

Licences for Manufacturers of Pharmaceutical Products

Notes for the guidance of applicants

Part I - Introduction

Under the Pharmacy and Poisons Ordinance, “manufacture” means the preparation of pharmaceutical products for sale or distribution and “manufacturer” has a corresponding meaning. Repackaging of pharmaceutical products for the purpose of sale falls within the ambit of the definition of “manufacture”.

2. Part VII of the Pharmacy and Poisons Regulations relates to the licensing of pharmaceutical manufacturers.

3. No person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products on these premises.

4. Each product will also need to be registered under Part VIII of the Regulations by the manufacturer before it can be sold in Hong Kong.

5. A licensed manufacturer selling his own products by way of wholesale dealing does not require a wholesale poisons licence, but he shall comply with the requirements under Part VI of the Regulations in the same way as a wholesale dealer.

6. The licensing authority is an Executive Committee of the Pharmacy and Poisons Board. The criteria which the Executive Committee must consider in granting a manufacturer’s licence are as follows:-

- a. The operations to be carried out.
- b. The premises where the operations are to take place.
- c. The equipment available on these premises for carrying out the above operations.
- d. The qualifications and experience of the persons who will supervise the operations.
- e. The arrangements made for securing and maintaining adequate records in respect of the products manufactured.

7. A licence may be granted subject to any conditions imposed. It may be restricted to certain manufacturing operations or products in accordance with the competence of, and facilities available to, the manufacturer. An annual licence fee of \$2680 is payable.

8. Any licence for manufacturer may be suspended or revoked if the licensee has failed to comply with the conditions imposed or with any provisions of the Pharmacy and Poisons Regulations.

9. Application for licences – There is no prescribed form for applications for licences. All applications should be made in writing and should include, in so far as is relevant, the particulars set out in Part II of these notes, in the order included. Each of the items noted in Part II should be included. Where an item does not apply or the information is not available, this fact should be stated against the item heading. The application must be signed by the applicant.

10. All applications for a licence for manufacturer and any enquiries on these matters should be sent to the Inspection and Licensing Section, Pharmaceutical Service, Department of Health, 3/F., Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon.

Part II - Particulars to be included in applications for a Licence for Manufacturer

1. Name and address of the applicant.
2. Activities to which the licence is to relate -
 - a. State whether –
 - (i) manufacture, or
 - (ii) filling and packing, or
 - (iii) both.
 - b. In the case of manufacture, state the operations to be carried out and the names and descriptions of the products involved.
3. Premises
 - a. Give the address of all premises at which
 - (i) any of the operations listed under (2) above are to be carried out; and
 - (ii) pharmaceutical products are stored.
 - b. Give a brief description, at each of the addresses at (a) (i) above, of the equipment and facilities available to carry out the operations listed under (2). The model and capacity of the equipment should also be given.
 - c. Provide a floor-plan of the premises showing the factory layout and the positions of the equipment, furniture, etc.
4. Details of other manufacturing or processing operations – Describe any operations relating to products not covered by the definition of “pharmaceutical products” in the Ordinance, carried out on the premises listed under (3) (a).
5. Key personnel – List of names and H.K.I.D. no. of supervisory personnel, directors and owners.
6. Qualifications of supervisory personnel – State the name, qualifications and experience of the persons in charge of production and quality control respectively.
7. Records – Give an outline of the arrangements for maintaining production, quality control, distribution and recall records.

Part III - Applications for licences to manufacture Dangerous Drugs

Manufactures of Dangerous Drugs are required to hold an additional licence issued by the Director of Health under the Dangerous Drugs Ordinance, Cap. 134. The licence may be restricted to the manufacture of Part II dangerous drugs and Barbitone only.

2. All applications for licences to manufacture dangerous drugs should be made in writing to the address shown in paragraph 10 of Part I of these notes. The particulars to be included in the application are the same as these described in Part II of these notes. The application should also specify whether the full licence or the restricted licence is being applied for.

3. On the grant of a licence, a fee of \$2680 is charged. An annual licence fee of \$2680 is also payable.

4. The performance pledge of the Department of Health is that applications will be approved within two months.

NB 1. 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.

2. Copies of the Pharmacy and Poisons Ordinance, the Dangerous Drugs Ordinance and their Regulations 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.legislation.gov.hk>.