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 before any proprietary Chinese medicine (pCm) is imported to or exported from 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.

Under the current arrangement, the application for the licences can be initiated at the <u>Import & Export Control Team, Chinese Medicine Regulatory Office of the Department of Health.</u>

2. Eligibility

I. Import Licence of proprietary Chinese medicine (pCm)

- Holders of valid Manufacturer's licence of pCm (only limited to importing pCm as a raw material to manufacture its own product, according to S 158(7) of Chinese Medicine Ordinance),
- (b) Holder of valid Wholesaler's Licence of pCm ("Certificate of registration of proprietary Chinese medicine" or "Notice of confirmation of transitional registration of proprietary Chinese medicine" (Cert Holder). If the wholesaler is not a cert holder, he will need a written authorization by the cert holder,

(c) Organizations granted exemption by the Chinese Medicines Board from obtaining a wholesaler licence for importing pCm under section 158(1) of the Chinese Medicine Ordinance

II. Export Licence of pCm

- (a) Holders of valid Manufacturer's licence of pCm (only for exporting its own products),
- (b) Holder of valid Wholesaler's Licence of pCm.

3. Method 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 pCm 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 duly filled application forms together with supporting documents listed under the Paragraph 4 of this guideline to the Import & Export Control Team, CMRO (address: 16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon) before any import/export of pCm.

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

Application for an import licence should be made on either

(a) 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/about_us/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 (original copy only).

- (c) The application forms (TRA 187 and TRA394) are available for sale at the following locations:
 - 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. Documents for applying Import/Export Licence of pCm

I. Proof of eligibility

A. Online application through the Trade Single Window

Once the Holders of Wholesaler of pCm 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 pCm subscribe to Import/Export licences of pCm 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 pCm or Manufacturer Licence in pCm. This can be done by submitting a copy of its trader's licence or by quoting the trader licence number on the application form;

 Organizations granted exemption by the Chinese Medicines Board from obtaining a wholesaler licence for importing pCm under section 158(1) of the Chinese Medicine Ordinance should provide a copy of their exemption letter.

II. Supporting documents for importing registered pCm

A. Online application through the Trade Single Window

Holders of "Certificate of registration of proprietary Chinese medicine" or "Notice of confirmation of transitional registration of proprietary Chinese medicine" (Cert Holders), including holders of manufacturer's licence of pCm or wholesaler's licence of pCm, need not provide additional document. If the applying wholesaler is not the cert holder, it need to upload the authorization letter from the cert holder.

B. Submission of application in person

A copy of the following valid document and relevant authorization document –

- i. "Certificate of registration of proprietary Chinese medicine"; or
- ii. "Notice of confirmation of transitional registration of proprietary Chinese medicine".

If a manufacturer licence holder is importing the pCm for packing purpose according to S 158(7), it had to declare "For packing" on the import licence application form.

III. Supporting documents for importing unregistered pCm (applies to both applying via TSW or paper submission)

The following documents should be uploaded according to the instructions of the TSW homepage or submitted during paper submission.

- (a) If the pCm to be imported is for re-export purpose, 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,
- (b) Certificate for clinical trial and medicinal test;

- (c) A document issued under section 158(1) of the Chinese Medicine Ordinance by the Chinese Medicines Board, certifying that an exemption has been given for the pCm to be registered for the purposes of education or scientific research.
- (d) 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 4(III)(a)). 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).

Additional documents may be requested when necessary.

IV. Supporting documents for applying Export Licence for registered pCm (applies to both applying via TSW or paper submission)

These documents should be uploaded onto the TSW homepage or submitted with the paper application forms. Applicants should ensure that the document is valid.

- (i) "Certificate of registration of proprietary Chinese medicine"; or
- (ii) "Notice of confirmation of transitional registration of proprietary Chinese medicine";

V. Supporting documents for applying Export Licence for pCm for re-export

For applicants who had applied for Import Licence for pCm for re-export, they should input the Import Licence number of the relevant import licence.

For paper submission, applicants can submit a copy of the import licence for the pCm..

Additional documents may be requested when necessary.

The supporting documents supplied by the applicant (including, import

authorization letters, master formula of pCm issued by manufacturers, declaration letters by laboratories) 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.

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 on this website is prepared by the Chinese Medicine Council of Hong Kong to facilitate applications of Import/Export Licences of Chinese herbal medicines and registered proprietary Chinese medicines. 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 Chinese Medicine Council of Hong Kong 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 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.

[#] 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.

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 medicine products 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 containing Chinese herbal medicines 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 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. 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 August 2023

Appendix 1 <u>How to Complete Import Licence Application Form for Proprietary</u> <u>Chinese Medicines</u>

When completing the licence application, please read the following guidelines carefully. <u>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 2 for cross-referencing purpose.</u>

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. 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 (<u>http://www.censtatd.gov.hk/</u>); 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).

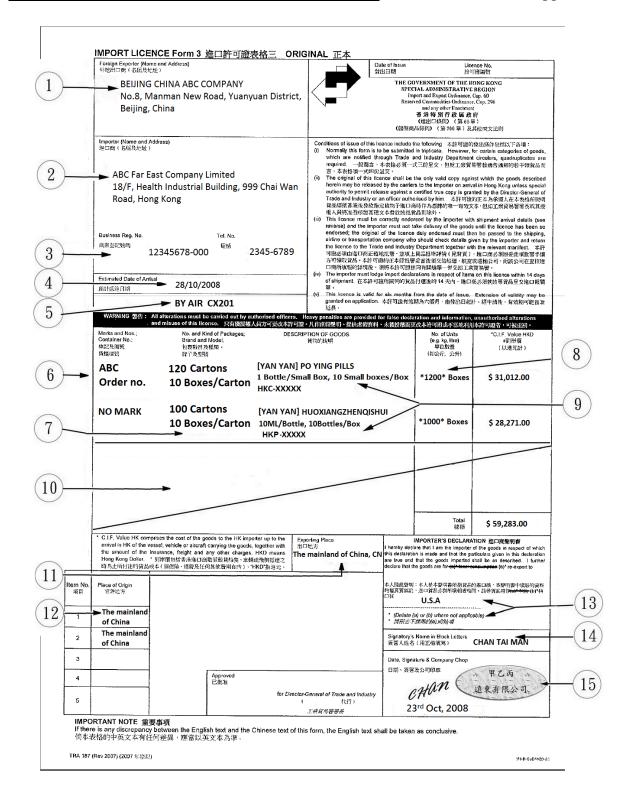
(14) Signatory's Name in Block Letters

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.

Specimen of a completed import licence form for pCm



Appendix 3 <u>How to Complete Export Licence Application Form for Proprietary</u> <u>Chinese Medicines</u>

When completing the licence application, please read the following guidelines carefully. <u>The numbers given below against each of these guidelines correspond to the numbers in</u> circles in the specimen of **Export Licence Form 6 (white) (TRA 394)** at Appendix 4 or **Export Licence Form (TRA CMRO E)** at Appendix 5 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. 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 (<u>http://www.censtatd.gov.hk/</u>); 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)".

(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

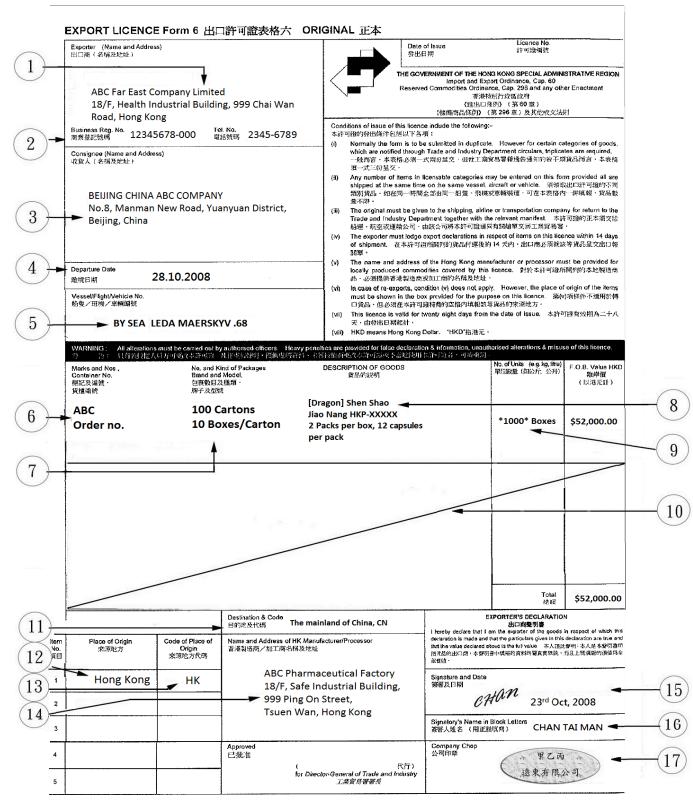
Please insert the date and sign the application. The declaration must be signed by an authorized official of the company. Declaration cannot be made on behalf of another company.

(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.



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 394 (Rev 2007) (2007 年修訂)

Appendix 5

-	出口許可證表格 Expo Exporter (Name and Address)	ort Licence Form	OR		te of Issue 出日期		.icence No. 午可證編號
	出口商(名稱及地址) ABC Far East Cor 18/F, Health Ind Road, Hong Kong	ustrial Building	, 999 Chai Wan		THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGIO Import and Export Ordinance, Cap 60 and any other Enactment 音楽特別行政區政府 (進出口條例) (第60章)及其他成文法則		
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I	Departure Date	28 Oct, 2	2020	(vi) This licence is valid for twent 計。	ty eight days from the	date of issue. 本許可證有效期	明為二十八天,由發出日期起
1	ŧ境日期 /essel/Flight/Vehicle No.			(vii) HKD means Hong Kong Doll	ar. "HKD"指港元。		
	出雙/斑機/車輛編號		MAERSKYV, 68	l for false declaration & information, una	uthorised alterations &	misuse of this licence	
5	 告:只有獲授權人員: Marks and Nos., No. au Container No. Brand 標記及編號, 包裹 	方可更改本許可證。凡作店 ad Kind of Packages and Model 数目及種類		權而更改本許可說或不當地使用本語 Description of Goods 貸品的說明		No. of Units (e.g. kg, litre) 單位數量(如公斤,公升)	F.O.B. Value HKD 離岸價(以港元計)
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Ŧ	Hong Kong	нк г	18/F, Safe Industrial Street, Tsuen Wan, N	building, 999 Ping On .T.	Signature and D 簽署及日期		an 15 Oct, 2020
$\frac{1}{2}$	Hong Kong	НК		eutical Company Limited heng Factory Building, Big g. Kowloon	Signatory's Nam	e in Block Letters	
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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)

Appendix

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	中成藥進口許 Import Licence	可證 for Proprietary Chin	usa Madicinas	衛生署中醫察 Chinese Medicine Regulatory		of Health			
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ies 5.項 日	(Code) Place of Origin (代明) 地球地力	No. and Kind of Periodese Science 2.3, State	Description of Goods in g. [Board] Product Name #) 유유사회에서 40 [바구] 프라오베 . # 유유사회에		No. of Units	CLP, Value HKD Biower(LOR) (201)			
1	(CN) THE MAINLAND OF CHINA	6 carton	IRP-XXXXX [AB Brand] CD pills # 100 pills per bottle,	Independent	3000 box	3,120			
2	(CN) THE MAINLAND OF	3 certon	HKG-YYYYYY		2000 box	1.875			
-	CHENA		[IF Brand] GH OIL (H) # 10ml per bottle,	18eth Wheet		.,			
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		Director-General of Tra 貿易署署長 (禁州的		Name (\$2.5) and a state					
				New #281 YIP MAN					
				Dee 日間: 2023-06-12 (YYYY40400 年-月-日)					
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貨品抵埠詳情

Importer must type is and/oid details and sign that these details are true and convect before tradecing licence to shipping, aidine or transportation company concerned. Shipping, aidine or transportation company must check typed details aquinant Bill of LadingAle Wayhill and manifest and sign in space provided that this has been done. 個口際必須打上兌出標準評情,並供基礎確認常識的資料是真實正確的,然後將本許可證證交經證、概定 家庭輸公司。有關的設置,你立家運輸公司必須將其關約實料與是單位還是單反點單(對上下預定白機需要證明解於安置。

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				出口商聲明書 Iherety declare that I an the support of the pool in respect of which this declaration is made and that the periodical along in this declaration are true and that the value declared above is the full value. 本人通此意可:本人是本意的音乐就像是些创造口前:本意的音卡课程的深刻地震赏赏演成:而且上深课 我的情况和全部情况: Name YIP MAN 姓名				
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