Chinese Medicine Regulatory Office
Department of Health

Guidelines for Application for Import/Export Licence of Proprietary Chinese Medicines

Under the Import and Export Ordinance (Cap. 60 of the Laws of Hong Kong) and its subsidiary legislation, an import/export licence must be obtained from the Chinese Medicines Import / Export Control Team, Chinese Medicine Regulatory Office of the Department of Health before any proprietary Chinese medicine (pCm) is imported to or exported from Hong Kong.

2. 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.

3. Applicant should submit the documents listed under the Paragraph 5 or 6 of this guideline to the Chinese Medicine Regulatory Office of the Department of Health (address: 16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon) before any import/export of pCm.

4. How to Purchase the Application Form

Application for an import licence should be made on Import Licence Form 3 (TRA 187) and application for an export licence should be made on Export Licence Form 6 (TRA 394).

The application forms are available for sale at the following locations:
(a) Shroff and Form Sales Counter, Trade and Industry Department, 13/F, Trade and Industry Tower, 3 Concorde Road, Kowloon City (Tel No.: 2398 5325).
5. **Required documents for applying Import Licence for pCm**

(a) A duly completed Import Licence Form 3 (blue) (TRA 187) in quadruplicate.

(b) A copy of a valid Wholesaler Licence in Proprietary Chinese Medicines or a copy of Manufacturer* Licence in Proprietary Chinese Medicines; or a copy of the document certifying that the organization has been given an exemption by the Chinese Medicines Board of obtaining a licence of importing such pCm under section 158(1) of the Chinese Medicine Ordinance.

(*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.)

(c) A copy of following valid document and relevant authorization 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 under the Chinese Medicine Council of Hong Kong, certifying that an exemption has been given for the pCm to be registered for the purposes of education or scientific research.

(d) If the pCm to be imported is for re-export purpose and no document as stated in 5(c) 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. The formula should also show the name and dosage form of the pCm, name, address and company stamp of the manufacturer.
(e) According to the Chinese Medicine Ordinance, a Wholesaler of pCm may import a pCm of a reasonable quantity for the purpose of providing samples for pCm registration. Applicant should mark “for registration purpose” on the form and should explain in writing the purpose of import and quantity required. Applicant should submit a copy of the formula of pCm listed with one hundred percent ingredients issued by the manufacturer (For details of the master formula, please refer to 5(d)). If the applicants are importing the pCm for analysis purpose, they should provide a declaration letter issued by a local laboratory recognized by the Chinese Medicines Board, in order to certify or justify that the quantity imported is necessary for conducting a specified test (or examination).

(f) Additional documents may be requested when necessary.

6. **Required documents for applying Export Licence for pCm**

(a) A duly completed Export Licence Form 6 (white) (TRA 394) in triplicate.

(b) A copy of a valid Wholesaler Licence in Proprietary Chinese Medicines or a copy of valid Manufacturer Licence in Proprietary Chinese Medicines.

(c) 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”;

(d) If the pCm to be exported is for re-export purpose and no document as stated in 6(c) can be provided, applicants can submit a copy of the import licence for the pCm instead.

(e) Additional documents may be requested when necessary.

7. **Processing Procedure**

(a) After submitting the application form, a receipt will be issued with a reference number to the applicant. Please retain the receipt.

(b) The issuance of an import or export licence is normally 2 working days after receipt of the duly completed application form together with all necessary documents that showed compliance with licence issuance requirements#. Please collect your import/export licence according to the instructions as printed on the receipt (For enquiries, please call 3904 9230 / 2319 5119).

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# Applications for import licences of proprietary Chinese medicines and export licences of proprietary Chinese medicines shall comply with international agreements applicable to Hong Kong. Applications that fail to do so may be rejected.
(c) Should the applicant fail to duly complete an application form or provide valid supporting documents, our staff will request the applicant to amend the application form or provide further documents at a specified time. If the applicant fails to do so, the application form will be returned and a notice of refusal will be issued.

(d) For import licence applications, the applicant will be given the original and duplicate of licence. The original is to enable the licensee to take delivery of the goods from the carrier (shipping company, airline or transportation company). Please note that under Section 8 of the Import and Export Ordinance, the original must be presented to the carrier within 7 days after importation of the goods, irrespective of whether whole or part of the consignments of goods is delivered. The duplicate is for the licensee’s retention.

(e) For export licence applications, the licensee will be given only the original, which should be surrendered to the carrier, without which the carrier is forbidden under Section 10 of the Import and Export Ordinance from accepting the goods for export.

(f) After the expiry of the validity of an issued licence, the unused copies of the expired licence should be returned to the department for cancellation.


(a) To comply with the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), please take note of the provisions concerning the enlisted endangered species of Chinese herbal medicines stated in the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586 of the Laws of Hong Kong).

(b) If the pCm to be imported or exported belong to endangered species, the applicant has to apply to the Agriculture, Fisheries and Conservation Department for import licence, export licence or possession licence. For any enquiries, please call the Citizen’s Easy Link (telephone: 2150 6973)

9. Relevant codes of practice and laws

The applicants must comply with codes of practice of trades of proprietary Chinese medicines and relevant laws. For details, please refer to the Practising guidelines for traders of Chinese medicines issued by the Chinese Medicines Board under the Chinese
Medicine Council of Hong Kong. Applications for Import Licence for proprietary Chinese medicines and Export Licence for proprietary Chinese medicines that failed to comply with the relevant codes of practice and laws may be rejected.

This document is only for general reference and guidance and must not be treated as a complete or authoritative statement of the law on any particular case. Please refer to the Chinese Medicine Ordinance and the Import and Export Ordinance for the relevant legal provisions.

Chinese Medicine Regulatory Office

Department of Health

December 2019
Appendix 1

How to Complete Import Licence Application Form for Proprietary Chinese Medicines

When completing the licence application, please read the following guidelines carefully. The numbers given below against each of these guidelines correspond to the numbers in circles in the specimen of import licence application at Appendix 2 for cross-referencing purpose.

Points to note: No erasure or correction fluid should be used on import licence form. Errors should be clearly and tidily crossed out. Please initial, date and apply your company’s chop against all amendments, defacements, additions or deletions made. No more than three chops for amendment are allowed for each application. Any amendments of the issued import licence could only be made by the Department upon receipt of written applications for amendments by the firms concerned.

(1) Foreign Exporter (Name and Address)

Please give the name and full address. The country/territory must be clearly specified and should be tallied with the “exporting place” stated in item 11.

(2) Importer (Name and Address)

Please give the name and full address. P.O. Box number or application submitted by “Company A on behalf of Company B” will not be accepted.

(3) Business Reg. No.

Please give the first 11 digits of your business registration number (e.g. 12345678-000).

(4) Estimated Date of Arrival

If the exact date is not known, please provide an estimated date of arrival. Import licence application should be submitted well before the estimated date of arrival to allow sufficient time for the application to be processed and approved.

(5) Vessel/Flight/Vehicle Number

Please state the mode of transport (delivery by air, sea or lorry, etc), and give the shipping, flight or vehicle number, if available.

(6) Marks and Nos.; Container No.

Please give the shipping marks and numbers. If there are no shipping marks and
numbers, the words “No marks” should be stated.

(7) **No. and Kind of Packages**
Please indicate the number of packages/cartons, etc. in both words and numerals and specify the type/mode/form of packages.

(8) **No. of Units**
Please put “*” in front of and behind the numeral showing the quantity of each item of goods and give the appropriate unit, e.g. pcs, ml, gram, etc. in which the quantity of the goods is expressed.

(9) **Description of Goods**
There should be no more than five items on each application form. Please give detailed product description for each item, including:

(i) The name of the proprietary Chinese medicine should be in the format “Brand or Trademark (if any)+ Name of the product”,
(ii) Packing specification. Please refer to Annex 1 for written format reference,
(iii) The reference number, i.e. “HKC-XXXXX” or “HKP-XXXXX” (if applicable).

(10) **Blank space must be crossed out**

(11) **Exporting Place***
This is the exporting country/territory of the goods, i.e. the country/territory in which the exporter is located.

(12) **Place of Origin***
Origin country/territory for each item of goods must be specified. This is the country/territory where the goods are manufactured and is not necessarily the “exporting place” stated in item 11.

(*Note: The name of related country/territory can be referred to the latest version of “Classification of Countries/Territories” in the website of Census and Statistics Department (http://www.censtatd.gov.hk); details can be found in “Booklet of ”How to Complete and Lodge Import/Export Declarations”” and “Hong Kong Imports and Exports Classification List (Harmonized System)”.*)
(13) **Importer’s Declaration**

Please indicate whether the goods are for local consumption or for re-export. If the goods are for re-export, please name the country/territory to which the goods will subsequently be re-exported. (Please note that approval of your import licence application does not necessarily mean that a subsequent export licence application for re-export of the goods will be approved).

(14) **Signatory’s Name in Block Letters**

Please fill in “signatory’s name” in block letters in accordance with his/her Hong Kong identity card or passport. Surname or initials of signatory is not accepted.

(15) **Date, Signature and Company Chop**

Please insert the date and sign the application. The declaration must be signed by an authorized official of the company. Declaration cannot be made on behalf of another company. The company chop should be clear and legible and affixed on each and every page of the application form.
IMPORT LICENCE Form 3

BEIJING CHINA ABC COMPANY
No.8, Mamnan New Road, Yuanyuan District, Beijing, China

ABC Far East Company Limited
18/F, Health Industrial Building, 999 Chai Wan Road, Hong Kong

Certificate of Issue:
Government of the Hong Kong Special Administrative Region
Office of Export Control, Cap. 100
Department of Commerce

Date of Issue: 28/10/2008

Licence No.: 123456-789-00

No. of Cartons: 120

Order No.: ABC

Description: YAN YAN PO YING PILLS

No. of Boxes: 10

Description: HUOXIANGZHENQISHUI

NO MARK

Total: HKD $59,283.00

DECLARES

The undersigned hereby declare that the goods covered by this licence are for the mainland of China, and the above description are correct.

The undersigned declares that the goods are for the mainland of China.

The undersigned declares that the goods are for the mainland of China.

Date of Issue: 23rd Oct, 2008

Approval

Director-General of Trade and Industry

IMPORTANT NOTE

If there is any discrepancy between the English text and the Chinese text of this form, the English text shall be taken as conclusive.

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Appendix 3

How to Complete Export Licence Application Form for Proprietary Chinese Medicines

When completing the licence application, please read the following guidelines carefully. The numbers given below against each of these guidelines correspond to the numbers in circles in the specimen of export licence application at Appendix 4 for cross-referencing purpose.

**Points to note:** No erasure or correction fluid should be used on export licence form. Errors should be clearly and tidily crossed out. Please initial, date and apply your company’s chop against all amendments, defacements, additions or deletion made. No more than three chops for amendment are allowed for each application. Any amendments of the issued export licence could only be made by the Department upon receipt of written applications for amendments by the firms concerned.

(1) **Exporter (Name and Address)**

Please give the name and full address. P.O. Box number or application submitted by representative other than the exporter will not be accepted.

(2) **Business Reg. No.**

Please give the first 11 digits of your business registration number (e.g. 12345678-000).

(3) **Consignee (Name and Address)**

Please give the name and full address. P.O. Box number will not be accepted. The information therein must tally with the information stated in “Destination and Code” in item 11.

(4) **Departure Date**

If the exact date is not known, please provide an estimated date of departure. Export licence application should be submitted well before the estimated date of departure to allow sufficient time for the application to be processed and approved.

(5) **Vessel/Flight/Vehicle No.**

Please state the mode of transport (delivery by air, sea or lorry, etc) and give the shipping, flight or vehicle number, if available.

(6) **Marks and Nos.; Container No.**
Please give the shipping marks and numbers. If there are no shipping marks and numbers, the words “No marks” should be stated.

(7) No. and Kind of Packages
Please indicate the number of packages/cartons, etc. in both words and numerals and specify the type/mode/form of packages.

(8) Description of Goods
There should be no more than five items on each application form. Please give detailed product description for each item, including:

(i) The name of the proprietary Chinese medicine should be in the format “Brand or Trademark (if any) + Name of the product”,
(ii) Packing specification. Please refer to Annex 1 for written format reference,
(iii) The reference number, i.e. “HKC-XXXXX” or “HKP-XXXXX” (if applicable).

(9) No. of Units
Please put “*” in front of and behind the numeral showing the quantity of each item of goods and give the appropriate unit, e.g. pcs, ml, gram, etc. in which the quantity of the goods is expressed.

(10) Blank space must be crossed out

(11) Destination and Code *
This is the destination country/territory of the exports. The code number need not be given, if unknown.

(12) Place of Origin*
Origin country/territory for each item of goods must be specified. This is the country/territory where the goods are manufactured and is not necessarily the country/territory where the exporter is located.

(13) Code of Place of Origin*
The code number need not be given, if unknown.

(*Note: The name of related country/territory can be referred to the latest version of “Classification of Countries/Territories” in the website of Census and Statistics Department (http://www.censtatd.gov.hk/); details can be found in “Booklet of “How to Complete and Lodge Import/Export Declarations”” and “Hong Kong Imports and Exports Classification List (Harmonized System)”).

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(14) **Name and Address of HK Manufacturer/Processor**

For goods manufactured in Hong Kong, please give the name and full address of the Hong Kong manufacturer or processor. For re-exports, name and address of the manufacturer can be omitted. However, the origin/territory of the re-exports must be indicated in “Place of Origin”.

(15) **Signature and Date**

Please insert the date and sign the application. The declaration must be signed by an authorized official of the company. Declaration cannot be made on behalf of another company.

(16) **Signatory’s Name in Block Letters**

Please fill in “signatory’s name” in block letters in accordance with his/her Hong Kong identity card or passport. Surname or initials of signatory is not accepted.

(17) **Company Chop**

The company chop should be clear and legible and affixed on each and every page of the application form.
**Sample of a completed export licence form for pCm**

**APPENDIX 4**

**EXPORT LICENCE Form 6 出口許可證表格六 ORIGINAL 正本**

- **Exporer (Name and Address)**
  ABC Fer East Company Limited
  18/F, Health Industrial Building, 999 Chai Wan Road, Hong Kong

- **Business Reg. No.**
  12345678-000

- **Toll No.**
  2345-6789

- **Consignee (Name and Address)**
  BEIJING CHINA ABC COMPANY
  No.8, Manman New Road, Yuanyuan District, Beijing, China

- **Date of Issue**
  28.10.2008

- **Purpose of Shipment**
  BY SEA LEDA MAERSKYYV .68

**Conditions of issue of this licence include the following:**

- Normality the form is to be submitted in duplicate. However, if a licence is required, the form is to be submitted in triplicate.
- The name and address of the exporter must be clearly written on the form.
- The name and address of the consignee must be clearly written on the form.
- The date of issue must be clearly written on the form.
- The purpose of the shipment must be clearly written on the form.
- The number of items and the description of the goods must be clearly written on the form.

**Description of Goods**

- **Marks and No. of parcels**
  ABC
- **No. and Name of Origin**
  Hong Kong
- **Description of Goods**
  100 Cartons
  Jiao Nang Hkp-xxxxx
  2 Packs per box, 12 capsules per pack
- **No. of Units (or kg) (Total 100) (Specify)**
  *1000* Boxes
- **F. O. B. Value (HK$) (Total)**
  $52,000.00

**Destination & Code**

- **Mainland of China, CN**
  ABC Pharmaceutical Factory
  18/F, Safe Industrial Building, 999 Ping On Street, Tsuen Wan, Hong Kong

**Exporter's Declaration**

- **Name and Address of HK Manufacturer/Processor**
  ABC Pharmaceutical Factory
  18/F, Safe Industrial Building, 999 Ping On Street, Tsuen Wan, Hong Kong

- **Signature and Date**
  CHAN TAI MAN
  23rd Oct, 2008

**Important Note**

- If there is any discrepancy between the English text and the Chinese text of this form, the English text shall be taken as conclusive.
- The Chinese text is for reference only and should not be used for legal purposes.

*TRA 394 (Rev 2002) ©2007 (revised)*

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