

Letterhead of The Hong Kong Association of The Pharmaceutical Industry

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Tuesday, 17th November, 1998

Ms Doris Chan
Clerk to Legislative Council Panel on Health Services
Legislative Council
Legislative Council building,
8 Jackson Road
Hong Kong

Dear Ms Chan,

Following a recent meeting with Mr. Michael Ho and representatives of this Association, I attach a copy of the HKAPI's **Position Paper on The Need for Better Control of Unregistered Pharmaceuticals in Hong Kong**. We would welcome an early opportunity to meet the Legislative Council Panel on Health Services to answer any questions they may have on this.

Yours sincerely,

Joy Ottway (Mrs)
Executive Director

1968-1993 25 years contributing to QUALITY health care
Member: International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
Associate Member: Federation of Medical Societies of Hong Kong

**The Need for Better Control of
Unregistered Pharmaceuticals in Hong Kong**

Prepared by
The Hong Kong Association of the Pharmaceutical Industry
September 1998

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Unregistered drugs have always posed a risk to the community. But now due to changing economic circumstances, the risk of unregistered drugs entering Hong Kong is increasing.

An unregistered drug typically falls into three broad categories:

- a) pharmaceuticals entering Hong Kong through illegal channels (smuggled drugs);
- b) counterfeit pharmaceuticals entering Hong Kong through illegal channels; and,
- c) pharmaceuticals entering Hong Kong for one purpose, but actually used for another.

While the presence of unregistered drugs in Hong Kong is not yet a cause for panic, the Hong Kong Association of the Pharmaceutical Industry (HKAPI), calls on the Government to acknowledge the risk, and work cooperatively with industry, to ensure the public health and safety risks posed by unregistered drugs, are kept at a minimum.

There are two reasons for the increased risk of unregistered pharmaceutical products entering Hong Kong now, more than at any other time. These are:

- a) the depreciation of currencies of Hong Kong's neighbors, that make purchasing products across borders cheaper and,
- b) the increase of joint ventures in China that manufacture many pharmaceuticals, not registered in Hong Kong.

The reason for the need to register pharmaceuticals is self-evident. The Government is tasked with the responsibility to ensure that adequate research has been conducted on pharmaceuticals, their indications, efficacy and safety.

Pharmaceuticals need to be transported in temperature, light and humidity controlled conditions to ensure the quality of the drugs. To safeguard the Hong Kong community the Government is tasked with ensuring importation channels maintain appropriate standards.

The risks to the community of unregistered drugs fall into three categories. Those risks produced by:

- a) incorrect handling procedures;
- b) the inability to recall unregistered product; and,
- c) inadequate labeling and instruction literature.

a) Incorrect Handling Procedures

To ensure the stability of a pharmaceutical preparation for the period of its intended shelf life, the product must be stored under proper conditions. The deterioration of a product is an ongoing process, which begins when it is manufactured, and is accelerated by poor formulation, poor packaging and especially, poor storage or handling conditions.

The formulation and packaging of the products are controlled by the manufacturers according to Good Manufacturing Practices (GMP) or local manufacturing standards. Once the product leaves the manufacturer, the stability of the product greatly depends on the conditions under which the products are transported, stored and handled.

Temperature, light and humidity are the major environmental factors that influence the stability of products.

(i) Temperature

An increase in temperature generally increases the rate of chemical degradation, which eventually leads to the deterioration of the pharmaceutical product's potency. Therefore, one method of reducing the degradation of products is to store them under controlled temperatures.

Temperature can also affect the physical degradation rate of products. For instance, an increase in temperature may cause creams or emulsions to separate into two phases. On the other hand, freezing the creams or emulsions

may cause crystallization, decreasing their usability.

(ii) **Light**

In addition to temperature, the degradation of pharmaceutical products especially photo sensitive drugs can also be caused by light (room light or sunlight). In products exposed to light, photolysis reaction or oxidative process would take place thereby damaging the products.

(iii) **Humidity**

Moisture or humidity is the third of the major factors affecting the stability of pharmaceutical products, Exposure to moisture will damage a product, through a process of premature disintegration and decomposition. Moisture also serves as a nutrient media for the growth of micro organisms therefore potentiating the risk of bacterial contamination.

(iv) **Consequences**

The major consequence of the improper storage of pharmaceuticals is the loss of potency and the related loss of efficacy of the medication. If patients take these sub-potent products, they will not receive the full benefit of the medication and thus their health may worsen.

In the case of acute conditions such as asthma or angina, their condition may be fatal if the potency of the medications is reduced. In the case of antibiotics, where the potency is reduced, the patient is likely to be re-infected,

prolonging the treatment period, which can lead to increased resistance.

b) Inability to Recall

Obviously the previous situations cause great risks to patients, and represent a hidden burden to the health care system. When pharmaceuticals are registered and imported legally the chances of mishandling are minor; and, should an error or product defect be discovered, the authorised importers can trace the affected pharmaceuticals and recall them. Unregistered pharmaceuticals, once in circulation, cannot be tracked.

c) Inadequate Labeling and Usage Instruction Literature

It is a legal requirement that all pharmaceuticals are labeled in accordance with the regulations of the HKSAR Government. This is to ensure that physicians and patients have the correct information in relation to:

- (i) specific indications;
- (ii) contra-indications, side-effects and precautions;
- (iii) dosage; and
- (iv) pharmacodynamic data for prescribing physicians.

If a pharmaceutical enters Hong Kong SAR illegally, it is unlikely to have the necessary information included in the pack.

a) Reasons for Pharmaceutical Imports

Pharmaceuticals are imported to Hong Kong for any of six possible purposes. These are for:

- (i) transit before exportation to countries other than Hong Kong
- (ii) manufacturing and compounding as finished products for local sale (in most cases) or for re-export
- (iii) registered medical practitioners or dentists for named-patient treatments, who require a particular drug that is not yet registered in Hong Kong
- (iv) application of product registration should the Department of Health determine that they require a sample.
- (v) conducting clinical trials under a clinical trial certificate that is valid for two years.
- (vi) for sale to prescribing physicians, hospitals, pharmacies and authorized retail outlets.

b) The Process for Registered Drug Entry to Hong Kong

The licences involved in the process of importing registered pharmaceuticals into Hong Kong are :

- (i) the **Wholesale Poisons Licence**, which is required by wholesalers to import or export controlled pharmaceutical products
- (ii) the **Certificate of Product Registration**, which entitles the licensee to import the pharmaceuticals for distribution;
- (iii) the **Importer/Exporter Licence**, which is required for wholesalers of non-poisons only;
- (iv) the **Import Licence**, which enables the importer to bring a package of pharmaceutical goods into Hong Kong for sale in Hong Kong;
- (v) the **Import Licence** which enables the importer to bring a package of pharmaceutical goods into Hong Kong, for re-export; no Certificate of Product Registration is required for applying for the Licence and,
- (vi) the **Export Licence**, which enables the exporter to export a package of pharmaceutical goods out of Hong Kong

c) Application Process for Licences

- (i) *Application Process for a Wholesale Poisons Licence or Importer/Exporter Licence*
 - 1. The applicant is required to make application to the Department of Health. The application covers details of the business registration, organization structure and personnel background, office

and storage space layout. Proof of agency may be required. If the organization is to handle pharmaceuticals under the dangerous drugs category, a qualified pharmacist will also need to be employed by the organization.

2. The Department of Health will then inspect the site checking storage space (should be clearly segregated from other goods) and storage conditions, locking facilities if poisons are involved and the recall system.
3. If all the categories are fulfilled a Wholesale Poisons Licence will be issued.

(ii) Application Process for a Certificate of Product Registration

1. The Certificate of Product Registration has a life span of 5 years and is issued by the Department of Health. It provides the holder with the right to import a particular pharmaceutical or pharmaceutical component.

(iii) Application for an Import Licence for Products to be sold in Hong Kong

A letter of authorization from the manufacturer is not required if the certificate of product registration holder is the importer himself. However, in all cases, a copy of a valid wholesale poisons licence or importer/exporter licence should accompany the application.

1. The importer applies to the Department of Health for an import licence. The applicant provides a copy of the Certificate of Product Registration and a copy of his Wholesale Poisons Licence or Importer/Exporter Licence only. Neither letter of authorization from manufacturer nor company's business registration is required.
2. The Department of Health certifies the application and keeps one copy, before passing the application to the Department of Trade.
3. The Department of Trade records the details of the Import Licence and returns it to the applicant via the Department of Health.
4. When the goods arrive the applicant provides a copy of the Import Licence to the Customs and Excise Department officials before collecting the goods and storing them.

(iv) ***Application for an Import Licence for products to be re-exported***

The application for an Import Licence is the same as that in paragraph (iii) above, except the certificate of Product Registration is not required.

(v) ***Application for an Export Licence***

No manufacturer's authorization letter, no certificate of product registration and business registration are required.

There is one major risk of unregistered pharmaceuticals being distributed in Hong Kong in the system described in the previous section. Where products are imported with a view to re-export, there is no check to ensure that the pharmaceuticals earmarked for export, actually leave the Hong Kong SAR.

Therefore the Hong Kong Association of the Pharmaceutical Industry calls upon the Hong Kong SAR Government to require any person who wishes to import pharmaceutical products into Hong Kong SAR for re- export purposes to produce one of the following documents:

- a) a Letter of Authorization from the manufacturer allowing the importer to bring the product into the Hong Kong SAR; or
- b) a Free Sale Certificate from the source country; or,
- c) proof that the product will be re-exported to another country.