

立法會
《中醫藥條例》、《中醫藥〈費用〉規例》及《中藥規例》
的生效日期公告小組委員會會議

**Legislative Council Subcommittee on Commencement Notices under
the Chinese Medicine Ordinance, Chinese Medicine (Fees) Regulation and Chinese
Medicines Regulation**

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DRAFT

Your Ref.:

File Ref.: <Type> - <Year> - <No.>

2/F, Public Health Laboratory Centre,

382 Nam Cheong Street,

Kowloon.

Date: <Date>

<Company Name>

<Company Address>

Dear Sir/Madam,

Application for registration of proprietary Chinese medicine

<Chinese Name of Product>

<English Name of Product>

I refer to your application for registration of the above proprietary Chinese medicine to the Chinese Medicines Board. Your application is approved.

A certificate of registration of a proprietary Chinese medicine will be issued to you upon payment of the prescribed fee. Please bring along the enclosed Notification of Payment together with the prescribed fee to our office during office hours (Monday to Friday: 9:00am to 12:00noon, 2:00 to 4:00pm; Saturday: 9:00am to 12:00noon) or send in the payment by cheque through mail. For payment by mail or by cheque, please use a crossed cheque or bank draft payable to "The Government of the Hong Kong Special Administrative Region". Please write the company name on the back of the cheque.

For enquiries, please call 2126 5115.

Yours faithfully,

For Chinese Medicines Committee

DRAFT

CHINESE MEDICINE ORDINANCE

(Chapter 549)

CERTIFICATE OF REGISTRATION OF PROPRIETARY CHINESE MEDICINE

This is hereby certified that <Company Name> (<Company Address>) has been issued with a permit No. <Reg. Code Title>-<Year>-<No.> (<Class>) authorizing <Eng. pCm Name> (<Chin. pCm Name>) to be sold in Hong Kong.

2. This certificate will be valid until <Expiry Date>.

3. No change in the registered particulars of this proprietary Chinese medicine shall be made during the effective period of this registration without the approval of the Chinese Medicines Board.

Conditions:

<Licence Condition(s)>

Date: <Date of issue>

for Chinese Medicines Committee

DRAFT

File Ref.: <Type> - <Year> - <No.>
2/F, Public Health Laboratory Centre,
382 Nam Cheong Street,
Kowloon
Date: <Date>

<Company Name>
<Company Address>

Dear Sir/Madam,

Letter of notification for transitional registration
of proprietary Chinese medicines

The Chinese Medicines Board of the Chinese Medicines Council of Hong Kong acknowledges receipt of your application for transitional registration of proprietary Chinese medicine for the product stated below. In accordance with section 128 of Chinese Medicine Ordinance (Cap 549), you may continue to sell the proprietary Chinese medicine (pCm) stated below until i) the issue of a certificate of registration, or ii) the refusal of the application for registration of that proprietary Chinese medicine, or iii) such date as may be specified and promulgated by Secretary for Health, Welfare and Food by notice published in the Gazette (whichever is the earliest).

Product Name: <Chinese Name of Product>

<English Name of Product>

Name of Manufacturer: <Name of the Manufacturer>

Transitional registration number: <Reg. Code Title> - <No.>

Please quote the transitional registration number for any queries.

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For Chinese Medicines Board

The Chinese Medicines Board imposes the following conditions (if any)

1. Holder of this notification should submit the documents stated in the “Transitional Registration Checklist (B)” & “Transitional Registration Checklist (C)”, in accordance to the selected registration group of pCm, on or before 30 June 2005 and 30 June 2009 respectively.
2. Holder of this notification should attach / print the above stated transitional registration no. on the package label.

Your Ref.:

File Ref.: <Type> - <Year> - <No.>

32/F, Wu Chung House,

213 Queen's Road East,

Wanchai, Hong Kong.

Date: <Date>

<Company Name>

<Company Address>

Dear Sir/Madam,

Refusal of application for registration of proprietary Chinese medicine

<Chinese Name of Product>

<English Name of Product>

I regret to inform you that your application for registration of the above proprietary Chinese medicine is not approved for the following reason(s):

Reason(s):

<Reason(s) for Rejection>

With reference to the above decision made by the Chinese Medicines Committee, you may, within 14 days of the receipt of this notification of decision, request the Chinese Medicines Board to review the decision in accordance with section 140 of the Chinese Medicine Ordinance, Cap. 549 of the Laws of Hong Kong, and state the reasons relied upon.

For enquiries, please call 2126 5115.

Yours faithfully,

For Chinese Medicines Committee

Reasons for rejection of registration of proprietary Chinese medicine

Examples of reasons for rejection	
a	The applicant cannot provide sufficient information to substantiate the safety of that pCm
b	Refer to the heavy metals and toxic elements test report which is submitted by the applicant. The content levels of the heavy metals and toxic element of that pCm exceed the maximum permitted levels.
c	Refer to the pesticide residues test report which is submitted by the applicant. The content levels of the pesticide residues of that pCm exceed the maximum permitted levels.
d	Refer to the microbial limit test report which is submitted by the applicant. The pCm does not pass the microbial limit test.
e	The applicant cannot provide sufficient information to substantiate the efficacy of that pCm
f	The 'Interpretation and principle for formulating a prescription', which is submitted by the applicant, is not rational.
g	The 'certificate of analysis', which is submitted by the applicant, does not comply with the requirement of the Chinese Medicines Board.
h	The 'certificate of analysis', which is submitted by the applicant, is not performed in the test laboratories that comply with the requirement of the Chinese Medicines Board.
i	The applicant cannot provide labels that comply with legal requirement
j	The applicant cannot provide package insert that comply with legal requirement

DRAFT

Your Ref.:

File Ref.: <Type> - <Year> - <No.>

2/F, Public Health Laboratory Centre

382 Nam Cheong Street

Kowloon

Date: <Date>

<Company Name>

<Company Address>

Dear Sir/Madam,

Review of decision for registration of proprietary Chinese medicine

<Chinese Name of Product>

<English Name of Product>

I refer to your request of review of decision of the Chinese Medicines Committee by the Chinese Medicines Board on <date>, about the refusal of application for registration of pCm. The decision of the Chinese Medicines Board is as follows:

Result:

The application for registration of pCm is not approved.

Reason(s):

<Reason(s) for Rejection>

In accordance with section 141 of the Chinese Medicine Ordinance (Cap. 549), you may appeal to the Court of First Instance against the decision of the Chinese Medicines Board within 1 month from the date of service of this notice.

For enquiries, please call 2126 5115.

Yours faithfully,

For Chinese Medicines Board