. the CPM product reference number and batch number for each product (next to the corresponding product name)
b. A declaration on the absence of any poisons as defined in the Poisons Act (Cap. 234) and any active synthetic substance in the CPM
c. Test results of toxic heavy metals
d. Test results of microbial contamination
e. Other documents and test results as may be required by the licensing authority
f. Notification of CPM Import and Test Report Submission

13.2 The required documents (a) to (f) are to be submitted within 2 months of import to the CHPB by email: HSA_CPM@hsa.gov.sg. The company shall receive an acknowledgement from the CHPB within 1 month from the date of submission of the required documents if they are in order. It is advisable for the company to retain the acknowledgement from CHPB till the expiry of the CPM. Please note that there should be no sale / supply of the imported CPM unless and until the required test reports with satisfactory results are submitted.

13.3 Please be reminded that non-submission or late submission (exceeding 2 months of import) of the required documents is an offence under the Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2007.

14. Application of Certificate for Exporter of CPM (Free Sale Certificate)

14.1 Some importing countries may require a certificate to show that a CPM is approved for sale and distribution in Singapore. To assist in such scenarios, companies may apply for a Certificate for Exporter of CPM, also known as a Free Sale Certificate.

14.2 Each certificate is specific to one product and allow the inclusion of up to five importing countries.
Apply online

15. Guideline on Signatory of Forms and Undertaking for CPM

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:

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

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF6.4_Website undertaking	Manufacturer
2	CPMF8.3_Advertisement Undertaking	Manufacturer
3	CPMF9.6_TSE undertaking	Manufacturer
4	CPMF11.5_Info for Fermented Substance	CMM Supplier and Manufacturer
5	CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Manufacturer
6	Undertaking to test products at accredited labs	Manufacturer

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

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF5.3_Forensic classification	Importer or Overseas Manufacturer or Product Owner
2	CPMF6.4_Website undertaking	Importer
3	CPMF8.3_Advertisement Undertaking	Importer
4	CPMF9.6_TSE undertaking	Importer
5	CPMF10.3_Undertaking form for Amended formula	Overseas Manufacturer
6	CPMF11.5_Info for Fermented Substance	CMM Manufacturer and Importer
7	CPMF13.4a_Storage Condition of CPM - Imported Products	Importer
8	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer
9	Undertaking to test products at accredited labs	Importer

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

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF5.3_Forensic classification	Primary Assembler or Overseas Manufacturer or Product Owner
2	CPMF6.4_Website undertaking	Primary Assembler
3	CPMF8.3_Advertisement Undertaking	Primary Assembler
4	CPMF9.6_TSE undertaking	Primary Assembler
5	CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Primary Assembler
6	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer
7	Undertaking to test products at accredited labs	Primary Assembler

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

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF5.3_Forensic classification	Secondary Assembler or Overseas Manufacturer or Product Owner
2	CPMF6.4_Website undertaking	Secondary Assembler
3	CPMF8.3_Advertisement Undertaking	Secondary Assembler
4	CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Secondary Assembler
5	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer
6	Undertaking to test products at accredited labs	Secondary Assembler

* Forms are available at Annexes 1-7

Annex 1: CPMF5.3_Forensic Classification

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

FORENSIC CLASSIFICATION IN COUNTRIES OF SALES

The forensic classification of the product in the various countries where it is being sold are as follows (please tick where applicable):

Country of sale *	Forensic classification					
	Chinese medicine	Traditional medicine	Complementary medicine (Australia)	Health / dietary supplement	Food	Others (please specify)
China						
Taiwan						
Malaysia						
Australia						
South Korea						
Japan						
USA						

** If product is sold in other countries in addition to those listed above, please also include them in the table above with the appropriate forensic classification in these countries. If the rows in the table are insufficient, please attach the additional information on a separate sheet.*

Name: _____ Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 5.3

Annex 2: CPMF6.4_Website Undertaking

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

Website address stated on packaging materials or linked from QR code on packaging materials: _____

CHINESE PROPRIETARY MEDICINE (CPM) UNDERTAKING FORM: WEBSITE ADDRESS OR QR CODE ON PACKAGING MATERIALS

I _____ (full name) being a person authorised by my company to make this application hereby undertake to:

- Ensure that the product claims on the website would not exceed those which are stated on the final packaging materials for the above product.
- Comply with the Medicines (Medical Advertisements) Regulations 1977, including the need if any, to apply for the relevant advertisement permits for the advertisement and sales promotion of the product on the website. I understand that approval for sale of the above product, where appropriate, does not imply that the product name and/or its claims will be allowed for advertising purposes.
- Refrain from using the CPM product approval as a marketing tool to advertise or promote the above product on the website.

Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 6.4

Annex 3: CPMF8.3_Advertisement Undertaking

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

Manufacturer: _____

CHINESE PROPRIETARY MEDICINES (CPM) UNDERTAKING FORM FOR ADVERTISEMENTS

I _____ (full name) being a person authorised by my company to make this application hereby make the following undertaking:

- I understand that the above product, with its product name and claims, is not appropriate for the purpose of advertising and I undertake that that no form of advertisement will be conducted if the product is approved for listing.

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.

Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 8.3

Annex 4: CPMF9.6_TSE Undertaking

To: **Complementary Health Products Branch**
Health Products Regulation Group, Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

Manufacturer: _____

UNDERTAKING FORM: EVIDENCE FOR TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) STATUS OF ANIMAL-DERIVED MATERIALS**

I _____ (full name) being a person authorised by my company to make this application hereby undertake that the above product complies with the Complementary Health Products Branch (CHPB) TSE Guidelines* of the Health Sciences Authority (HSA) if it contains animal-derived materials**, and I hold evidence to demonstrate that the product is prepared:

i) From animal-derived materials** without any risk of exposure to TSE, and the health authorities in the country of origin has endorsed that they are sourced from TSE-free herds.

ii) By a manufacturing process with adequate measures taken to prevent cross-contamination between different tissues from different categories of infectivity.

iii) By a manufacturing process that has shown experimentally to minimise the TSE transmissible agent, if the above product contains tallow and/or gelatin derived from animal-derived materials** (including those for making capsule shells).

Should the above product be listed by HSA, I shall retain all the necessary evidence at all times while the above product remains listed, and would supply the evidence to HSA if required to do so. I shall report any changes in the TSE status of the animal-derived materials** of the above product to the Complementary Health Products Branch as soon as possible.

I hereby declare that the information on this form is current and correct.

Signature: _____ Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

** The TSE Guidelines for minimising the risk of contamination in CPM is available at the following HSA webpage: https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/tse-guidelines.pdf*

*** From species known to be affected by TSE e.g. ruminants like cattle, buffalo, sheep, goat, deer, antelope etc.*

CPMF 9.6

Annex 5: CPMF10.3_Undertaking Form for Amended Formula

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name of amended formula (English / Chinese): _____

_____

Brand name: _____ Dosage form: _____

Original product name in the country of origin: _____

CHINESE PROPRIETARY MEDICINE (CPM) UNDERTAKING FORM FOR AMENDED FORMULA (修改方)

I _____ (full name) being a person authorized by my company to make this application hereby:

- Confirm the changes to the following ingredients in the original formula for the product to be marketed in Singapore:

S/N	Latin Name	Chinese Name	Remarks*

*To specify the change(s) e.g. deletion, substitution with another ingredient, quantity adjustment to certain % etc.

- Certify that I hold evidence to support the indications and claims on the label and package insert (if any) of the above amended formula.

- Undertake that should the above product (amended formula) be listed by the Health Sciences Authority, I shall retain the evidence at all times while the above product remains listed, and would supply the evidence to the Health Sciences Authority if required to do so.

I hereby declare that the information on this form is current and correct.

Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 10.3

Annex 6: CPMF11.5_Info for Fermented Substance

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name 所申请的中成药产品名称：_____

(English / Chinese)（英文/中文）：_____

Brand name 商标名：_____ Dosage form 剂型：_____

Manufacturer 所申请的中成药成品的生产商：_____

INFORMATION REQUIRED FOR FERMENTED SUBSTANCE(S) IN CPM
中成药中所含的发酵成份的信息资料

A. Please fill up the following 请填写以下信息（信息需由生产发酵成份的厂商提供）：

I. Fermented Substance(s) (e.g. Cordyceps, Red Yeast Rice)发酵成份（如虫草菌丝体，红曲）:
1. Species (Please include strain identification report, except for *Monascus pupureus*) 发酵成份所使用的菌种的名称（请附上菌种的鉴定报告，红曲霉菌种不需要提交）
2. Source(s), including the name(s) and address(es) of the manufacturer(s) 发酵成份的来源，请指明其生产商的名称和地址

B. Please fill up and attach the following 请填写以下信息:

I. Fermented Substance(s):发酵成份的外观描述及化学特性	Name of Document(s) Attached 请呈交文件，并在此注明所附文件名
Please submit the specifications and Certificate of Analysis (COA) of the fermented substance(s), including description of physical characteristics such as colour, texture and quantity of active constituents (e.g. adenosine ≥XX%) 请呈交发酵物的规格及检验报告，需注明其物理性状，如颜色和质地等，及其有效化学组分的含量要求（如腺苷≥XX%）	
II. Details of Manufacturing Process of Fermented Substance(s):发酵的详细工艺过程	Name of Document(s) Attached 请呈交文件，并在此注明所附文件名
Please submit the manufacturing process in the form of flowchart(s), and indicate the type of fermentation (e.g. liquid/solid) and conditions used (e.g. temperature, pressure, humidity) 请呈交发酵的工艺流程图，并指明发酵的类型（如固体/液体），以及发酵的条件（如温度、压力、湿度）	
2. Manufacturer's licence and GMP Certificate, where applicable 生产发酵物的厂商的生产许可证及 GMP 证书，如有	

C. Please confirm the following and attach the required details where applicable
请确认并根据要求附加详细资料：

I. Details of Manufacturing Process of Fermented Substances: 发酵的详细生产工艺	Yes/No 有/没有	If yes, details to be submitted 如有，请提交相关资料
1. Animal-derived materials used, if any (e.g. animal lipids in culture media) 是否使用来源于动物的成份（如以动物油脂作为培养基），如有		1. List of animal-derived materials 列出使用的来源于动物的成份 2. If ruminant-derived material is used, please attach CPMF9.6* 如含反刍动物成份，需填表格 CPMF9.6*
2. Impurities / By-products produced during manufacturing, if any 杂质/发酵过程的副产品，如有		Allowable impurities / by-products limits / specifications 允许的杂质/发酵过程的副产品的限量/规格
3. Solvents / chemicals used for purification, if any 是否使用溶剂/化学品进行提纯，如有		List of solvents / chemicals 列明所用的溶剂/化学品名
4. Solvents / chemicals used for extraction, if any 是否使用溶剂/化学品进行提取		List of solvents / chemicals 列明所用的溶剂/化学品名
5. Hazardous additives, e.g. bleaching agents used during manufacturing 是否使用了有害的添加剂，如发酵过程中使用漂白剂		List of hazardous additives and the allowable residual limits 列明该添加剂及允许的限量
6. Residues, if any 残留物，如有		Allowable residues limits / specifications 允许的残留物的限量/规格

*CPMF9.6_TSE undertaking form, to be filled up by the local applicant, can be downloaded from the HSA website. 表格 CPMF9.6 可由卫生科学局网站下载，并需由本地的产品申请人填写。

D. Additional Information 其它附加资料：

Details 详细资料	Yes/No 有/没有	If yes, Name of Document(s) Attached 如有，请呈交文件，并在此注明所附文件名
1. Information on system for quality control (e.g. SOPs or workflows to avoid strain mutation, degeneration and contamination in the fermented substance) 质量控制的相关资料（如：避免菌种变异、衰退及污染的标准作业程序或流程）		
2. COA of the fermented substance showing testing of other by-products or toxic substances, 发酵物中可能产生的副产品或有毒物质的检验报告		
3. Composition of culture media used in manufacturing process 生产过程中所使用的培养基的组成成分		

E. Manufacturer of Fermented Substances 生产发酵物厂商的详细资料：

I hereby declare that the above information on this form is current and correct. 我声明以上所提供的信息是完全真实并正确的。

Name 姓名：_____ Designation 职务：_____

Name and address of company 生产发酵物的厂商名称及地址：_____

_____

Tel 电话：_____ Fax 传真：_____ Date 日期：_____

Signature 签名：_____

F. Local Applicant 本地申请者的详细资料:

Should the above CPM product be listed by HSA, I shall report any changes to the above details to the Complementary Health Products Branch as soon as possible. 以上产品若经卫生科学局登记后有任何变更，我会尽快通知辅助医疗保健产品组.

Name 本地申请人的姓名：_____ Designation 职位：_____

Name of company: 本地申请公司的名称：_____

Tel 电话：_____ Fax 传真：_____ Date 日期：_____

Signature 申请人签名：_____

Annex 7a: CPMF13.4a_Storage Condition of CPM - Imported Products

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

STORAGE CONDITION OF CHINESE PROPRIETARY MEDICINES (CPM) – IMPORTED PRODUCTS 中成药产品的贮存条件 – 适用于进口的中成药产品

Product name 产品名称 (English / Chinese) (英文/中文)	
Brand name 商标	
Dosage form 剂型	Capsule / Granules / Liquid / Ointment / Pill / Powder / Tablet / Tea / Others* 胶囊 / 颗粒 / 合剂 / 软膏剂 / 丸剂 / 散剂 / 片剂 / 茶剂 /其它* If others, please state: _____ 如为其它,请注明: _____
Pack size 包装规格	

STORAGE CONDITION 贮存条件

Storage temperature (°C) 贮存温度	Below 25 °C / Below 30 °C / Others* 低于 25 °C / 低于 30 °C / 其它* If others, please state: _____ 如为其它,请注明: _____
Relative humidity (%) 相对湿度	Not more than 75% / Others* 不超过 75% / 其它* If others, please state: _____ 如为其它,请注明: _____

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.
我保证所提供的上述信息是正确的,并保证如果有任何修改将会通知辅助医疗保健产品组.

Name (姓名): _____ Designation (职务): _____

Name of company (公司名称): _____

Tel (电话): _____ Fax (传真): _____ Date 日期: _____

Signature (签名): _____

* Please select the appropriate 请选择适合的选项
CPMF 13.4a

Annex 7b: CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

STORAGE CONDITION AND CONTAINER(S) OF CHINESE PROPRIETARY MEDICINES (CPM) – LOCALLY MANUFACTURED / PRIMARY ASSEMBLED PRODUCTS
中成药产品的贮存条件和贮存容器 - 适用于本地生产的 / 一级分装的中成药产品

Product name 产品名称 (English / Chinese) (英文/中文)	
Brand name 商标	
Dosage form 剂型	Capsule / Granules / Liquid / Ointment / Pill / Powder / Tablet / Tea / Others* 胶囊 / 颗粒 / 合剂 / 软膏剂 / 丸剂 / 散剂 / 片剂 / 茶剂 /其它* If others, please state: _____ 如为其它,请注明: _____
Pack size(If different material, please submit separate form) 包装规格(如产品有多种包装规格，且使用不同的包装材料,请填写多份表格)	

STORAGE CONDITION 贮存条件

Storage temperature (°C) 贮存温度	Below 25 °C / Below 30 °C / Others* 低于 25 °C / 低于 30 °C / 其它* If others, please state: _____ 如为其它,请注明: _____
Relative humidity (%) 相对湿度	Not more than 75% / Others* 不超过 75%/其它* If others, please state: _____ 如为其它,请注明: _____

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* Please select the appropriate 请选择适合的选项
CPMF 13.3b

STORAGE CONTAINER(S) 贮存容器

Primary packaging (immediate layer in contact with the product) **内层包装(直接接触产品的包装)**			
Type of container 容器类型 (Please refer to Page 4 for pictorial description) (请参阅第四页图示)	Bottle / Sachet / Blister / Tea bag / Re-sealable bag / Others* **瓶子 / 小袋 / 泡板 / 茶包 / 可开合密封袋 / 其它*** If others, please state: _____ 如为其它,请注明: _____		
Container material 容器材料	Plastic / Glass / Aluminum / Aluminum PVC / Others* 塑料 / 玻璃 / 铝箔 / 铝塑 / 其它* If others, please state: _____ 如为其它,请注明: _____ If plastic, please indicate if it is PETE / HDPE / UPVC / LDPE / PP / PS* 如为塑料,请指明是 PETE / HDPE / UPVC / LDPE / PP / PS*		
Tamper-evident 拆封标志	Yes / No* 有 / 没有*		
Protection from moisture 是否加入防潮剂	Yes / No* 有 / 没有*	Protection from light 避光	Yes / No* 有 / 没有*
CONTAINER CLOSURE （FOR BOTTLES) **瓶盖**			
Type of closure system 瓶盖类型 (Please refer to Page 4 for pictorial description) (请参阅第四页图示)	Screw cap / Flip-top cap / Pull-off cap / Others* 旋转 / 翻转 / 拉启式 / 其它* If others, please state: _____ 如为其它,请注明: _____		
Closure system material 瓶盖材料	Plastic / Glass / Aluminium / Others* 塑料 / 玻璃 / 铝箔 / 其它* If plastic, please indicate if it is PETE / HDPE / UPVC / LDPE / PP / PS* 如为塑料,请指明是 PETE / HDPE / UPVC / LDPE / PP / PS* If others, please state: _____ 如为其它,请注明: _____		

* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Secondary packaging (if any) **外层包装(如果有)** Is packaging critical (i.e. give additional protection to the product) : Yes / No* 是否为重要包装(会影响产品有效期): 是 / 不是* If yes, please explain purpose (e.g. protect from light, moisture): _____ 如果是,请解释目的(如:避光,防潮): _____	
Type of container 容器类型 (Please refer to Page 4 for pictorial description) (请参阅第四页图示)	Bottle / Box / Bag / Re-sealable bag / Others* 瓶子 / 盒子 / 袋子 / 可开合密封袋 / 其它* If others, please state: _____ 如为其它,请注明: _____
Container material 容器材料	Paper / Plastic / Glass / Aluminum / Aluminium PVC / Others* 纸 / 塑料 / 玻璃 / 铝箔 / 铝塑 / 其它* If others, please state: _____ 如为其它,请注明: _____ If plastic, please indicate if it is PETE / HDPE / UPVC / LDPE / PP / PS* 如为塑料,请指明是 PETE / HDPE / UPVC / LDPE / PP / PS*
Tamper-evident 拆封标志	Yes / No* 有 / 没有*

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.
我保证所提供的上述信息是正确的,并保证如果有任何修改将会通知辅助医疗保健产品组.

Name (姓名) (Dr/Mr/Mdm/Ms*): _____

Designation (职务): _____ Signature (签名): _____

Name of company (公司名称): _____

Tel (电话): _____ Fax (传真): _____

Date (日期): _____

Please note that the detail submitted on this form is for Authority's information only.
请注意, 以上信息仅供当局备案.

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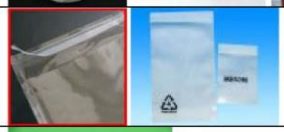
* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Type of storage container 贮存容器的类型

Bottle 瓶子	
Re-sealable bag 可开合密封袋	
Sachet 小袋	
Blister 泡板	
Tea bag 茶包	

Type of closure system 瓶盖类型

Screw cap 旋转	
Flip-top cap 翻转	
Pull-off cap 拉启	
Tamper-evident seals 内包装的拆封标志	

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* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Annex 8: Physical Specifications of the Product

Physical specifications required for different dosage forms:

Dosage Form	Physical Specifications Required
Capsule	Filling variation
	Water content
	Disintegration
Granules	Filling/filling variation (for single dose packing)
	Water content
	Granules size variation
	Dispersibility
Liquid (Mixture)	Filling/filling variation (for single dose packing)
	pH
	Relative density
	Sucrose content (where applicable)
	Preservatives (where applicable)
Liquid (Syrup)	Filling/filling variation (for single dose packing)
	pH
	Relative density
	Sucrose content (where applicable)
	Preservatives (where applicable)
Liquid (Tincture)	Filling/filling variation (for single dose packing)
	Determination of ethanol
	Determination of methanol

Pills	Filling/filling variation (for single dose packing)
	Weight variation
	Water content
	Disintegration
Powder	Filling/filling variation (for single dose packing)
	Water content
	Uniformity
	Particle size variation
Suppository	Weight variation
	Disintegration
Tablet	Weight variation
	Disintegration
Tea	Filling/filling variation (for single dose packing)
	Water content
	Weight variation (for tea lumps only)
	Dispersibility (for sugar containing tea lumps only)

Please note that for all dosage forms, in addition to the above, the following must be specified:

i. unit weight
ii. minimum fill (for multiple dose product)

Revision History

Version	Date of publication	Summary of changes*
19	November 2024	• Included documents related to DEG and EG • Included description of manufacturing process and finished product specifications as required documents
20	January 2025	• Included elaboration on the turn-around-time

*Editorial changes are not reflected

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

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HSA
Health Sciences Authority