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I. CHECKLIST

Application for Wholesale Dealer Licence/Antibiotics Permit/ Wholesale Dealer's Licence to Supply Dangerous Drugs

Please submit the following documents with the application form. Please provide a written explanation if any of the documents is not submitted, and ensure only valid documents are submitted should they have a validity period.

☐ (1) A completed application form

☐ (2) Copy of Business Registration Certificate

☐ (3) If there are storage facilities at other premises:
(a) Copy of the applicant's Branch Business Registration Certificate of the other premises

OR

(b) Copy of Tenancy Agreement

OR

(c) Copy of Logistics Services Agreement

☐ (4) Information on Directors / Sole Proprietor / Partners:
(a) For limited companies:
(i) Copy of Certificate of Incorporation; and
(ii) "Form NAR1" from Companies Registry and its payment receipt; for newly formed limited companies, photocopy of "Form NNC1" or "Form NNC1G" and its payment receipt

OR

(b) For companies run by sole proprietorship:
Copy of "Form 1(a)" from the Business Registration Office and its payment receipt

OR

(c) For companies run by partnership:
Copy of "Form 1(c)" from the Business Registration Office and its payment receipt

☐ (5) A list issued by the applicant with name(s) in English and Chinese, Hong Kong Identity Card number(s)/ Passport number(s) and posts of the sole proprietor/ partners/ directors and each key personnel (e.g. person in charge of poisons and pharmaceutical products and deputy person in charge of poisons and pharmaceutical products), the list should be signed by the person in charge of business (the list should state the name of person in charge of business, date of signature and stamped with company chop) (refer to Appendix 1)

☐ (6) A signed declaration of each owner (i.e. sole proprietor or partner) or director, and each key personnel (e.g. person in charge of poisons and pharmaceutical products and deputy person in charge of poisons and pharmaceutical products) indicating whether he/she has been an owner, a director or an employee of other trader(s) of western medicines in the past three years (i.e. importer/ exporter, retailer, wholesaler or manufacturer, regardless of whether the trader is still in business) (refer to Appendix 2a) [If so, please submit the documents as required in (7) and (8). If not, please go to (9).]

☐ (7) Signed statement of relevant working experience by each owner or director, and each key personnel (e.g. personal resume stating the full English name of the company, position and period (from month/year to month/year) (refer to Appendix 2b)

☐ (8) Certifications of the above relevant working experience, e.g. testimonials from previous employer(s)

☐ (9) Scope of Business:
Copy of document(s) showing offer for sale and purchase of antibiotics/ poisons/ dangerous drugs/ pharmaceutical products.

(a) Import/ Export Only:

(i) Import: e.g. Price quotations or proforma invoice from overseas supplier and relevant product information (e.g. photo(s) of product unit carton or package insert, which can show the ingredients, dosage, and storage condition)

(ii) Export: e.g. Enquiry from overseas purchaser on price quotations and relevant document proving the purchaser in overseas country is legally authorized to handle the antibiotics/ poisons/ dangerous drugs/ pharmaceutical products

OR

(b) Local distribution involved:

(i) For the applicant who is a product certificate holder of pharmaceutical product, copy of Certificate of Drug/ Product Registration and relevant product information (e.g. photo(s) of product unit carton or package insert, which can show the ingredient(s), dosage, and storage condition)

OR

(ii) For the applicant who is not a product certificate holder of pharmaceutical product, copy of Certificate of Drug/ Product Registration, copy of agency agreement document(s)/ agency appointment letter from the product certificate holder and relevant product information (e.g. photo(s) of product unit carton or package insert, which can show the ingredient(s), dosage, and storage condition)

OR

(iii) For the applicant dealing in non-pharmaceutical products, copy of agency agreement document(s)/ agency appointment letter from your supplier together with information of the products (e.g. photo(s) of product unit carton or package insert, which can show the ingredient(s) and storage condition)

☐ (10) Floor plan of the premises mentioned in the application form:

(a) Floor plan of the entire floor where the premises are located. The following should be included in the floor plan:

(i) Name and address of applicant's company;

(ii) Room number of all units on the same floor (if any) and location of the applicant's company; and

(iii) Applicant's signature, date and company chop.

(b) Layout of the premises. The following should be included in the layout:

(i) Name and address of applicant's company;

(ii) Location(s) of all compartments and storage facilities (if any) inside the premises and purpose of each location/room;

(iii) Dimensions of all compartments, areas and total area of the premises;

(iv) Applicant's signature, date and company chop.

☐ (11) Floor plan of the storage facilities at other premises (if any):

(a) Floor plan of the entire floor where the storage facilities at other premises is located. The following should be included in the floor plan:

(i) Name of applicant's company and address of the storage facility;

(ii) Room number of all units on the same floor (if any) and location of the applicant's company;

(iii) Applicant's signature, date and company chop.

(b) Layout of the storage facilities at other premises. The following should be included in the layout:

(i) Name of applicant's company and address of the storage facility;

(ii) Location(s) of all compartments and storage facilities inside the premises and purpose of each location/room;

(v) Dimensions of all compartments, areas and total area of premises;

(vi) Applicant's signature, date and company chop.

☐ (12) Layout of the storage facilities:

The following should be included in the layout:

(a) Name of applicant's company and address of the storage facility;

(b) Dimensions and areas of storage facilities;

(c) Areas for storing "Quarantined", "Released", "Rejected", "Returned" and "Recalled" products;

(d) Location(s) of air-conditioning outlet(s) and/or air-conditioner(s);

(e) Location(s) of pest control device(s);

(f) Location(s) of temperature and humidity uniformity assessment;

(g) Location(s) of shielded window (if any); and

(h) Applicant's signature, date and company chop.

Note:

1. If storage facilities involve cold room/ pharmaceutical refrigerator/ freezer, please submit trading documents of the cold chain product(s) as stated in (9).

2. If cold room/pharmaceutical refrigerator/ freezer is involved, refer to Appendix 3.

3. If products going to be handled are "medical devices" and/or "industrial chemicals" and/or "hair dye", submission of documents as required in (12) and (13) is exempted.

☐ (13) For each storage facilities:

(a) Calibration certificate of the hygrothermometer(s) installed in the storage facilities. The calibration certificate must be issued by the manufacturer or laboratory accredited by HOKLAS or CNAS or Mutual Recognition Arrangement Partners for HOKLAS;

(b) Temperature and humidity uniformity assessment with a conclusion (specify the reason of choosing the designated location for daily temperature and humidity monitoring);

(c) Daily temperature and humidity monitoring record (should be started after the temperature and humidity uniformity assessment at the designated location(s) chosen for daily monitoring);

(d) Cleaning procedure and record (specify the items and frequencies of cleaning procedure); and

(e) Pest control procedure and record (specify the items and frequencies of pest control procedure).

☐ (14) For application for Wholesale Dealer's Licence to Supply Dangerous Drugs (Part I) only: Photocopy of the Certificate of Registration and Annual Practising Certificate of the registered pharmacist supervising the transactions of dangerous drugs.

Remarks: In addition to the documents as stated in this checklist above, other relevant supporting documents/ information may be required to substantiate the application. Applications with incomplete application and submission of documents as stated in this checklist and without a written explanation will not be accepted.

Appendix 1

(For reference purpose)

Director & Staff List

Name (in English) *(Surname first, then Given name)*	**Name (in Chinese)** *(Surname first, then Given name)*	**HKID/Passport No.**	**Position**

Signature of Person-in-charge of Business : _____

Name of Person-in-charge of Business : _____

Name of Business : _____

Company Chop : _____

Date : _____

[All personnel listed in the above table should provide a signed declaration.]
[Fill in Details as stated on Hong Kong Identity Card / Passport]

Appendix 2a

(For reference purpose)

Declaration

I, ***Mr/ Mrs/ Miss/ Ms** _____ (_____),
Full Name (*Surname first, then Given name)*: (in English) (in Chinese)
***HKID / Passport** No.: _____ hereby declare that I ***have been / have not been** an owner, a director or an employee of **other trader(s)#** of western medicines in **Hong Kong for the past three years** (i.e. importer/exporter, retailer, wholesaler or manufacturer, regardless whether the trader(s) is/are still in business.)
[If so, please list out the relevant information in the following table.]

Details of relevant working experiences at other# **Pharmaceutical Trader(s) in Hong Kong** in the **past three years**:

Full Name of Company (in English)	**Position Held**	**Period (from month/year to month/year)**
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	

[1]WDL: Wholesale Dealer Licence
[2]PIC: Person-in-Charge (or deputy) of Poisons / Pharmaceutical Products

I declare that the information given in this declaration is true, correct and complete. I understand that making false declaration will be liable to criminal prosecution.

Signature : _____
Name : _____
Name of Business : _____
Contact number : _____
E-mail Address : _____
Date : _____

 # Not including the company under this application
[Fill in Details as stated on Hong Kong Identity Card / Passport]
**** Delete as appropriate***

Appendix 2b

(For reference purpose)

Statement of Relevant Working Experiences in Western Medicine Traders

I, ***Mr/ Mrs/ Miss/ Ms** _____ (_____),

Full Name (*Surname first, then Given name)*: (in English) (in Chinese)

***HKID / Passport** No.: _____ hereby declare that I have the following relevant working experiences in Hong Kong western medicine trader(s).

Details of relevant working experiences at **other[#] Pharmaceutical trader(s) in Hong Kong**:

Full Name of Company (in English)	**Position Held**	**Period (from month/year to month/year)**
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	
	[☐ [1]WDL [2]PIC / deputy PIC (if applicable)]	

[1]WDL: Wholesale Dealer Licence
[2]PIC: Person-in-Charge (or deputy) of Poisons / Pharmaceutical Products

I declare that the information given in this Statement of Relevant Working Experiences in Western Medicine Traders is true, correct and complete. I understand that making false declaration will be liable to criminal prosecution.

Signature : _____

Name : _____

Name of Business : _____

Date : _____

 # Not including the company under this application
[Fill in Details as stated on Hong Kong Identity Card / Passport]
**** Delete as appropriate***

Appendix 3
CHECKLIST OF

Application involving set up of pharmaceutical grade cold room, refrigerator(s) or freezer(s)

Please submit this checklist along with all the following documents, or otherwise we will be unable to process your application. Please provide a written explanation for each of the documents not submitted.

☐ (1) Overview of cold chain equipment (if multiple pieces of equipment are involved, please list on a separate sheet the details of each piece of equipment):

(a) Type of pharmaceutical grade facility/equipment:

☐ Cold room ☐ Refrigerator ☐ Freezer ☐ Others (please specify: _____)

(b) Brand: _____

(c) Model number: _____

(d) Operating range (^{o}C): _____

(e) Exterior dimensions (mm): (Width × Depth × Height) _____

(f) Interior dimensions (mm): (Width × Depth × Height) _____

(g) Net capacity (liters): _____

(h) Temperature uniformity assessment date and brief conclusion: _____

(i) Open door test date and brief conclusion: _____

(j) Close door / Power failure test date and brief conclusion: _____

(k) Mode of remote alarm and alarm settings: _____

(l) Back-up power test date and brief conclusion: _____

(m) Holding duration of validated cold box: _____

(n) Product name, active ingredient(s) and labelled storage condition of cold chain product to be handled: _____

☐ (2) Layout of the cold room / refrigerator(s) / freezer(s) including the following items:
- (a) Name of applicant's company and the address of storage facility;
- (b) Dimensions and areas of the cold room / refrigerator(s) / freezer(s);
- (c) Areas for storing "Quarantined", "Released", "Rejected", "Returned" and "Recalled" products;
- (d) Location(s) of temperature uniformity assessment ("assessment points");
- (e) Signature of the person in charge (PIC) of cold chain, date and company chop

☐ (3) Valid calibration certificate of each piece of the data logger(s) installed in the cold room / refrigerator(s) / freezer(s):
- (a) Should demonstrate the data logger(s) are calibrated for the operating range required by the pharmaceutical products stored in the cold room / refrigerator(s) / freezer(s);
- (b) Must be issued by the manufacturer or a laboratory accredited by HOKLAS or CNAS or Mutual Recognition Arrangement Partners for HOKLAS

☐ (4) Temperature uniformity assessment report:
- (a) The interval of the data logger(s) should be set at 1 minute or less;
- (b) At least 3 assessment points in every refrigerator and freezer, and 4 assessment points in the cold room (please justify the number of assessment points) with not less than 24 hours consecutive record at each point;
- (c) Procedure, data analysis, conclusion and raw data should be included;
- (d) Specify which designated location(s) will be used for daily monitoring in the conclusion

☐ (5) Temperature monitoring record (with at least 3 consecutive days data):
- (a) Should be started after the temperature uniformity assessment at the designated location(s) chosen for daily monitoring;
- (b) The interval of the data logger(s) should be set at 1 minute or less

☐ (6) Open door test report:
- (a) Procedure, data analysis, conclusion and raw data should be included

☐ (7) Close door / Power failure test report:
- (a) Procedure, data analysis, conclusion and raw data should be included

☐ (8) Temperature alarm test report:
- (a) Remote alarm (e.g. SMS/email alert);
- (b) Door open alarm (if any);
- (c) Specify the alarm settings and procedures for alarm test;
- (d) Provide raw data and screenshots of the remote alarm (High/Low alarm and door open alarm)

☐ (9) Alarm sensor calibration certificate or report (unless the alarm is triggered by a calibrated data logger)

☐ (10) Back-up power test report:
- (a) Procedure, data analysis, conclusion and raw data should be included

☐ (11) Procedures for receipt, storage and delivery of cold chain products

☐ (12) Contingency plan during power failure or temperature excursion

☐ (13) Specification of the cold room / refrigerator(s) / freezer(s)

☐ (14) Back-up power specification

☐ (15) Specification and/or validation report of the cold box to be used for delivery of cold chain product (unless a calibrated data logger is used for temperature monitoring during delivery)

(a) For validation report, procedure, data analysis, conclusion and raw data should be included

☐ (16) Product information showing the active ingredient(s), dosage and storage condition of the cold chain product to be handled, e.g. photo(s) of product unit carton or package insert

☐ **I have read through the contents of this checklist and confirm the information and reports provided are correct, dated and signed by the PIC responsible for cold chain management with company's chop.**

☐ **All sections of this checklist have been completed with necessary documents attached.**

☐ **I confirm the cold chain facility under this application is suitable for storage of cold chain products.**

Signature of cold chain PIC : _____ Company chop : _____

Name of cold chain PIC : _____ Date : _____

Remarks: In addition to the documents as stated in this checklist above, other relevant supporting documents/ information may be required to substantiate the application. Applications with incomplete submission of documents as stated in this checklist and without a written explanation will not be accepted.

Please observe the contents in relation to cold chain management from the "Code of Practice for Holder of Wholesale Dealer ", including but not limited to section 2.12, 3.6 and 3.17.

Appendix 4

Storage facilities or additional warehouses for poisons/pharmaceutical products outside the premises

(As stated on Business Registration Certificate / Lease Contract / Pharmaceutical Logistics Services Agreement)

		Storage facility / Additional warehouse 1	Storage facility / Additional warehouse 2 (if applicable)
Address of the storage facility or additional warehouse outside the premises (in English)			
Total area of storage facility or additional warehouse outside the premises		m^2	m^2
Branch Business Registration Number of the applicant (not applicable if a lease contract or a pharmaceutical logistics services agreement is submitted)			
Person in charge of the storage facility or additional warehouse outside the premises	Name (in English)		
	Name (in Chinese)		
	HKID number		
	Position		
	Office phone number		
	Mobile number		
	E-mail address		
☐ Lockable storage room (area)		m^2	m^2
☐ Lockable cabinet (dimensions)		m Width Depth Height	m Width Depth Height
☐ Lockable cold room (area)		m^2	m^2
☐ Lockable pharmaceutical grade refrigerator (dimensions)		m Width Depth Height	m Width Depth Height
☐ Lockable pharmaceutical grade freezer (dimensions)		m Width Depth Height	m Width Depth Height

Written explanation is required for the following situation:

i. Company with storage facility located at the same address as another holder of Wholesale Dealer Licence; or
ii. If there is no storage facility within the business premises, the company must explain on why storage facility cannot be provided within the business address of the premises.

☐ I have provided written explanation.

☐ I understand all applications of storage facilities or additional warehouses outside the premises are subjected to consideration and approval by the Pharmacy and Poisons (Wholesale Licences) Committee.

Signature of Person-in-Charge of Business: _____

Name of Person-in-Charge of Business: _____

Position of Person-in-Charge of Business: _____

Name of the business: _____

Date: _____

COMPANY CHOP