

General Knowledge on Medicine Registration

According to the laws of Hong Kong, medicines to be applied on human or animal bodies for diagnosis, treatment, relief or prevention of diseases must be registered with the Pharmacy and Poisons Board (PPB) prior to their sale in the market.

Persons responsible for making such applications include:

1. the local manufacturers, if the medicines are manufactured in Hong Kong;
2. the importers, if the medicines are manufactured outside Hong Kong.

Pharmaceutical products are required to conform to the standards on safety, efficacy and quality before they can obtain registration. Such requirement aims at providing the public with safeguard on safety, efficacy and quality of medicines available in the market. Therefore, the applicant has to provide a set of information including production formula, product specification, laboratory report and manufacturer licence in his/her application for registration for the approval of the PPB.

Upon registration, the medicine will be given by the PPB a registration number, such as HK-12345, which is required to be printed on the medicine label. Members of the public can therefore check from the registration number on the label to see if the medicine is registered or not.

Apart from the registration number, the label should also bear the following general information:

1. Name of product
2. Name and quantity of active ingredients
3. Name of manufacturer
4. Batch number
5. Expiry date
6. Method of storage, if there are special requirements
7. Method of use, dosage and dosing intervals, if the medicine is sold over the counter

If you have complaints against registered or non-registered medicines, please call the complaint hotline at 2572 2068.