

**Guidance Notes on Application for Variation of Registered Particulars of
Registered Proprietary Chinese Medicines**

(A) Introduction

1. According to sections 124(1) and (2) of the Chinese Medicine Ordinance (“the Ordinance”), the holder of a certificate of registration (“the Certificate”) may, on payment of a prescribed fee, apply in writing to the Chinese Medicines Board (“the CMB”) for approval to vary the registered particulars of the proprietary Chinese medicine (“pCm”) to which the Certificate relates. If the CMB is satisfied that the proposed variation will not adversely affect the safety, quality and efficacy of the relevant pCm, it may approve the variation as proposed in the application.

2. According to section 15 of the Chinese Medicines Regulation, the registered particulars for a pCm include:
 - (a) its Chinese and English name;
 - (b) its dose form;
 - (c) the name and quantity of each of its active ingredient;
 - (d) the name and quantity of each of its excipient (if any);
 - (e) its specification;
 - (f) its indication (if any);
 - (g) its dosage and method of usage;
 - (h) each of its labels to be attached or printed on its package;
 - (i) the package insert to be supplied for its sales inside Hong Kong;
 - (j) each of the package inserts to be supplied for its sales outside Hong Kong (if any);
 - (k) the name and address of each of its manufacturer; and
 - (l) its function or pharmacological action.

The abovementioned items (a), (b) and (c) shall not be varied. Any variation of these items will require a new application for registration of the pCm.

3. According to sections 124(4) and (5) of the Ordinance, where the variation of the registered particulars of a pCm registered under section 121 of the Ordinance takes effect, the pCm to which the registered particulars were related before the variation shall cease to be a pCm registered under that section. In addition, where by virtue of section 124(4) a pCm ceases to be a pCm registered under section 121, the relevant applicant shall before the relevant variation takes effect, recall or cause to recall, to the extent reasonably possible, the pCm already supplied.

(B) Requirements for Application

4. Application for variation of registered particulars of a registered pCm can only be made by the holder of the pCm's Certificate ("the Applicant"), who shall complete the Application Form for Variation of Registered Particulars of Registered Proprietary Chinese Medicines ("the Application Form").
5. If the application involves a change of the Certificate holder, the new holder shall complete page 3 of the Application Form. He/She shall fulfill the requirements under section 120 of the Ordinance and hold a valid Manufacturer Licence in Proprietary Chinese Medicines or Wholesaler Licence in Proprietary Chinese Medicines.

(C) Obtaining the Application Form

6. The Application Form can be obtained from:
 - a. **the Chinese Medicine Regulatory Office ("CMRO") of the Department of Health ("DH") during office hours**

Address: 16/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon

Office hours: Monday to Friday (9:00 a.m. to 5:30 p.m.)
Saturdays, Sundays and general holidays (Closed)

- b. **the Chinese Medicine Council of Hong Kong website at <http://www.cmchk.org.hk>**

(D) Submitting the application

7. The Applicant shall submit the duly completed Application Form together with the documents and information required for the item(s) to be varied (please refer to Appendix I and Appendix II). You may submit the application:
 - a. by mail to the CMRO of the DH (see above for the address);
 - b. by hand to the CMRO of the DH during office hours (see above for the office hours); or
 - c. by e-Form submission (applicable to holders of recognised organisational digital certificates only).

(Website: <https://eform.cefs.gov.hk/form/dh0044/en/>)

8. The CMRO will issue a General Demand Note to the Applicant. The Applicant can make payment according to the payment methods stated in the General Demand Note. For details on the prescribed fees related to the registration of pCm, please refer to Appendix I of the Application Handbook for Registration of Proprietary Chinese Medicines. All application fees paid will not be refunded regardless of whether the application is approved.

(E) Issuance of Acknowledgement Letter and Reminder

9. Upon receipt of an application and the prescribed fees, the Applicant shall receive an acknowledgement letter, on which a registration number of the relevant pCm is shown for the Applicant's case of enquiry.
10. If the Applicant has not submitted all the required documents for the application for variation of registered particulars, or if the proposed variation(s) is/are against the requirements of the relevant guidelines stipulated by the CMB, the DH will issue a reminder to the Applicant. If the Applicant fails to submit the required documents to the CMB within the specified period stated in the reminder, the application will be deemed withdrawn. All application fees paid will not be refunded.

(F) Application results

11. The CMB shall notify the Applicant in writing of whether the application for variation of registered particulars is successful, together with the details of the variation and its effective date. If the Applicant is required to collect a new Certificate, he/she is required to return the original Certificate to the CMRO of the DH in order to obtain the new one. If the application is rejected by the CMB, the Applicant will receive a notification specifying the reasons for the rejection.

(G) Variation of information

12. Should there be any variation of the personal data or other declared information submitted during the processing of the application by the CMB, the Applicant shall notify the CMRO of the DH in writing or by fax as soon as possible:

Address: 16/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon
Fax: 2319 2664

(H) Enquiries

13. Should the Applicant have any enquiry regarding this set of Guidance Notes, please contact the CMRO of the DH by telephone or by fax:

Enquiry hotline: 3904 9130

Fax: 2319 2664

Appendix I –

Documents Required for the Application for Variation of Registered Particulars of pCm

	Proposed variation of registered particulars	Documents required [※]
1.	Chinese and English product name	A new application for registration of pCm is required
	Chinese and English trade mark text	<input type="checkbox"/> Colour proofs of the new label and package insert with detailed description of the variation
2.	Dose form	A new application for registration of pCm is required
3.	Name and quantity of each active ingredient	A new application for registration of pCm is required
4.	Name and quantity of each excipient	<input type="checkbox"/> Master formula and manufacturing method issued by the manufacturer(s) <input type="checkbox"/> Basis for supporting the product stability (i.e. real-time stability test report or accelerated stability test report for 3 batches of product) <input type="checkbox"/> Latest product specification, method and certificate of analysis
5.	Specification	<input type="checkbox"/> Master formula and manufacturing method issued by the manufacturer(s) <input type="checkbox"/> Basis for supporting the product stability (i.e. real-time stability test report or accelerated stability test report for 3 batches of product) <input type="checkbox"/> Latest product specification, method and certificate of analysis <input type="checkbox"/> Colour proofs of the new label and package insert with detailed description of the variation
6.	Indication	<input type="checkbox"/> Basis for supporting the variation (e.g. documentary proof of the variation issued by the country of origin or non-clinical/clinical study data, etc.) <input type="checkbox"/> Colour proofs of the new label (if applicable) and package insert with detailed description of the variation

	Proposed variation of registered particulars	Documents required [※]
7.	Dosage and method of usage	<input type="checkbox"/> Basis for supporting the variation (e.g. documentary proof of the variation issued by the country of origin or non-clinical/clinical study data, etc.) <input type="checkbox"/> Colour proofs of the new label and package insert with detailed description of the variation
8.	Each of the labels to be attached or printed on the package of the pCm	
	No change to the content, only with change(s) in the typesetting, fonts, use of traditional and simplified Chinese, colours, designs, patterns, package designs and/or font sizes, etc.	<input type="checkbox"/> Colour proof of the new label with detailed description of the variation
	Chinese and English product name	A new application for registration of pCm is required
	Chinese and English trade mark text	<input type="checkbox"/> Colour proof of the new label with detailed description of the variation
	Name and/or quantity of active ingredient	<input type="checkbox"/> (For application without variation of master formula) Colour proof of the new label with detailed description of the variation (For application with variation of master formula) A new application for registration of pCm is required
	Registration number of the pCm	A new application for registration of pCm is required
	Name of the holder of the certificate of registration	Please refer to Appendix II
	Name of the manufacturer(s)	Please refer to Item 10 of Appendix I
	Packing specification	Please refer to Item 5 of Appendix I
	Dosage and method of usage	Please refer to Item 7 of Appendix I
	Expiry date	<input type="checkbox"/> Basis for supporting the product stability (i.e. real-time stability test report or accelerated stability test report for 3 batches of the product)

Proposed variation of registered particulars	Documents required [※]
9. Package insert to be supplied for sales inside Hong Kong or each of the package inserts to be supplied for sales outside Hong Kong	
No change to the content, only with change(s) in the typesetting, fonts, use of traditional and simplified Chinese, colours, designs, patterns, package designs and/or font sizes, etc.	<input type="checkbox"/> Colour proof of the new package insert with detailed description of the variation
Chinese and English product name	A new application for registration of pCm is required
Chinese and English trade mark text	<input type="checkbox"/> Colour proof of the new package insert with detailed description of the variation
Name and quantity of active ingredient	<input type="checkbox"/> (For application without variation of master formula) Colour proof of the new package insert with detailed description of the variation (For application with variation of master formula) A new application for registration of pCm is required
Name of the holder of the certificate of registration	Please refer to Appendix II
Name of the manufacturer(s)	Please refer to Item 10 of Appendix I
Dosage and method of usage	<input type="checkbox"/> Basis for supporting the variation (e.g. documentary proof of the variation issued by the country of origin or non-clinical/clinical study data, etc.) <input type="checkbox"/> Colour proofs of the new label (if applicable) and package insert with detailed description of the variation
Functions or pharmacological action	
Indications	
Contra-indications	
Side effects	
Toxic effects	
Precautions to be taken regarding the use	
Storage instructions	<input type="checkbox"/> Basis for supporting the product stability (i.e. real-time stability test report or accelerated stability test report for 3 batches of product) <input type="checkbox"/> Colour proof of the new package insert with detailed description of the variation

	Proposed variation of registered particulars	Documents required [※]
	Packing specification	Please refer to Item 5 of Appendix I
10.	Name and address of the manufacturer(s)	<input type="checkbox"/> Certified true copies of the manufacturing authorisation and free sale documentation issued by the country of origin <input type="checkbox"/> Product specification, method and certificate of analysis of the pCm produced by the new manufacturer(s) <input type="checkbox"/> Test reports on heavy metals and toxic elements, microbial limit and pesticide residues of the pCm produced by the new manufacturer(s) <input type="checkbox"/> Master formula and manufacturing method issued by the new manufacturer(s) <input type="checkbox"/> Colour proofs of the new label and package insert with detailed description of the variation
11.	Functions or pharmacological action	<input type="checkbox"/> Basis for supporting the variation (e.g. documentary proof of the variation issued by the country of origin or non-clinical/clinical study data, etc.) <input type="checkbox"/> Colour proofs of the new label (if applicable) and package insert with detailed description of the variation

※ If the item applied for variation involves change of other registered particulars, the Applicant shall submit application in one go together with all relevant supporting documents. The CMB may require the Applicant to submit, when necessary, other information and documents as the basis for supporting the variation.

Appendix II –

Documents Required for Variation of Information of Certificate Holder

	Item(s) proposed to be varied	Documents required [※]
No substantive change of Certificate holder		
1.	<u>Variation of the company name only</u> (where the Certificate holder is a <u>wholesaler of pCm</u>)	<input type="checkbox"/> Copy of the Certificate (the original copy shall be returned to the CMB upon approval of application) <input type="checkbox"/> Copies of Business Registration Certificate and Wholesaler Licence in Proprietary Chinese Medicines showing the new company name <input type="checkbox"/> (For limited company) Copy of documentary proof issued by the Companies Registry for the name variation <input type="checkbox"/> Colour proofs of the new package insert and label with detailed description of the variation
2.	<u>Variation of the company name only</u> (where the Certificate holder is a <u>manufacturer of pCm</u>)	<input type="checkbox"/> Copy of the Certificate (the original copy shall be returned to the CMB upon approval of application) <input type="checkbox"/> Copies of Business Registration Certificate and Manufacturer Licence in Proprietary Chinese Medicines showing the new company name <input type="checkbox"/> (For limited company) Copy of documentary proof issued by the Companies Registry for the name variation <input type="checkbox"/> Colour proofs of the new package insert and label with detailed description of the variation

	Item(s) proposed to be varied	Documents required*
3.	<u>Variation of the company address only</u> (where the Certificate holder is a <u>manufacturer of pCm</u>)	<input type="checkbox"/> Copy of the Certificate (the original copy shall be returned to the CMB upon approval of application) <input type="checkbox"/> Copies of Business Registration Certificate and Manufacturer Licence in Proprietary Chinese Medicines showing the new company address <input type="checkbox"/> Test reports on heavy metals and toxic elements, microbial limit and pesticide residues of the relevant pCm produced at the new company address <input type="checkbox"/> Colour proofs of the new package insert and label with detailed description of the variation (if applicable)
Substantive change of Certificate holder		
4.	The new Certificate holder <u>is not involved in the manufacturing of the pCm</u>	<input type="checkbox"/> Copy of the Certificate (the original copy shall be returned to the CMB upon approval of application) <input type="checkbox"/> Copies of Business Registration Certificate and Wholesaler Licence in Proprietary Chinese Medicines of the new Certificate holder <input type="checkbox"/> Letters issued by the manufacturer(s) of the pCm confirming the new Certificate holder in Hong Kong and specifying the pCm to be transferred ^o <input type="checkbox"/> Certified true copies of the manufacturing authorisation and free sale documentation issued by the country of origin <input type="checkbox"/> Colour proofs of the new package insert and label with detailed description of the variation <input type="checkbox"/> Information of person-in-charge of the new company

	Item(s) proposed to be varied	Documents required*
5.	The new Certificate holder <u>is involved in the manufacturing of the pCm</u>	<input type="checkbox"/> Copy of the Certificate (the original copy shall be returned to the CMB upon approval of application) <input type="checkbox"/> Copies of Business Registration Certificate and Manufacturer Licence in Proprietary Chinese Medicines of the new Certificate holder <input type="checkbox"/> Letters issued by the manufacturer(s) of the pCm confirming the new Certificate holder in Hong Kong and specifying the pCm to be transferred [⊙] <input type="checkbox"/> Colour proofs of the new package insert and label with detailed description of the variation <input type="checkbox"/> Master formula and manufacturing method issued by the new manufacturer(s) <input type="checkbox"/> Test reports on heavy metals and toxic elements, microbial limit and pesticide residues of the pCm produced by the new manufacturer(s) <input type="checkbox"/> Product specification, method and certificate of analysis of the pCm produced by the new manufacturer(s) <input type="checkbox"/> Information of person-in-charge of the new company

Note:

* If the item applied for variation involves change of other registered particulars, the Applicant shall submit application in one go together with all relevant supporting documents. The CMB may require the Applicant to submit, when necessary, other information and documents as the basis for supporting the variation.

⊙ The letters shall include:

1. A letter issued by the original Certificate holder consenting to the transfer of the listed registered pCm to the new Certificate holder
2. A letter issued by the new Certificate holder consenting to the acceptance of the listed registered pCm
3. A letter issued by the manufacturer(s) of the pCm confirming in writing the information of the new agent of the pCm in Hong Kong and specifying the name and registration number of the pCm