Department of Health Guidance Notes for the Application of Import and Export Licences

To avoid undue delay in the approval of applications for import and export licences, applicants are requested to note the followings:-

- 1. An application for Import Licence Form 3 covering pharmaceutical product or substance for local sale or distribution must be accompanied by a copy of the Certificate of Registration or Certificate for Clinical Trial/Medicinal Test of the product to be imported.
- 2. If the applicant is not the holder of a registration certificate of the product to be imported, the application must be supported by a written authorization from the relevant product registration certificate holder.
- 3. Full details concerning the products to be imported or exported such as description, quantity, literature, medicinal/therapeutic uses, product insert, etc should be provided. If the product is registered in Hong Kong, please state the Hong Kong Registration Number on the Import/Export Licence.
- 4. Applicant's signature and company's chop should be given on the application.
- 5. The Import Licence Form 3 should be completed in quadruplicate (original, duplicate, triplicate and copy) and Export Licence Form 6 in triplicate (original, duplicate and triplicate).
- 6. If the applicant is holder of Antibiotics Permit, Wholesale Dealer Licence, Manufacturer's Licence, Wholesale Dealer's Licence to supply Dangerous Drugs or Licence to manufacture Preparations of Dangerous Drugs, a copy of the relevant valid licence or permit should accompany the application for the import or export licence.
- 7. If the product or substance to be imported is:
 - (a) for the purpose of clinical trial or medicinal test; or
 - (b) for the purpose of treatment by a registered medical practitioner or a registered dentist, of a particular patient or, for the purpose of treatment by a registered veterinary surgeon of a particular animal; or
 - (c) by a pharmaceutical manufacturer for the purpose of manufacture or the compounding of pharmaceutical preparations, or
 - (d) for the purpose of application for registration of the substance,

it should be clearly stated on the Import Licence Form 3.

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. Please refer to the Pharmacy and Poisons Ordinance and Import and Export Ordinance for the relevant legal provisions.