Pharmacy and Poisons Board of Hong Kong
Pharmacy and Poisons Ordinance (Cap. 138)

Guidelines for Application for Change of Particulars of Wholesale Dealer Licence (Cap. 138 Pharmacy and Poisons Ordinance)/ Antibiotics Permit (Cap. 137 Antibiotics Ordinance)/ Wholesale Dealer's Licence to Supply Dangerous Drugs (Cap. 134 Dangerous Drugs Ordinance)

Should any Wholesale Dealer Licence/ Antibiotic Permit/ Wholesale Dealer's Permit holder wish to apply change of any particular(s); they shall submit application by writing to the Pharmacy and Poisons (Wholesale Licences) Committee (hereafter as 'the Committee') and/or Drug Office Licensing and Compliance Division Wholesalers Regulatory Unit (hereafter as 'Wholesalers Regulatory Unit') well in advance. The applied change of particulars shall be valid upon the Wholesale Dealer Licence holder obtained approval from 'the Committee' and/or 'Wholesalers Regulatory Unit'.

The licence holder must maintain the business of wholesale and storage of Poisons/Pharmaceutical Products according to the approved terms and condition under the respective licence(s) or 'permit' until further applied changes approved by the 'the Committee' and/or 'Wholesalers Regulatory Unit'. Under "Cap. 138 Pharmacy and Poisons Ordinance", '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 Ordinance" or "Antibiotic Ordinance" or "Dangerous Drugs Ordinance" Regulations, a "Code of Practice for Holder of Wholesale Dealer Licence", and/or has been convicted of a drug-related offence.

I. Application requirements

1. The applicant must be the licence holder (the holder's proprietor/ partner(s)/ director(s), person in charge of poisons and pharmaceutical products (hereafter as 'PIC of PP/Poisons') or deputy person in charge of poisons and pharmaceutical products (hereafter as 'DPIC of PP/Poisons'). If it is necessary to appoint an authorized person to handle the application, please attach an authorization letter signed by the license holder (refer to Appendix 12);and
2. The new applied change of particulars shall comply with the licensing requirements.
3. General requirements for personnel:
   - The licence holder shall notify 'the Committee' in writing of any change in its proprietor, partner(s) or director(s) within one month from the date of change.
   - The licence holder shall obtain approval from 'the Committee' and/or 'Wholesalers Regulatory Unit' prior to any change of 'PIC of PP/Poisons', 'DPIC of PP/Poisons person and/or 'PIC of Dangerous Drugs' and 'the Committee' and/or 'Wholesalers Regulatory Unit' shall not approve the change unless it considers the person nominated fit and proper.
4. 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.
5. 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 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".

II. Application procedures

How to obtain application forms

1. Application Form for Change of Particulars for Wholesale Dealer Licence/ Antibiotics Permit/ Wholesale Dealer's Licence to Supply Dangerous Drugs (hereafter as 'COP Application Form') can be obtained free of charge from:

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)*

2. 'COP Application Form' can also be download from the Drug Office official website: (https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html)

Submission of documents or information

Applicants are required to submit the following information:

1. A fully completed 'COP Application form'; and
2. Supporting documents in relation to the change of particulars. It is unnecessary to submit repeated supporting document(s) for different particular(s) of change; and
3. If the application only involves license cancellation, certified copy and/or license refund, the applicant only needs to complete the relevant appendix.
4. Applicant(s) may be required to submit original(s) with his/her signature and company chop for their supporting document(s).

How to submit application

Applicants may submit the application forms, the relevant information and documents via the following ways:

1. Mail to Licensing and Compliance Division, Drug Office, Department of Health by post or registered mail (the date shown on the post stamp will be taken as the submission date); or
2. Lodge to the Licensing and Compliance Division, Drug Office, Department of Health in person during office hours.

III. Application results

If the change application involved revise the terms and conditions on licence(s) and/or permit(s), the applicant will receive a demand note for payment of update of license. Upon the receipt of the prescribed fee, the applicant will be informed to present the original licence in person or by a representative on his/her behalf, to the 'Wholesalers Regulatory Unit' to complete necessary procedures; If the change application do not involved revise the terms and conditions on licence(s) and/or permit(s), the applicant will receive a written notification by 'Wholesalers Regulatory Unit' on behalf of 'the Committee' if the application is approved. If the application is rejected or required further revise that the applicant will still be notified by email or via phone call.

IV. Prescribed fee and methods of payment

The fee for change of particulars application per licence is HK$155. The Licensing and Compliance Division, Drug Office of the Department of Health will issue a General Demand Note to the applicant. The applicant could make payment according to the payment methods stated in the General Demand Note.

V. Enquiries

Further enquiries regarding the change of particulars as specified in the licence(s) and/or permit(s) or on the content of these guidelines can be made by calling the enquiry hotline, email or post to the 'Wholesalers Regulatory Unit':

Enquiry hotline: 3107 2194

Enquiry Email: enquirywru@dh.gov.hk

Address: Room 2001-2002, 20/F., Dah Sing Financial Centre 248 Queen's Road East, Wan Chai, Hong Kong

Checklist for Change of Licensed Particulars of Wholesale Dealer Licence (Cap. 138 Pharmacy and Poisons Ordinance)/ Antibiotics Permit (Cap. 137 Antibiotics Ordinance)/ Wholesale Dealer's Licence to Supply Dangerous Drugs (Cap. 134 Dangerous Drugs Ordinance)

Content of Change of Licensed Particulars Checklist:

※(Should maintain at least 1 storage facility)

No.	Change of Particulars Details	Submission of Supporting Documents (Refer to Page 3-4)
Company Information		
A	(i) Change of Company Name (Incorporated Company Only)	'COP Form' + 'COP Checklist Details' (1.a), (2.a), (2.b)
	(ii) Change of Company Name (Partnership Company Only)	'COP Form' + 'COP Checklist Details' (1.a), (2.c)
	(iii) Change of Company Name (Sole Proprietorship Company Only)	'COP Form' + 'COP Checklist Details' (1.a), (2.e)
Address / Storage※		
J	(i) Change of Premises Address (Room Temperature Storage)	'COP Form' + 'COP Checklist Details' (1.a), (13.a), (14.b), (15.b), (16)^, (17)^, (18)^, (19)^
	(ii) Change of Premises Address (Room Temperature + Cold Chain Storage)	'COP Form' + 'COP Checklist Details' (1.a), (13.a), (14.b), (15.b), (16)^, (17)^, (18)^, (19)^, (20)^
K	Updates of Layout within Approved Address **with Storage Area unchanged**	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.a), (14.b) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.c), (14.d)
L **M** **O**	(i) Within Approved Address: - Change or Addition of Store Room/Facilities or; - Change of Storage Room/Facilities Location, Layout, Shape or Size (Room Temperature Storage)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.a), (14.b), (15.b), (16)^, (17)^, (18)^, (19)^ Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.c), (14.d), (15.b), (16)^, (17)^, (18)^, (19)^
	(ii) Within Approved Storage Address: - Change or Addition of Store Room/Facilities or; - Change of Storage Room/Facilities Location, Layout, Shape or Size (Room Temperature Storage + Cold Chain Storage)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.a), (14.b), (15.b), (16)^, (17)^, (18)^, (19)^, (20)^ Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.c), (14.d), (15.b), (16)^, (17)^, (18)^, (19)^, (20)^
N	(i) Within Approved Store Room / Facilities: - Change of Layout with not affect the Storage Condition	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.a), (14.b), (15.a), (15.b) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.c), (14.d), (15.a), (15.b)
	(ii) Within Approved Store Room / Facilities: - Deletion of **Additional** Store Room / Facilities	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.b), (15.b) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.d), (15.b)
P **Q**	(i) Change or Addition of Pharmaceutical Refrigerator / Cold Room / Freezer	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.b), (15.b), (19)^, (20)^ Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.d), (15.b), (19)^, (20)^
	(ii) Deletion of Pharmaceutical Refrigerator / Cold Room / Freezer	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.b), (15.b) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.d), (15.b)

※(Should maintain at least 1 storage facility)

^(Not applicable for Wholesale Dealer Licence with 'NM'[1], 'MD'[2] or 'NT'[3] condition)

[1] NM: This licence only authorizes the holder to deal in non-medicinal poisons.

[2] MD: This licence only authorizes the holder to deal in medical devices containing poisons.

[3] NT: The licence holder has to notify the Pharmacy and Poisons (Wholesale Licences) Committee ("the Committee") and to provide storage facilities for pharmaceutical products in accordance with Section 2 of the Code of Practice before it may handle pharmaceutical products.

Content of Change of Licensed Particulars Checklist (Cont.):

No.	Change of Particulars Details		Submission of Supporting Documents (Refer to Page 3-4)
Others Licence Information			
R	Change or Addition of Transaction Record Format		'COP Form' + 'COP Checklist Details' (21)
S	With NC[4] and NM[1] or MD[2] Condition	(i) Remove NM[1] or MD[2] Condition) (To Allow Pharmaceutical Products/Poisons Trade in Room Temperature Storage condition)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (12.a), (14.b), (15.b), (16), (17), (18), (19) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (12.a), (14.d), (15.b), (16), (17), (18), (19), (25), (26)
		(ii) Remove NM[1] and NC[4] or MD[2] and NC[4] Condition) (To Allow Pharmaceutical Products/Poisons Trade in Cold Chain Storage condition)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (12.a), (14.b), (15.b), (16), (17), (18), (19), (20) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (12.a), (14.d), (15.b), (16), (17), (18), (19), (20), (25), (26)
	With NC[4] and IE[5] Condition	(i) Remove IE[5] Condition) (To Allow Pharmaceutical Products/Poisons in Room Temperature Storage condition Trade not bound to Import for Re-export only)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (12.b), (14.b), (15.b), (16), (17), (18), (19) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (12.b), (14.d), (15.b), (16), (17), (18), (19), (25), (26)
		(ii) Remove IE[5] and NC[4] Condition) (To Allow Pharmaceutical Products/Poisons in Cold Chain Storage condition Trade not bound to Import for Re-export only)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (12.b), (14.b), (15.b), (16), (17), (18), (19), (20) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (12.b), (14.d), (15.b), (16), (17), (18), (19), (20), (25), (26)
	With NT[3] and NC[4] Condition	(iii) Remove NT[3] Condition) (To Allow Pharmaceutical Products/Poisons Trade in Room Temperature Storage)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.b), (15.b), (16), (17), (18), (19) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.d), (15.b), (16), (17), (18), (19), (25), (26)
		(iv) Remove NT[3] and NC[4] Condition) (To Allow Pharmaceutical Products/Poisons Trade in Cold Chain Storage condition)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (14.b), (15.b), (16), (17), (18), (19), (20) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (14.d), (15.b), (16), (17), (18), (19), (20), (25), (26)
	With NC[4] Condition	(v) Change of Licence Condition (Remove NC[4]) (To Allow Pharmaceutical Products/Poisons Trade in Cold Chain Storage condition)	Storage at Licensed premises: 'COP Form' + 'COP Checklist Details' (12), (14.b), (15.b), (16), (17), (18), (19), (20) Storage at Additional Warehouse: 'COP Form' + 'COP Checklist Details' (12), (14.d), (15.b), (16), (17), (18), (19), (20), (25), (26)
U	(i) Change/Addition of Warehouse outside licensed premises (Room Temperature Storage)※		'COP Form' + 'COP Checklist Details' (1.b), (13.b), (14.d), (15.b), (16)^, (17)^, (18)^, (19)^, (25), (26)
	(ii) Change/Addition of Warehouse outside licensed premises (Room Temperature + Cold Chain Storage)※		'COP Form' + 'COP Checklist Details' (1.b), (13.b), (14.d), (15.b), (16)^, (17)^, (18)^, (19)^, (20)^, (25), (26)
	(iii) Change of Licensed Premises with storage facility at **approved additional warehouse only**※		'COP Form' + 'COP Checklist Details' (1.a), (13.a), (14.b), (15.b), (26)
	(iv) Change of Licensed Premises with storage facility at **unapproved additional warehouse only**※		'COP Form' + 'COP Checklist Details' (1.a), (1.b), (13.a), (13.b), (14.b), (14.d), (15.b), (16)^, (17)^, (18)^, (19)^, (25), (26), ((20)^ should be provided if cold chain storage involved)
	(v) Other changes not applicable to Item A-U(i-iv)		Please contact Drug Office 'Wholesale Regulatory Unit'

※*(Should maintain at least 1 storage facility)*

^*(Not applicable for Wholesale Dealer Licence with 'NM'[1], 'MD'[2] or 'NT'[3] condition)*

[1.] NM: This licence only authorizes the holder to deal in non-medicinal poisons.

[2.] MD: This licence only authorizes the holder to deal in medical devices containing poisons.

[3.] NT: The licence holder has to notify the Pharmacy and Poisons (Wholesale Licences) Committee ("the Committee") and to provide storage facilities for pharmaceutical products in accordance with Section 2 of the Code of Practice before it may handle pharmaceutical products.

[4.]NC: The licence holder must not handle pharmaceutical products that require cold chain management.

[5]IE: This licence only authorizes the holder to carry on the business of importing poisons/pharmaceutical products for re-export purpose.

Application Form for Change of Licensed Particulars of Wholesale Dealer Licence (Cap. 138 Pharmacy and Poisons Ordinance)/ Antibiotics Permit (Cap. 137 Antibiotics Ordinance)/ Wholesale Dealer's Licence to Supply Dangerous Drugs (Cap. 134 Dangerous Drugs Ordinance)

(*) represent must fill items

* **Name of Business:** _____

* **Application for Change for Licence (Licence number format: 1/2A/1234):**

☐ Wholesale Dealer Licence (WDL); Licence no: _____/2A/_____

☐ Antibiotics Permit (AP); Licence no: _____/1A/_____

☐ Wholesale Dealer's Licence to Supply Dangerous Drugs (Part I); Licence no: _____/6A/_____

☐ Wholesale Dealer's Licence to Supply Dangerous Drugs (Part II); Licence no: _____/5A/_____

* Change of Particulars Details		Change	Add	Delete	Details of Change (Provide details in written with signed and company stamped if needed)	Expected Effective Date
Company Information						
A	Company's Name	☐			Name:	
Address / Storage※						
J	Premises Address (with storage facility)	☐			Address:	
K	Premises Layout (storage area unchanged)	☐				
L	Store Room Location	☐	☐	☐	(e.g. Change of Store Room)	
M	Layout of approved Store Room with structural change (e.g. shape, size)	☐			(e.g. Extend or Minimize the Store Room Area)	
N	Layout of approved Store Room/ Facility without structural and the Storage Condition Change	☐			(e.g. Change of storing "Quarantined", "Released", "Returned", "Recalled", "Rejected" Area)	
O	Storage Facility (Room Temperature)	☐	☐	☐		
P	Pharmaceutical Grade Refrigerator	☐	☐	☐		
Q	Cold Room / Pharmaceutical Grade Freezer	☐	☐	☐		
Others						
R	Transaction Record Format	☐	☐			
S	Licensing Condition	☐			Licence Condition: (Details can refer to *Page 4*) ☐NM[1] ☐MD[2] ☐NT[3] ☐NC[4] ☐IE[5]	
U	Others (if item A – T is not applicable)	☐	☐	☐	(e.g. Change/Addition of Warehouse outside the Licensed Premises; Move of storage facilities from licensed premises to additional warehouse, etc.)	

* **Applicant information for COP application:**

Signature: _____ **Company Chop:** _____

Name: _____ **Application Date:** _____

Position: ☐ **Company Director/Partner/Sole Proprietor** ☐ **PIC of PP/Poisons** ☐ **DPIC of PP/Poisons**

* **If Authorized Person[1] required for application (if applicable, please sign the Appendix 12 of Page 11):**

Name: _____ **Position:** _____

Telephone Number: _____ **Email address:** _____

Checklist Details for Change of Licensed Particulars of Wholesale Dealer Licence (Cap. 138 Pharmacy and Poisons Ordinance)/ Antibiotics Permit (Cap. 137 Antibiotics Ordinance)/ Wholesale Dealer's Licence to Supply Dangerous Drugs (Cap. 134 Dangerous Drugs Ordinance)

Change of Licensed Particulars Checklist Details:

(1.a)	Copy of **Updated Business Registration Certificate** (within valid date)
(1.b)	Copy of **Licensee's Branch Business Registration Certificate of the other premises** or **Tenancy Agreement** or **Logistics Services Agreement** (within valid date)
(2.a)	Copy of **Form NNC2** (Notice of Change of Company Name with payment notice) from Business Registration Office and its **payment receipt**)
(2.b)	Copy of **Certification of Incorporation on the Change of Name**
(2.c)	Copy of **Form 1(c)** from Business Registration Office and its **payment receipt**
(2.e)	Copy of **Form 1(a)** from Business Registration Office and its **payment receipt**
(12.a)	**Trading documents** (At least 1 set of: Import + Export OR Import + Local Distribution OR Local Distribution + Export OR Local Distribution Document) with **Product Information**: *Import:* - Quotation from Foreign Seller to Applicant *Export:* - Quotation from Foreign Purchaser to Applicant - Relevant Document proving the Purchaser in Oversea Country is legally authorized to handle the pharmaceutical products *Local Distribution Document (For the applicant who is a product certificate holder of pharmaceutical product):* - Submit copy of Certificate of Drug/ Product Registration *Local Distribution Document (For the applicant who is NOT a product certificate holder of pharmaceutical product):* - Submit copies of agency agreement document(s) from the product certificate holder - Certificate of Drug/ Product Registration *Product Information:* (e.g. photo(s) of product unit carton, menu(s) or package insert) - Showing ingredient(s) of the products - Suggested dosage - Storage condition *(For Licence under NC[4] licensing condition should not handle product with cold chain storage condition under 8^{O}C)*
(12.b)	**Trading documents** (At least 1 set of: Local Distribution Document) with **Product Information**: *Local Distribution Document (For the applicant who is a product certificate holder of pharmaceutical product):* - Submit copy of Certificate of Drug/ Product Registration *Local Distribution Document (For the applicant who is NOT a product certificate holder of pharmaceutical product):* - Submit copies of agency agreement document(s) from the product certificate holder - Certificate of Drug/ Product Registration *Product Information:* (e.g. photo(s) of product unit carton, menu(s) or package insert) - Showing ingredient(s) of the products - Suggested dosage - Storage condition *(For Licence under NC[4] licensing condition should not handle product with cold chain storage condition under 8^{O}C)*
(13.a)	**Floor plan of the entire floor** where the **premises** are located including: - Name and address of applicant's company; - Room number of all units on the same floor (if any) and location of the applicant's company; and - Applicant's signature, date and company chop
(13.b)	**Floor plan of the entire floor** where the **additional warehouse outside the premises** are located including: - Name and address of applicant's company; - Room number of all units on the same floor (if any) and location of the applicant's company; and - Applicant's signature, date and company chop
(14.a)	**Existing Version Layouts of the premises** including: - Name and address of applicant's company; - Location(s) of all compartments and storage facilities inside the premises and purpose of each location/room; - Dimensions of all compartments and total area of the premises; and - Applicant's signature, date and company chop
(14.b)	**Proposed Version Layouts of the premises** including: - Name and address of applicant's company; - Location(s) of all compartments and storage facilities inside the premises and purpose of each location/room; - Dimensions of all compartments and total area of the premises; and - Applicant's signature, date and company chop

[4]NC: The licence holder must not handle pharmaceutical products that require cold chain management.

Change of Licensed Particulars Checklist Details (Cont.):

(14.c)	**Existing Version Layouts of additional warehouse outside the premises** including: - Name and address of applicant's company; - Location(s) of all compartments and storage facilities inside the premises and purpose of each location/room; - Dimensions of all compartments and total area of the premises; and - Applicant's signature, date and company chop
(14.d)	**Proposed Version Layouts of additional warehouse outside the premises** including: - Name and address of applicant's company; - Location(s) of all compartments and storage facilities inside the premises and purpose of each location/room; - Dimensions of all compartments and total area of the premises; and - Applicant's signature, date and company chop
(15.a)	**Existing Version Layouts of the storage facilities** including: - Name of applicant's company and address of the storage facility; - Dimensions and/or areas of storage facilities; - Areas for storing "Quarantined", "Released", "Rejected" , "Returned" and "Recalled" products^; - Location(s) of air-conditioning outlet(s) and/or air-conditioner(s)^; - Location(s) of pest control device(s)^; - Location(s) of temperature and humidity uniformity assessment^; - Location(s) of shielded window (if any); and - Applicant's signature, date and company chop
(15.b)	**Proposed Version Layouts of the storage facilities** including: - Name of applicant's company and address of the storage facility; - Dimensions and/or areas of storage facilities; - Areas for storing "Quarantined", "Released", "Rejected" , "Returned" and "Recalled" products^; - Location(s) of air-conditioning outlet(s) and/or air-conditioner(s)^; - Location(s) of pest control device(s)^; - Location(s) of temperature and humidity uniformity assessment^; - Location(s) of shielded window (if any); and - Applicant's signature, date and company chop
(16)	**Calibration certificate** of the hygrothermometer(s) installed in the proposed storage area (valid date should be covered the Temperature and Humidity Mapping & Daily Record Reports): - Calibration certificate must be issued by the manufacturer or laboratory accredited by HOKLAS or CNAS or Mutual Recognition Arrangement Partners for HOKLAS
(17)	**Temperature and humidity uniformity assessment** with a **conclusion** in the proposed storage area: - Report of the 3- consecutive day (3 time-sections including 'morning', 'afternoon' and 'noon' per each mapping location) recommended for at least 4 corners of the storage areas - Conclude and specify the reason of choosing designated location(s) that will place the temperature and humidity monitor for daily supervision (The suggested assessment method may differ which depends on the Actual Size and Layout of storage area)
(18)	**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) in the proposed storage area: *- For at least 3- consecutive day with 3 time-sections including 'morning', 'afternoon' and 'noon') at selected position(s) inside the storage areas* (The suggested assessment method may differ which depends on the Actual Size and Layout of storage area)
(19)	**Latest cleaning and pest control procedures** and **associated record** (specify the items and frequencies of relative procedure) in the proposed cold chain storage area
(20)	**CHECKLIST of Application involving set up of pharmaceutical grade cold room, refrigerator(s) or freezer(s)** ***(Page 8-9, Appendix 3)^***
(21)	Copy of **Transaction Record Form for Proposed Version**
(22)	**Declaration for Continue the Licence(s) with no PP/Poisons Trade or Storage Allowed** ***(Page 11, Appendix 11)***
(25)	**Storage facilities or additional warehouses for poisons/pharmaceutical products outside the premises** ***(Page 10, Appendix 4)***
(26)	**Written Explanation with Company Letterhead** including: - Name and address of applicant's company; - Reason for why storage facility cannot be provided within the business address of the premises; - Provide details of the store, routine monitoring and maintenance; - Applicant's signature, date and company chop

^(Not applicable for Wholesale Dealer Licence with 'NM'[1], 'MD'[2] or 'NT'[3] condition)

[1.] NM: This licence only authorizes the holder to deal in non-medicinal poisons.

[2.] MD: This licence only authorizes the holder to deal in medical devices containing poisons.

[3.] NT: The licence holder has to notify the Pharmacy and Poisons (Wholesale Licences) Committee ("the Committee") and to provide storage facilities for pharmaceutical products in accordance with Section 2 of the Code of Practice before it may handle pharmaceutical products.

[4.]NC: The licence holder must not handle pharmaceutical products that require cold chain management.

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 (°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

Appendix 11

(For reference purpose)

Declaration of Continuing the Wholesale Dealer Licence with NO PP/Poisons Trade and Storage

Name of Business: _____

Application for Change for Licence (Licence number format: 1/2A/1234):

☐ Wholesale Dealer Licence (WDL); Licence no: _____/2A/_____

☐ Antibiotics Permit (AP); Licence no: _____/1A/_____

☐ Wholesale Dealer's Licence to Supply Dangerous Drugs (Part I); Licence no: _____/6A/_____

☐ Wholesale Dealer's Licence to Supply Dangerous Drugs (Part II); Licence no: _____/5A/_____

I, ***Mr/ Mrs/ Miss/ Ms**_____ (_____),
Name (in English) Name (in Chinese) (if any)

***HKID / Passport** No.: _____ , the undersigned company's director hereby declare that once application accepted, the company **shall not involve in the dealing of business or storage relating to any licence restricted products** (e.g. pharmaceutical products / poisons / antibiotics permit / dangerous drugs). The company shall cease handling of ALL poisons or pharmaceutical products before a suitable storage facility for storing pharmaceutical products can be provided with required documents proof for the Committee's consideration and approval.

Contact Person (if different to the undersigned person):

Name: _____ Tel: _____

Signature of Director : _____

Name of Director : _____

Name of Business : _____

Contact No. : _____

Email Address : _____

Company Chop : _____

Date : _____

[Fill in Details as stated on Hong Kong Identity Card / Passport]

**** Delete as appropriate***

Appendix 12

(For reference purpose)

Authorization Letter

I, ***Mr/ Mrs/ Miss/ Ms**_____ (_____),
Name (in English) Name (in Chinese) (if any)

***HKID / Passport** No.: _____ , the undersigned company's director

hereby authorize _____ to act on behalf in all possible
(Authorized Person's Name)

manners to apply for Change of Particulars Application according to WDL-COP Form submitted on

_____ including signing and providing all documents relating to this matter.
(Application Date)

Signature of Director : _____

Name of Director : _____

Name of Business : _____

Contact No. : _____

Email Address : _____

Company Chop (Authorized Signature) : _____

Date : _____

[Fill in Details as stated on Hong Kong Identity Card / Passport]
**** Delete as appropriate***

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