

Department of Health

How to apply for an Import/Export Licence for Proprietary Chinese Medicine

Under the Import and Export Ordinance (Cap. 60 of the Laws of Hong Kong), an import/export licence must be obtained before any proprietary Chinese medicine (pCm) is imported or exported outside Hong Kong.

According to the Chinese Medicine Ordinance, “proprietary Chinese medicine” means any proprietary product-

- (a) composed solely of the following as active ingredients-
 - (i) any Chinese herbal medicines; or
 - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
 - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
- (b) formulated in a finished dose form; and
- (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

Applicants of an import/export licence for pCm should submit the following documents to the Drug Registration and Import/Export Control Division of the Department of Health (address: 3/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, Hong Kong) before any import/export of the pCm.

A. Import Licence (Form 3 - blue)

- (1) Submit a completed Import Licence Form 3 (TRA 187) in quadruplicate.

- (2) Provide the copy of following valid document and relevant authorisation document (if any)-
- (i) “Certificate of registration of proprietary Chinese medicine”; or
 - (ii) “Notice of confirmation of transitional registration of proprietary Chinese medicine”; or
 - (iii) “Certificate for clinical trial and medicinal test”; or
 - (iv) a document issued under section 158(1) of the Chinese Medicine Ordinance by the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong certifying that an exemption has been given for the pCm in question for the purposes of education or scientific research.
- (3) If the pCm to be imported is still under assessment for non-transitional registration, the application number of the pCm concerned shall be marked on the form.
- (4) If the pCm to be imported is used for the purpose of registration, applicants should mark “for registration purpose” on the form. The quantity of pCm to be imported should generally not exceed six selling units (e.g. six boxes or bottles) unless it is necessary for the purpose of conducting a specified test (or examination) as certified or justified by the local laboratory recognised by the Chinese Medicines Board.
- (5) If the pCm to be imported is for re-export purpose and no document as stated in (2) can be provided, applicants should mark “for re-export only” on the form and submit a copy of the formula of pCm listed with one hundred percent ingredients issued by the manufacturer.
- (6) If the pCm has been classified by the Proprietary Chinese Medicines Registration Unit of the Department of Health, please provide the relevant letter to facilitate the processing.
- (7) Provide a copy of a valid Wholesaler Licence in Proprietary Chinese Medicines/Chinese Medicines Trader Transitional Certificate (wholesaler licence in proprietary Chinese

medicines) or a copy of Manufacturer^[note] Licence/Chinese Medicines Trader Transitional Certificate (manufacturer^[note] licence in proprietary Chinese medicines), whichever is applicable; or a copy of the document certifying that the organisation has been given an exemption by the Chinese Medicines Board to import such pCm under section 158(1) of the Chinese Medicine Ordinance.

B. Export Licence (Form 6 - white)

- (1) Submit a completed Export Licence Form 6 (TRA 394) in triplicate.
- (2) Provide a copy of the following valid document (if any)-
 - (i) “Certificate of registration of proprietary Chinese medicine”; or
 - (ii) “Notice of confirmation of transitional registration of proprietary Chinese medicine”;
or
 - (iii) a document issued under section 158(1) of the Chinese Medicine Ordinance by the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong certifying that an exemption has been given for the pCm in question for the purposes of education or scientific research.
- (3) If the pCm to be exported is still under assessment for non-transitional registration, the application number of the pCm concerned shall be marked on the form.
- (4) If the pCm to be exported is for re-export purpose and no document as stated in (2) can be provided, applicants can submit a copy of the import licence for the pCm instead.
- (5) Provide a copy of a valid Wholesaler Licence in Proprietary Chinese Medicines/Chinese Medicines Trader Transitional Certificate (wholesaler licence in proprietary Chinese

^[note] Applicable only to the circumstances, as set out in section 158(7) of the Chinese Medicine Ordinance, that the proprietary Chinese medicines in question are imported or obtained by the manufacturer as raw materials for the purpose of manufacturing his own products. Applicants should mark “for the purpose of manufacturing his own products” on the import licence form.

medicines) or a copy of Manufacturer^[note] Licence/Chinese Medicines Trader Transitional Certificate (manufacturer^[note] licence in proprietary Chinese medicines), whichever is applicable; or a copy of the document certifying that the organisation has been given an exemption by the Chinese Medicines Board to import such pCm under section 158(1) of the Chinese Medicine Ordinance.

Please note the followings:

- (1) After submitting the application form, applicants will be issued a receipt with a number on it. Please keep it and collect your import/export licence according to the instructions as set out on it.
- (2) An application will be rejected if insufficient information is provided.
- (3) For enquiries, please call 2319 8460.

Drug Registration and Import/Export

Control Division

Department of Health

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