Chinese Medicine Regulatory Office Department of Health

Guidelines for Application for Import/Export Licence of Chinese herbal 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 before any of the 31 types of the Chinese herbal medicines (Chm) specified in Schedule 1 or the 5 types of the Chm specified in Schedule 2 (please refer to Appendix 1) can be imported into or exported from Hong Kong. This also applies to single Chinese medicine granules for prescription* containing the abovementioned 36 types of Chm.

[* Please refer to the "Practising Guideline for Wholesalers of Chinese Herbal Medicines" for trading requirements of single Chinese medicine granules for prescription.]

Under the current arrangement, the application for the licences should be submitted to the <u>Import & Export Control Team</u>, <u>Chinese Medicine Regulatory Office of the Department of Health beforehand</u>.

2. Eligibility

- (a) Holders of valid Wholesaler of Chm licence (if they are restricted by their licence to trade in Schedule 2 Chm only, they cannot import and export Schedule 1 Chm),
- (b) Holders of valid Manufacturer of Proprietary Chinese medicines (pCm) licence (only for importing Chm to manufacture its pCm),
- (c) Organizations granted exemption by the Chinese Medicines Board from obtaining a wholesaler licence for importing Chm under section 158(1) of the Chinese Medicine Ordinance.

3. Methods of applications

I. Online application through the Trade Single Window

Eligible traders or organizations should register with the Trade Single Window website of the Hong Kong Customs and Excise Department, subscribe to Import/Export licences of Chm services and submit applications. Please refer to "Demonstration of the use of Trade Single Window (pCm/Chm) (for reference only) (Chinese version only)".

II. Submission of application in person

Applicant should submit the completed application forms together with documents listed under the Paragraph 4 of this guideline to the Import & Export Control Team, 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 the Chm.

Business Hours

Mondays to Fridays:

9:00 a.m. – 1:00 p.m. and 2:00 p.m. – 5:30 p.m. (Closed on Saturdays, Sundays & Public Holidays)

For enquiries, please call 3904 9230

- (a) Application for an import licence should be made on Import Licence Form 3 (blue) (TRA 187) (quadruplicate copies).
- (b) Application for an export licence can be made on either
 - (i) Export Licence Form 6 (white) (TRA 394) (triplicate copies) or
 - (ii) Export Licence Form (TRA_CMRO_E) (original form only), a fillable PDF form downloaded from the CMRO website at

https://www.cmro.gov.hk/html/eng/aboutus/service/ieccm.html

Applicants could directly fill relevant information on the PDF form, print the application form on white A4 paper, and sign on the application form with black ink and stamp the company chop, <u>or</u> they could print the PDF form on white A4 paper, fill in the relevant information with black ink and accomplish with signature and company chop.

- (c) The application forms (TRA 187 and TRA394) are available for sale at the following locations:
 - (i) Shroff and Form Sales Counter, Trade and Industry Department, 13/F, Trade and Industry Tower, 3 Concorde Road, Kowloon City (Tel No.: 2398 5325).
 - (ii) Shroff Office, Chinese Medicines Management Division, CMRO, Department of Health, 16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon (Tel No.: 3904 9230).
 - (iii) Shroff Office, Drug Evaluation and Import/Export Control Division, Drug Office, Department of Health, Suite 2002-05, 20/F, AIA Kowloon

Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon (Tel No.: 3974 4180).

4. Supporting documents for applying Import/Export Licence for Chm or Single Chinese medicine granules for prescription

I. Proof of eligibility

A. Online application through the Trade Single Window

Once the Holders of Wholesaler of Chm licence, Holders of Manufacturer of pCm licence and Organizations granted exemptions under S158 (1) of the Chinese Medicine Ordinance from obtaining a licence to import Chm subscribe to Import/Export licences of Chm services, they are not required to upload their licenses during applications. Applicants are required to select the purpose of import on the screen.

B. Submission of application in person

- i. The applicant should indicate that he/she is representing the declared company, who bears a valid Wholesaler Licence in Chinese herbal medicines or Manufacturer Licence in proprietary Chinese medicines. This can be done by submitting a copy of its trader's licence or by quoting the trader licence number on the application form;
- ii. Organizations granted exemption by the Chinese Medicines Board from obtaining a wholesaler licence for importing Chm under section 158(1) of the Chinese Medicine Ordinance should provide a copy of its exemption letter.

II. Supporting documents for importing Chm or Single Chinese medicine granules for prescription

The following documents are required to be uploaded via the Trade Single Window Homepage or submitted during paper submissions.

(a) Copies of invoices or other documents evidencing business transactions. The documents should contain details such as particulars of the suppliers and the Chinese medicines traders who apply for the import of Chinese herbal medicines (e.g. company name,

- address and contact details, etc.), information of Chinese herbal medicines to be imported (e.g. name and quantity), date of transaction and reference number, etc.
- (b) A copy of written approval issued to the suppliers by the local supervisory authorities or related departments, stating that the suppliers are allowed to engage in trading or production of Chinese herbal medicines (e.g. the 《藥品經營許可證》(Pharmaceutical Trade Licence) or the 《藥品生產許可證》(Pharmaceutical Production Licence) issued by relevant regulatory authorities. If there is no regulation on business or production of Chinese herbal medicines in the country/territory where the supplier is located, the Import & Export Control Team will consider the application on individual basis.
- (c) For application for import licence of single Chinese medicine granules for prescription, please submit a sample of the label on the container or package (For details about the labelling requirement of single Chinese medicine granules for prescription, please refer to "Practising Guidelines for Wholesalers of Chinese Herbal Medicines"

Additional documents may be requested when necessary.

III. Supporting documents for exporting Chm or Single Chinese medicine granules for prescription

The following documents are required to be uploaded via the Trade Single Window Homepage or submitted during paper submissions.

(a) For application for export licence of single Chinese medicine granules for prescription, please submit a sample of the label on the container or package (For details about the labelling requirement of single Chinese medicine granules for prescription, please refer to "Practising Guidelines for Wholesalers of Chinese Herbal Medicines".

The supporting documents supplied by the applicant, for examples, trade documents, should contain the detailed contact information of the issuant (including address, telephone number and e-mail address). Our department may contact the issuant to verify the authenticity of the documents at times.

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5. Applicant's declaration

The applicant has to state the purpose of import/export. He has to declare that it (the company or organization) is the importer/exporter of the goods and that the information on the application form is true. Please note that according to the Import and Export Ordinance, it is an offence, in respect of an application for the issue of a licence, to make any statement or furnishes any information which is false or misleading in a material particular or omits any material particulars.

The data regarding licensed Chinese medicines traders and registered pCm on the Chinese Medicine Council of Hong Kong(the Council) website is prepared by the Council. The data is supplied to the Trade Single Window System in order to facilitate applications of Import/Export Licences of Chm and registered pCm. Whilst every care has been taken in preventing technical malfunctions, and in ensuring that the database is regularly updated, it is up to the applicant to check the accuracy of the information submitted. The Council cannot take responsibility for errors or omissions in the data or records, or for any consequences, direct or indirect, arising from such errors or omissions or from reliance thereon.

6. Processing Procedure

I. Online application through the Trade Single Window

- (a) The applicant will receive an acknowledgement e-mail after submission.
- (b) If the submission details comply with the licence issuance requirements, the application will be approved within 2 working days and the licence can be downloaded. Once submitted, the application details cannot be altered. If the application does not fulfil the issuance requirements, the application will be rejected and the reasons will be given. The applicants should print-out a copy of the original licence for import/export purpose as soon as possible.
- (c) The application details can be copied or saved as templates for resubmission of the application with latest updates

II. Submission of application in person

- (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

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requirements[#]. Please collect your import/export licence according to the instructions as printed on the receipt.

- (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. For export licence applications, the licensee will be given only the original.
- (e) 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.

7. Execution of licence

After applying for an import licence, the licensee should 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.

After applying for an export licence, the licensee should surrender the licence to the carrier, without which the carrier is forbidden under Section 10 of the Import and Export Ordinance from accepting the goods for export.

The applicant should ensure that they should retain a copy of the licence before delivering it to the carrier.

8. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

(a) To comply with the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), please take note of the latest 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).

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[#] Applications for import licence of proprietary Chinese medicines and export licence of proprietary Chinese medicines shall comply with international agreements applicable to Hong Kong. Applications that fail to do so may be rejected.

(b) If the Chm to be imported or exported belong to endangered species, the applicant has to apply to the Agriculture, Fisheries and Conservation Department (AFCD) for import licence, export licence or possession licence. For any enquiries, please call Licensing Unit, Endangered Species Protection Division, AFCD at 2150 6973

9. Relevant codes of practice and laws

The applicants must comply with codes of practice of trades of Chinese herbal 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 Chinese herbal medicines and Export Licence for Chinese herbal 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 August 2023

List of Chinese Herbal Medicines Requiring Import/Export Licence

Schedule 1 (31 types of toxic Chinese herbal medicines)

- 1. 山豆根(Radix Sophorae Tonkinensis)
- 2. 水銀(Mercury)
- 生千金子(unprocessed Semen Euphorbiae) 19. 砒石(Arsenolite)
- 生川島(unprocessed Radix Aconiti)
- 生天仙子(unprocessed Semen Hyoscyami) 21. 洋金花(Flos Daturae Metelis)
- 生天南星(unprocessed Rhizoma Arisaematis)
- 7. 生巴豆(unprocessed Fructus Crotonis)
- 生半夏(unprocessed Rhizoma Pinelliae)
- 9. 生甘遂(unprocessed Radix Kansui)
- 10. 生白附子(禹白附、關白 附)(unprocessed Rhizoma Typhonii or Radix Aconiti Coreani)
- 11. 生附子(unprocessed Radix Aconiti Lateralis)27. 斑蝥(Mylabris)
- 12. 生狼毒(unprocessed Radix Euphorbiae 28. 輕粉(Calomelas) Fischerianae, Radix Euphorbiae Ebracteolatae or Radix Stellerae)
- 13. 生草烏(unprocessed Radix Aconiti Kusnezoffii)
- 14. 生馬錢子(unprocessed Semen Strychni)
- 15. 生藤黃(unprocessed Resina Garciniae Morellae)
- 16. 白降丹(Mercurous chloride and mercuric chloride)

- 17. 朱砂(Cinnabaris)
- 18. 青娘蟲(Lytta)
- 20. 砒霜(Arsenic trioxide)
- 22. 紅娘蟲(Huechys)
- 23. 紅粉(Hydrargyri Oxydum Rubrum)
- 24. 鬼臼(桃耳七、八角蓮) (Radix or Rhizoma Podophylli emodis, or Radix or Rhizoma Dysosmatis)
- 25. 雪上一枝蒿(Radix Aconiti Brachypodi or Radix Aconiti Szechenyiani)
- 26. 雄黃(Realgar)

- 29. 雌黃(Orpiment)
- 30. 鬧羊花(Flos Rhododendri Mollis)
- 31. 蟾酥(Venenum Bufonis)

Schedule 2 (5 types of Chinese herbal medicines)

- 32. 威靈仙(Radix Clematidis)
- 33. 凌霄花(Flos Campsis)
- 34. 製川烏(processed Radix Aconiti)
- 35. 製草鳥(processed Radix Aconiti Kusnezoffii)
- 36. 龍膽(Radix Gentianae)

How to Complete Import Licence Application Form for Chinese Herbal 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 Form 3 (blue) (TRA 187)** at Appendix 3 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 company 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 as well as the trader licence number (if the trader licence is not provided). 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. kg/packages/cartons, 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 description for each item of the Chinese herbal medicines to be transported, including the name of each item (Please use the Chinese names stated in Schedule 1 and Schedule 2 of the Chinese Medicine Ordinance (the Ordinance)); and the Latin names of the Chinese herbal medicines should also be given as far as possible (Please use the Latin names stated in Schedule 1 and Schedule 2 of the Ordinance). The weight/quantity of the minimum packaging units, e.g. kg/packages/cartons should also be specified.

(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

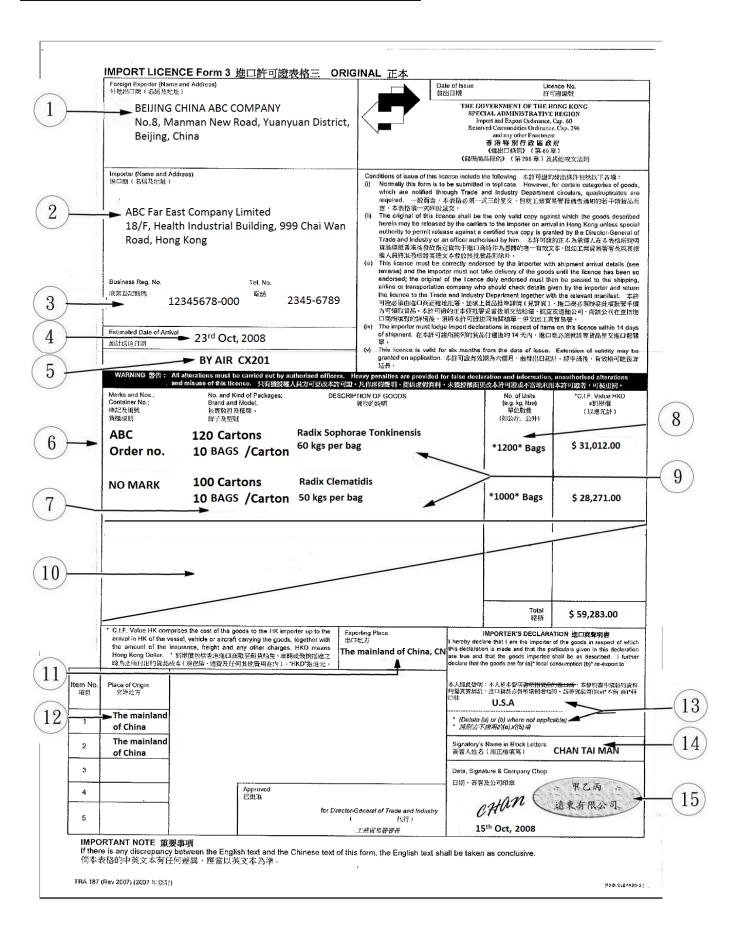
Please indicate whether the goods are for local consumption or for re-export. If the goods are for re-export, please name the country/territory to which the goods will subsequently be re-exported. (Please note that approval of your import licence application does not necessarily mean that a subsequent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



How to Complete Export Licence Application Form for Chinese Herbal 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 Form 6 (white) (TRA 394) at Appendix 5 or Export Licence Form (TRA CMRO E) at Appendix 6 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 company concerned.

(1) Exporter (Name and Address)

Please give the name and full address as well as the trader licence number (if the trader licence is not provided). 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 description for each item of the Chinese herbal medicines to be transported, including the name of each item (Please use the Chinese names stated in Schedule 1 and Schedule 2 of the Chinese Medicine Ordinance (the Ordinance)); and the Latin names of the Chinese herbal medicines should also be given as far as possible (Please use the Latin names stated in Schedule 1 and Schedule 2 of the Ordinance). The weight/quantity of the minimum packaging units, e.g. kg/packages/cartons should also be specified.

(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. kg/packages/cartons, 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 Rev. 08.2023

Imports and Exports Classification List (Harmonized System)".

(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 country/territory of the re-exports must be indicated in "Place of Origin".

(15) Signature and Date

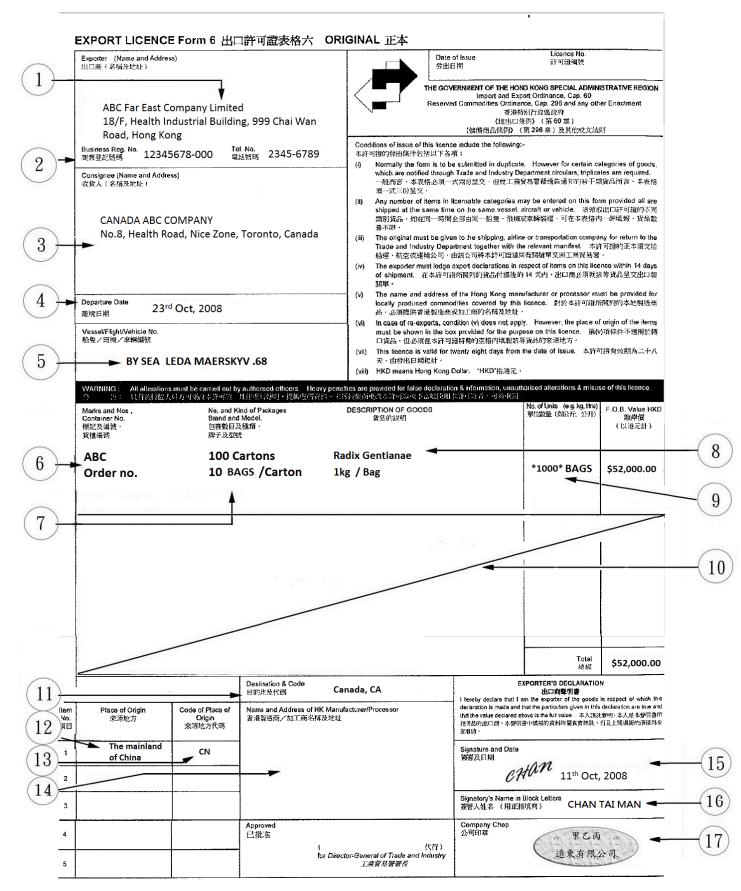
Please insert the date and sign the application. The declaration must be signed by an authorized official of the company. Declaration cannot be made on behalf of another company.

(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

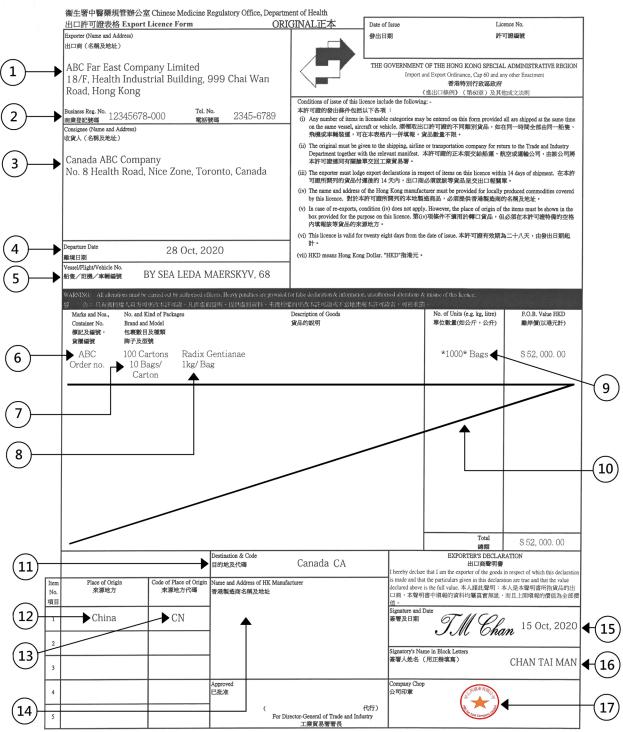
The company chop should be clear and legible and affixed on each and every page of the application form.



IMPORTANT NOTE 重要事項

If there is any discrepancy between the English text and the Chinese text of this form, the English text shall be taken as conclusive. 倘本表格的中英文本有任何差異・應當以英文本為準・

Appendix 6



IMPORTANT NOTE 重要事項

If there is any discrepancy between the English text and the Chinese text of this form, the English text shall be taken as conclusive. 倘本表格的中英文本有任何差異,應當以英文本為準。

TRA CMRO_E(Rev 2020)(2020年修訂)

Sample of Import Licence of Chm applied through Trade Single Window

Chinese Medicine Regulatory Office, Department of Health Import Licence for Chinese Herbal Medicines Resign Exposes Olone and Address 外电运口管 (名爾瓦思斯) Beljing ABC Company Lincided 8 Beljing Road, Beljing THE MAINLAND OF CHINA Lionee No. 許可**推場** CHMI202300***** 2023-06-12 (H-R-#-00MMYYTY) kUG_8G*** ERMANT OF THE HONG EONG SPECIAL ACHIEVEST Import and Export Ordinators, Cap 60 and any other En 管理時間子級基底形 (施出口服例) (第68年) 及其他成文法則 Imporer Okson and Address) 雅口地(名爾及地址) Tiletin Trading Company of this livence include the following 本种可能的数出版符色超以下多模。 all be the valid copy against which the pools described leaves may be release NF, BLOCK D, LOWLICK BUILDING, 888 WONGWONG ROAD, MONGKOK, KOWLOON on the recent stronger 1 code for recent contents cream and approved the statement of the nce must be surmorly endoned by the importer with shipment animal details (see the The license near the controlly enclosed by the supporter with shapeds attended that licen to
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ARRIVAL DETAILS

货品抵埠鲜情

Imposter must type in surfruit details and sign that these details are true and correct before busining Rismon to chipping, aidine or transportation company conserved. Shipping, aidine or transportation conserved. Shipping, aidine or

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