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/en/pharmaceutical_trade/eform/declare.html, a confirmation email would be sent on the same day upon successful online submission.

6. The applicant should complete Parts A, B and C of the application form. Section C must be signed by the applicant personally, otherwise this application will be treated as null or void. If the applicant fails to provide the required information, or the information filled in does not clearly show that the applicant meets the minimum application requirements, the application will not be accepted.

7. 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. Incomplete application will be treated as null or void and be returned to the applicant.

8. 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[1]; 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[1] on why storage facility cannot be provided within the business address of the premises.

9. Applicant must nominate a person-in-charge of poisons and pharmaceutical products ("PIC"), whom will be subjected to approval by the Pharmacy and Poisons (Wholesale Licences) Committee ("the Committee"). The nominated person must be a fit and proper person and also possess adequate knowledge to carry on trade related to the pharmaceutical industry. The nomination of a nominated person who is already a PIC for another holder of Wholesale Dealer Licence would normally not be considered.

10. 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[1] 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".

11. 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.

[1] The written explanation must be supported by relevant and sufficient reasons to the satisfaction of the Pharmacy and Poisons (Wholesale Licence) Committee. Each case will be considered on a case-by-case basis and at the discretion of the Committee.

12. 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.

13. 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.

14. 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

15. 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

16. 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.

17. 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.

18. 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.

19. 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.

20. Applicants and their employees or agents must not offer an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201) to any government officer or members of statutory organisations (including but not limited to the Pharmacy and Poisons Board and its Committees) in connection with their applications or while having dealings of any kind with government departments or statutory organisations.

** 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.