

**DEPARTMENT OF HEALTH  
PHARMACEUTICAL SERVICE  
PHARMACEUTICALS REGISTRATION  
SECTION**

**Guidance Notes on  
Registration of Pharmaceutical Products**

**Pharmaceutical products subject to registration**

1. Under the Pharmacy and Poisons Regulations, pharmaceutical products must be registered with the Pharmacy and Poisons Board before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use. A pharmaceutical product means any substance, or mixture of substances, used for administration to human beings or animals for

- (A) the diagnosis, treatment, mitigation, alleviation or prevention of disease or its symptoms; or
- (B) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or its symptoms; or
- (C) altering, modifying, correcting or restoring any organic function.

2. In deciding whether or not your product is a pharmaceutical product, you should take into account the composition of your product and the nature of the claims you make in relation to the product. In general, if your product contains a drug substance in its composition, or if it carries medicinal claims in its label, leaflet, brochure, wrapper, advertisements and other promotional materials, it will fall within the meaning of pharmaceutical product and registration is required. Products commonly referred to as cosmetics, toiletries and disinfectants which do not contain any drug ingredient in its composition and which are sold without any medicinal claims may be excluded. However, it is your obligation to have complete knowledge of the ingredients of products. If the composition of the products for sale is found to contain substances that fall within the meaning of pharmaceutical product, you might commit an offence of the sale of an unregistered pharmaceutical product.

**Criteria for registration**

3. Your pharmaceutical product will only be approved for registration if it meets the criteria of safety, efficacy and quality relevant to it.

**Who should apply?**

4. If your pharmaceutical product is manufactured in Hong Kong, the person responsible for obtaining registration of the product is the manufacturer.

5. If your pharmaceutical product is manufactured outside Hong Kong, the person responsible for obtaining registration is the importer, or the Hong Kong branch, subsidiary, representative, agent or distributor of the manufacturer.

**Pharmaceutical products not subject to registration**

6. Products which fall under the following categories are not required to be registered with the Pharmacy and Poisons Board:

- (A) products containing only proprietary Chinese medicines or Chinese herbal medicines as defined in the Chinese Medicine Ordinance (Cap. 549);
- (B) drug substances imported by pharmaceutical manufacturers solely for the purpose of manufacturing their own pharmaceutical products;
- (C) products imported by or under the direction of a registered medical practitioner or a registered dentist for the treatment of a particular patient, or of a registered veterinary surgeon for the treatment of a particular animal;
- (D) products imported for re-export only;
- (E) products manufactured in Hong Kong for export by the manufacturer only.

**Where to apply?**

7. You can obtain application forms for the registration of pharmaceutical products at the following website: <http://www.psdh.gov.hk/eps/eng/html/pharm6.pdf>. You can also obtain them from:

Pharmaceuticals Registration Section  
 3/F, Public Health Laboratory Centre,  
 382 Nam Cheong Street,  
 Shek Kip Mei, Kowloon,  
 Hong Kong. (Enquiries: 2319 8458)

**How to apply?**

8. You should hand in the completed application form to the Pharmaceuticals Registration Section along with:

- (A) the application fee (currently \$1,100. Please also see paragraph 15);
- (B) the attached Checklist (**Appendix 1**) duly completed;
- (C) the following particulars:
  - a) copy of the business registration certificate of the applicant;
  - b) certified true copy of the manufacturer's licence;

- c) (for products manufactured outside Hong Kong) information on the manufacturing facilities and practices of the manufacturer.  
(In dealing with an application relating to a pharmaceutical product manufactured outside Hong Kong, the methods, standards and conditions of manufacture of the pharmaceutical product will also be taken into consideration. Applicants should therefore supply detailed information regarding the manufacturer including the manufacturing and quality control facilities, technical personnel, etc);
- d) certified true copy of the Good Manufacturing Practices (GMP) Certificate of the manufacturer;
- e) original or certified true copy of the free sale certificate of the product issued by the country of origin;
- f) for products containing a new chemical or biological entity:
  - (i) official evidence of registration approval of the product (e.g. original or certified true copies of free sale certificates) by two or more of the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA;
  - (ii) expert evaluation reports on the safety, efficacy and quality of the product;
- g) clinical and scientific documentation substantiating the safety and efficacy of the product (except for generic products the originator product of which has been registered in Hong Kong for over 5 years);
- h) one set of original or prototype sales pack (outer carton and container label) of each pack size of the product, complying fully with the appropriate labelling requirements (please read the attached "Guidelines on the Labelling of Pharmaceutical Products" at **Appendix 2**);
- i) The following document(s) to support the proposed indication(s) and other information in the package insert (if any):
  - (i) copy of reputable references (e.g. American Hospital Formulary Service Drug Information, British National Formulary (BNF), Medicines Compendium, Drug Information Handbook, Drug Facts and Comparisons, Martindale the Complete Drug Reference or Physicians' Desk Reference); and / or
  - (ii) documentary evidence showing that the package insert has been approved by one of the listed countries in section 8 (C) f) (i);

- j) a sample of the product as it will be sold to the purchaser, for imported products, you are reminded to apply for an import licence before importing the product samples. Please refer to the attached "How to apply for Import and Export Licences for Pharmaceutical Products and Medicines", "How to complete Import and Export Licence forms for Pharmaceutical Products and Medicines" and "Import and Export Licences Notes for the Guidance of Applicants" at **Appendix 4** for details.
- k) detailed qualitative and quantitative composition of the finished product, issued by the manufacturer;
- l) specifications of the product issued by the manufacturer showing compliance with one or more of the following, unless otherwise justified: Pharmacopoeia of the People's Republic of China, British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, Japanese Pharmacopoeia and/or United States Pharmacopoeia;
- m) method of analysis of the product;
- n) certificate of analysis of a representative batch of the finished product, issued by the manufacturer or the company performing the analysis;
- o) stability test data of the product at one of the following Temperature (°C)/Relative Humidity (RH) conditions:

	<b>Real Time Testing Condition</b>
(i)	30°C±2°C/75%±5% RH
(ii)	30°C±2°C/65%±5% RH
(iii)	25°C±2°C/60%±5% RH (with appropriate labelling of storage condition in Chinese & English)
	<b>Accelerated Testing Condition</b>
(iv)	40°C±2°C/75%±5% RH for 6 months

(Other temperature/relative humidity conditions could be adopted where justified)

- p) Bioequivalence (BE) data for anti-epileptic drugs\*. The BE studies should be conducted in accordance to World Health Organization guidance on the "Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability" or other international guideline.

(\*includes: Carbamazepine, Clobazam, Clonazepam, Clorazepate, Divalproex, Ethosuximide, Ethotoin, Felbamate, Fosphenytoin, Gabapentin, Lamotrigine, Lacosamide, Levetiracetam, Mephenytoin, Mesuximide, Oxcarbazepine, Pheneturide, Phensuximide Phenytoin, Pregabalin, Primidone, Rufinamide, Sultiame, Tiagabine, Topiramate, Trimethadione, Vigabatrin, Valproates and Zonisamide)

### **Registration of products containing vitamins, minerals, etc.**

9. Special exemptions are provided for the quality analysis of products containing vitamins, minerals, etc. Please refer to the attached "Guidelines on the Testing of Pharmaceutical Products containing Vitamins, Minerals, etc." at **Appendix 3** for details.

### **Use of materials of animal origin**

10. If materials of animal origin are used in the manufacturing of the product, you should also provide documentary evidence obtained from the manufacturer on the source of the animals, the nature of the animal tissues used in the manufacturing and the production processes, showing compliance with one or more of the safety measures taken to minimize the risk of communicable diseases that can be transmitted to human, including but not limited to Transmissible Spongiform Encephalopathy (TSE) transmission promulgated by the European Medicines Agency, USA or Australia. The following documents are relevant:

- (A) "Notes for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" released by the European Medicines Agency (EMEA/410/01);
- (B) the general monograph of the European Pharmacopoeia on "Products with risk of transmitting agents of animal spongiform encephalopathies";
- (C) "Risk and regulatory assessment of lactose and other products prepared using calf rennet" released by the European Medicines Agency;
- (D) "Guidance for Industry on the sourcing and processing of gelatin to reduce the potential risk posed by Bovine Spongiform Encephalopathy (BSE) in FDA-regulated products for human use" released by the FDA;
- (E) "Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongiform encephalopathies (TSEs)" released by the Therapeutic Goods Administration of Australia.

### **General**

11. When an application for registration is submitted, the attached Checklist at **Appendix 1** should also be completed and submitted, to ensure that all the information set out in paragraph 8 (C) above is provided.

12. In filling in the particulars specified in the application form, if the space provided is insufficient, a separate piece of paper may be used with a proper reference made in the application form.

13. For products of the same description, composition and strength but different package sizes, only one application is required. For instance, only one application is required for "ABC Tablet 100mg" of package sizes 10's, 100's and 1,000's. However, two separate applications are required, for "ABC Tablet 100mg" and "ABC Tablet 50mg" respectively. Similarly, separate applications are required for a product presented in different dose forms, e.g. injection, tablet and capsule.

**Registration fee**

14. When an application is approved, you will be asked to pay a registration fee (currently \$1,370 per product) and receive the relevant certificate of registration. Payment should be made by post or in person at the address specified in paragraph 7 above. Cheques should be made payable to "The Government of the Hong Kong Special Administrative Region" and crossed.

Hours of payment:

Monday to Friday

9:00 am to 1:00 pm

2:00 pm to 5:30 pm (Tuesday to Friday) or 5:45 pm (Monday)

**Infringement of patent right**

15. Please note that the Pharmacy and Poisons Board does not take the factor of "patent right" into consideration while deciding on an application for registration of a pharmaceutical product/substance. Nevertheless, an applicant shall not overlook the issue of infringement of patent right as the following persons may be liable for infringement of a generic version of a patented product registered in Hong Kong:

- (A) a manufacturer or importer of the product;
- (B) a wholesaler or retailer of the product; and
- (C) a hospital, doctor, dentist or anybody using or dispensing the product.

You are therefore reminded to ensure that your product does not infringe any patent right. Since each case of possible infringement of patent right will turn on its own particular facts, if you have any doubts about your position in this regard, you should consult your own lawyer.

**Enquiries on progress of applications**

16. At any time during the application process, you can enquire with the officer at the Pharmaceuticals Registration Section handling your application about the progress of the application. The name and telephone number of the officer are shown in the letter of response issued to you in respect of the application.

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 and its subsidiary legislation can be purchased by calling the Publications Sales Section of Information Services Department at Tel: 2537 1910, or by email at [puborder@isd.gov.hk](mailto: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/eng/home.htm>.