Guidance Notes on Application of Wholesale Dealer Licence

Version March 2024

Pharmacy and Poisons Board of Hong Kong

CONTENTS

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

1. A company wishes to deal in any poison and/or pharmaceutical product by way of wholesale dealing must first obtain a Wholesale Dealer Licence. "Poison" means a substance (or a preparation containing the substance) specified in the Poisons List made under the Pharmacy and Poisons Ordinance ("PPO") (Cap. 138). Pharmaceutical product* means any substance or combination of substances as defined under section 2 of PPO.

2. If the company wishes to deal in any substance or preparation to which the Antibiotics Ordinance (Cap. 137) applies, an application for an Antibiotics Permit is required in addition to the Wholesale Dealer Licence.

3. If the company wishes to deal in a Part I dangerous drug specified in the First Schedule of the Dangerous Drugs Ordinance ("DDO") (Cap. 134), an application for a Wholesale Dealer's Licence to Supply Dangerous Drugs is required in addition to the Wholesale Dealer Licence. However, if the company wishes to deal in preparation(s) specified in Part II of the First Schedule of DDO only, an application for a Wholesale Dealer's Licence to Supply Dangerous Drugs (Part II) is required in addition to the Wholesale Dealer Licence.

4. If the poison that the company wishes to deal in is a psychotropic drug or a Part I dangerous drug, then a registered pharmacist must be employed to handle all transactions of the psychotropic drug/ Part I dangerous drug. A list of psychotropic drugs can be found in the Appendix A of "Code of Practice for Holder of Wholesale Dealer Licence" (available at the Pharmacy and Poisons Board of Hong Kong webpage https://www.ppbhk.org.hk/eng/files/PPB_COP_WDL.pdf).

5. Application forms for Wholesale Dealer Licence/ Antibiotics Permit/ Wholesale Dealer's Licence to Supply Dangerous Drugs are available, by downloading from the Drug Office webpage https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/lic_guide_main.html free of charge or collecting in person during the following hours at the address below:

Licensing and Compliance Division,
Drug Office,
Department of Health,
Room 2001-2002,
20/F., Dah Sing Financial Centre
248 Queen's Road East,
Wan Chai, Hong Kong

Monday to Friday
9:00 a.m. to 1:00 p.m.
2:00 p.m. to 5:45 p.m.
(up to 6:00 p.m. on Monday)
(Closed on Saturdays, Sundays & Public Holidays)

Alternatively, an electronic version of the application form is available at https://www.drugoffice.gov.hk/eps/do/tc/pharmaceutical_trade/eform/declare.html, a confirmation email would be sent on the same day upon successful online submission.

6. The completed application form together with the relevant documents indicated in the Checklist should be submitted by post or in person to the above address; if the application form is submitted online, relevant documents indicated in the Checklist should be marked with the references number shown on the confirmation email and sent to enquirywru@dh.gov.hk in accordance with the File Format Standards for Electronic Application stated in this guideline. For enquiry, please call 3107 2194 or email to enquirywru@dh.gov.hk.

7. General requirements for premises:
    - Only companies occupying commercial premises or industrial buildings would be considered;
    - Companies occupying ground floor or retail premises would normally not be considered;
    - Companies operating in secretarial or accountancy service holding companies would not be considered;
    - Companies sharing premises with another holder of Wholesale Dealer Licence would require a written explanation; and
    - If there is no storage facility within the business premises, the company must maintain adequate lockable storage facilities at another premises, and provide a written explanation on why storage facility cannot be provided within the business address of the premises.

8. There must be adequate lockable storage facilities with appropriate temperature and humidity for keeping antibiotics/ poisons/ dangerous drugs/ pharmaceutical products within the premises. If there is no storage facility within the premises, the company must maintain adequate lockable storage facilities at another premises, and provide a written explanation on why storage facility cannot be provided within the business address of the premises, provide details of the store, routine maintenance and monitoring. Application with storage facilities outside the premises are subjected to consideration and approval by the Pharmacy and Poisons (Wholesale Licences) Committee ("the Committee") on a case by case basis. If the application involved handling of Part I Dangerous Drugs, lockable receptacle designated for storage of Part I Dangerous Drugs must be made available. Detailed requirements on the storage facilities are set out in the "Code of Practice for Holder of Wholesale Dealer Licence".

9. An inspection by a pharmacist inspector will be conducted at the company's premises. Application for Wholesale Dealer Licence will be considered by the Committee. In granting a Wholesale Dealer Licence, the Committee must take into consideration, including but not limited to the followings:
    - Results of the inspection, which provide evaluation on whether the premises under application are fit for the licence purposes;
    - Results of the interview conducted against the person-in-charge of poisons and pharmaceutical products and deputy person-in-charge of poisons and pharmaceutical (if applicable), which provide evaluation on whether the interviewee(s) is/are fit and possess adequate knowledge to conduct relevant trade;
    - Previous drug-related conviction(s), in particular those having significant impact to the public interest, of the applicant or his key personnel;
    - Previous disciplinary action(s) against the applicant or his key personnel; and
    - Other licensing criteria applicable to the Wholesale Dealer Licence.

10. If approved, a Wholesale Dealer Licence will be issued by the Committee. The licence may contain such conditions as the Committee may think fit to impose. The Committee may revoke a Wholesale Dealer Licence or suspend it for a period it thinks fit, issue a warning letter, or vary a condition of the licence, if, in the Committee's opinion, the licensed wholesale dealer has contravened a condition of the licence or any of the regulations provided by the Pharmacy and Poisons Regulations, a code of practice applicable to the holder of Wholesale Dealer Licence, or has been convicted of a drug-related offence.

11. For Antibiotics Permit and Wholesale Dealer's Licence to Supply Dangerous Drugs, the applications will be considered by the Director of Health. If approved, an Antibiotics Permit/ a Wholesale Dealer's Licence to Supply Dangerous Drugs will be issued. The permit/ licence may contain such conditions as the Director of Health may think fit to impose, and may be revoked at any time.

12. Payment of prescribed fee will be required when the Wholesale Dealer Licence/ the Wholesale Dealer's Licence to Supply Dangerous Drugs is ready for collection. Notification of payment will be sent by mail or by email. The prescribed fees are as follows:

- Wholesale Dealer Licence: HK$625
- Wholesale Dealer's Licence to Supply Dangerous Drugs: HK$860

13. The application fee for Antibiotic Permit should be paid after submission of application documents. Notification of payment will be sent by mail or by email. The application fee is not refundable and is as follows:

- Antibiotics Permit: HK$450

14. Upon settling of payment, the applicant will be notified by staff of the Department of Health via phone to collect the relevant approved licence/ permit. The applicant may then choose to receive the relevant licence/ permit by mail or collect in person at the address stated in paragraph (5) above.

15. The performance pledge of the Department of Health is that application will be processed and approved within two months, if the applicant has submitted all the documents required and shown to have adequate and satisfactory storage facilities. A confirmation notice will be issued to the applicant upon receipt of complete application and supporting documents.

16. Any applicant aggrieved by a decision made by the Committee in respect of the applicant may, in the prescribed manner, appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

17. These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular case. Copies of the Pharmacy and Poisons Ordinance, Antibiotics Ordinance, Dangerous Drugs Ordinance and their subsidiary legislations may be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910 or by email at puborder@isd.gov.hk. Contents of the relevant legislation may also be found at the Department of Justice's website http://www.elegislation.gov.hk.

** Under section 2 of the Pharmacy and Poisons Ordinance, Cap. 138.*

"pharmaceutical product"

(a) means a substance or combination of substances that—

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to—

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product

"advanced therapeutic product" *means any of the following products that is for human use -*

(c) a gene therapy product;

(d) a somatic cell therapy product;

(e) a tissue engineered product

File Format Standards for Electronic Application for Wholesale Dealer Licence / Antibiotics Permit / Wholesale Dealer's Licence to Supply Dangerous Drugs

Documents submitted electronically should be submitted in a manner and format specified below:

1. Where electronic records are compressed, the following compression standards shall be followed:
   - Zip file (.zip);
   - GNU zip file (.gz);
   - 7-Zip file (.7z); or
   - RAR file (.rar)

2. The size of each attachment attached should not exceed 2MB, and the total size of attachments should not exceed 10MB.

3. The total number of attachments should not exceed 25.

4. Each document attached should be numbered, named and grouped according to the documents required on the Checklist.

5. All electronic documents should be given, served and presented in the following file format standards:

File Format	Standard(s)	Page Size
Formatted Document File Format	Microsoft Rich Text Format (RTF);	A4 or A3
	Microsoft Word format (.doc);	
	ISO/ IEC 29500-1 format (.docx); or	
	OpenOffice.org format (.odt)	
Portable Document Format	Searchable Adobe Portable Document Format (PDF) v1.2, 1.3, 1.4, 1.5, 1.6 or 1.7 (ISO 32000-1)	
	Adobe Portable Document Format (PDF) v1.2, 1.3, 1.4, 1.5, 1.6 or 1.7 (ISO 32000-1)	
Graphics or Image Format	Portable Network Graphics (PNG);	
	Graphics Interchange Format (GIF); or	
	Joint Photographic Experts Group (JPEG)	

6. Electronic documents given, served or presented as a document requiring signature listed on the Checklist must be signed with a digital signature, or signed by a person designated in the document with a wet ink signature and scanned as an electronic document.

7. When a digital signature is used, a recognized digital certificate issued by a recognized certification authority defined by the Office of the Government Chief Information Officer (eg. Hongkong Post Certification Authority) shall be attached to the document requiring signature in accordance with the following standards:
   (i) Secure Multipurpose Internet Mail Extension (S/MIME) standard;
   (ii) Public-Key Cryptography Standards (PKCS #7);
   (iii) PDF v1.5/ 1.6/ 1.7 (ISO 32000-1) or v2.0 (ISO 32000-2:2017); or
   (iv) XML Signature Syntax and Processing standard.

For an electronic document which comprises multiple pieces of electronic records requiring signature, each individual piece of electronic record should be separately signed digitally.

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
Room 2001-2002, 20/F, Dah Sing Financial Centre,
248 Queen's Road East, Wan Chai, Hong Kong
Tel: 3107 2194 Fax: 3107 0221

衞生署藥物辦公室
牌照及監察科
香港灣仔皇后大道東 248 號
大新金融中心 20 樓 2001-2002 室
電話：3107 2194 傳真：3107 0221

II. Application for Wholesale Dealer Licence

(Only applicable for products regulated under Cap. 138 Pharmacy and Poisons Ordinance)

FOR OFFICIAL USE ONLY

Signature: _____

Checked by / Post: _____

Date: _____

PART A DETAILS OF THE APPLICANT

(As stated on Business Registration Certificate / Hong Kong Identity Card / Passport)

Name of business (in English): _____

_____

Name of business (in Chinese): _____

Address of business (in English): (referred to hereinafter as "the premises") _____

_____

Business Registration Number: _____

Business fixed-line phone number: _____ Fax number: _____

Business E-mail address: _____

Person in charge of business

Name (in English): _____

Name (in Chinese): _____ HKID/Passport number: _____

Position: ☐ Proprietor ☐ Partner ☐ Director ☐ Others (Manager): _____

Office phone number: _____ E-mail address: _____

Applicant MUST nominate a person in charge of poisons and pharmaceutical products

Name (in English): _____

Name (in Chinese): _____ HKID number: _____

Position: _____ E-mail address: _____

Office phone number: _____ Mobile number: _____

Applicant may also nominate a deputy to act during the temporary absence of the person in charge of poisons and pharmaceutical products, if applicable

Name (in English): _____

Name (in Chinese): _____ HKID number: _____

Position: _____ E-mail address: _____

Office phone number: _____ Mobile number: _____

PART B DETAILS OF THE BUSINESS

Scope of Business (may choose more than one)**:**

☐ Import ☐ Export ☐ Local Distribution

Products to handle (may choose more than one)**:**

☐ Pharmaceutical Products ☐ Advanced Therapy Products ☐ Medical Devices ☐ Industrial Chemicals ☐ Hair Dyes

Premises:

Total area: _____ m^2

Building type: ☐ Industrial ☐ Commercial

Storage facilities for poisons/pharmaceutical products (may choose more than one)**:**

☐ Within the premises

Storage facilities for poisons/pharmaceutical products within the premises (may choose more than one)**:**

	Storage facility 1	**Storage facility 2 (if applicable)**	**Storage facility 3 (if applicable)**
☐ Lockable storage room (area)	m^2	m^2	m^2
☐ Lockable cabinet (dimensions)	m Width Depth Height	m Width Depth Height	m Width Depth Height
☐ Lockable cold room (area)	m^2	m^2	m^2
☐ Lockable pharmaceutical grade refrigerator (dimensions)	m Width Depth Height	m Width Depth Height	m Width Depth Height
☐ Lockable pharmaceutical grade freezer (dimensions)	m Width Depth Height	m Width Depth Height	m Width Depth Height

☐ Outside the premises (*Note: If you only select this option, please provide a written explanation on why storage facility cannot be provided within the business address of the premises, provide details of the store, routine monitoring and maintenance, making reference to* ***Appendix 4*** *of the Checklist*)

PART C DECLARATION OF THE APPLICANT

☐ I would like to apply for Wholesale Dealer Licence according to the Pharmacy and Poisons Ordinance. I hereby declare that the information given is true and correct.

☐ I understand that I have to submit the documents listed in the **"Checklist for Application for Wholesale Dealer Licence / Antibiotics Permit / Wholesale Dealer's Licence to Supply Dangerous Drugs"** for completion of the application.

☐ I understand that I have to read the **"Guidelines for Application for Wholesale Dealer Licence / Antibiotics Permit / Wholesale Dealer's Licence to Supply Dangerous Drugs"**.

☐ I understand that upon approval of the application, company name, address and contact will be published on the List of Licensed Wholesale Dealer at the website of the Pharmacy and Poisons Board of Hong Kong for public's view.

☐ I understand that if there is any amendment to the details of the applicant, I shall send it in writing to the Drug Office of the Department of Health as soon as possible.

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

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
Room 2001-2002, 20/F, Dah Sing Financial Centre,
248 Queen's Road East, Wan Chai, Hong Kong
Tel: 3107 2194 Fax: 3107 0221

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III. 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)	Name (in Chinese)	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: (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 **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)**

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 : _____

[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: (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 **Pharmaceutical trader(s) in Hong Kong**:

Full Name of Company (in English)	**Position Held**	**Period (from month/year to month/year)**

Please use a separate sheet to illustrate working experiences in western medicine traders outside Hong Kong

Signature : _____

Name : _____

Name of Business : _____

Date : _____

[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): _____

☐ (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

☐ **I have read through the contents of this checklist and confirm the information and report(s) provided are correct.**

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

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 Licence (2021)", 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

Statement of Purposes

Purpose of Collection

1. This personal data are provided by licence applicants for the purposes of application for licences under the Pharmacy and Poisons Ordinance, the Antibiotics Ordinance and the Dangerous Drugs Ordinance. The personal data provided will be used by DH for the following purposes:

(a) Proof of eligibility for a licence
(b) Assessment of whether the applicant is a fit and proper person to be granted a licence

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to prove your eligibility for a licence, or to assess whether you are a fit and proper person to be granted a licence.

Classes of Transferees

3. The personal data you provide are mainly for use within DH and the Pharmacy and Poisons Board. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to:

Senior Pharmacist
Licensing and Compliance Division
Drug Office
Department of Health
Room 2001-2002, 20/F, Dah Sing Financial Centre,
248 Queen's Road East, Wan Chai, Hong Kong.
Telephone Number: 3107 2194