CB(1)814/99-00

January 14, 2000

Hon Margaret NG
Chairman
Bills Committee on Trade Marks Bill
The Hong Kong Legislative Council
8 Jackson Road
Central
Hong Kong

Dear Ms. Ng,

Re. The Issue of Safety on Public Health on Parallel-Import Pharmaceuticals

The Hong Kong Association of the Pharmaceutical Industry (HKAPI) is an association that aims at enhancing the quality of healthcare in Hong Kong. We understand that the bills committee is now discussing the bill that helps modernize measures on protection of intellectual property rights. This will have an impact on the protection of patent rights of pharmaceuticals and also public health safety. In particular, we would like to highlight on the issue of parallel-import pharmaceuticals, what we call "unregistered pharmaceuticals".

We would like to draw your attention to Clause 19 of the bill, which provides that trade mark proprietors have no right to prevent parallel importation of goods, unless fulfilling prescribed conditions. This clause has the potential effect of encouraging parallel-import pharmaceuticals or "unregistered pharmaceuticals" to enter into Hong Kong and affect safety on public health.

The Association considers that this poses a hazard to Hong Kong people, since unregistered pharmaceuticals have significant risks of impaired quality and effectiveness. Currently, pharmaceutical products are the only products that need to the approved by the Government with a stringent process. If their control is relaxed by the bill, safety on public health will be endangered.

Our views are documented in the policy paper titled "The Need for Unregistered Pharmaceutical Controls in Hong Kong" (attached). In essence, we consider that the Government should strengthen control measures to forbid "unregistered pharmaceutical" from entering Hong Kong to safeguard safety on public health.

We had presented the policy paper and our views to LegCo's Health Services Panel early last year. The paper was also circulated to LegCo members, the Government and experts in the healthcare field. We have received wide spread support from various parties.

Because of the importance of the issue, the Association feels obliged to state its position clearly. We are glad to present our views to the bills committee as it deems fit.

If there is any query, please feel free to contact me at 28359870, or Robert Siu, Executive Director of HKAPI, at 25283061.

Yours sincerely,

Alice Chin
President

The Need for Unregistered Pharmaceutical Controls in Hong Kong

Position Summary

February 1999

Introduction

This document is a summary of the position paper prepared by the Hong Kong Association of the Pharmaceutical Industry (HKAPI) addressing the issue of unregistered pharmaceuticals in Hong Kong with respect to their risks in public health and safety. The position paper was sent to Legislative Council Members in late 1998.

The position paper presents the reasons for the increasing risk of unregistered pharmaceuticals, the categories of risk, the legal means of entry of pharmaceuticals to the SAR, the current system's weakness, and, policy recommendations.

Reasons For the Increasing Risk of Unregistered Pharmaceutical Products Entering Hong Kong

The increasing risk of unregistered pharmaceuticals arises from:

- The plunging currencies of Hong Kong's neighbors, that make purchasing of pharmaceutical products across borders cheaper, and

- The increase in joint ventures in China that manufacture many pharmaceuticals, not registered in Hong Kong.

Risks of Unregistered Pharmaceuticals to the Community

1. Incorrect handling procedures

- No pharmaceutical product is stable indefinitely. The deterioration of a product is an ongoing process, which begins when it is manufactured, and will be accelerated by poor formulation, poor packaging and poor storage or handling conditions.
- Temperature, light and humidity are the major environmental factors that influence the stability of products and thus damage the products before its supposed expiry date. Unregistered pharmaceuticals were often ended in the hands of non-professionals, which may unknowingly expose products to unfavourable environmental conditions.
- Major consequences of the improper storage of pharmaceuticals are the loss of potency and the related loss of efficacy of the medication. In acute conditions such as asthma, their condition may be fatal if the potency of medications is reduced. In the case of antibiotics, the patient is likely to be reinfected.

2. Inability to recall unregistered products

   Should there be errors or defects with a product, the proper registration process allows the pharmaceutical companies to trace the affected pharmaceuticals and recall them. Unregistered pharmaceuticals, once in circulation, cannot be tracked or recalled.

3. Inadequate labeling and instruction literature

   It is legal requirement that all pharmaceuticals are labelled. This is to ensure that physicians have the correct information to prescribe. If a pharmaceutical enters Hong Kong illegally, it is unlikely to have the necessary information, such as specific indications and dosage, included in the pack; and it is even more unlikely to have this information in Chinese.

Methods of Entry of Pharmaceuticals into Hong Kong

Currently, pharmaceuticals can be imported to Hong Kong for the purpose of local sales, clinical trials, application for registration, or re-export.

Licences involved in the process of importing registered pharmaceuticals into Hong Kong include the Wholesale Poisons Licence, the Certificate of Product Registration, the Import Licence and the Export Licence.

System Weaknesses

Under the current licensing system, the application requirements for the first three purposes mentioned above are sufficient to ensure that imported pharmaceuticals are used for what they are intended.

Yet there is no check to ensure that pharmaceuticals earmarked for re-export actually leave the Hong Kong SAR. This provides a loophole that allows unregistered pharmaceuticals to be distributed in Hong Kong, and create risks on public health and safety to the people of Hong Kong.

Recommendations

Given the related risks to public health and safety, HKAPI urged for the co-operation among the Government, the Legislative Council and the industries to close the loophole.

HKAPI calls upon the Government to require additional documentation from any person who wishes to import pharmaceutical products into the territory for re-export purposes. For example, a Letter of Authorization from the manufacturer, which allows the importer to bring the pharmaceutical product into the Hong Kong SAR, will help minimise the risk posed by unregistered products on public health and safety.

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The Need for Unregistered Pharmaceutical Controls in Hong Kong

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

CONTENTS

1. INTRODUCTION

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) legal pharmaceuticals brought into Hong Kong through illegal channels (smuggled drugs);

b) illegal pharmaceuticals brought into Hong Kong through legal and illegal channels (counterfeit drugs); and,

c) those pharmaceuticals that are brought into Hong Kong for one purpose, but actually used for another.

While the presence of unregistered drugs in Hong Kong is no 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.

2. THE RISKS

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 plunging currencies of Hong Kong's neighbors, that make purchasing products across borders more cheaply, most attractive; 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, and safety.

Pharmaceuticals need to be transported in temperature, light and humidity controlled conditions in order to guarantee the safety of the drugs. To ensure the safety of 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

No pharmaceutical product is stable indefinitely. 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 is out of the control of the manufacturers, the stability of the product greatly depends on the conditions under which the products are 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 reaction, which eventually leads to the degradation 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 at 0c, decreasing their usability.

(ii) Light

In addition to temperature, the degradation of pharmaceutical products especially photolabile drugs can also be caused by light (room light or sunlight). In general, the shorter the wavelength, the more damaging the effect. In products exposed to light, a photolysis reaction would take place. Once the drug molecules have attained sufficient energy, degradation of the product would occur.

(iii) Humidity

Moisture or humidity is the third of the major factors affecting the stability of pharmaceutical products. Exposure to moisture may cause a product to separate into individual crystals.

(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 may 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 patient distress, and represent a hidden burden to the health care system. Where pharmaceuticals are registered the chances of mishandling are minor; and, should an error be discovered, the registration process allows the pharmaceutical companies to trace the affected pharmaceuticals and recall them. Unregistered pharmaceuticals, once in circulation, cannot be tracked.

c) Inadequate Labeling and Instruction Literature

It is a legal requirement that all pharmaceuticals are labeled. This is to ensure that physicians have the correct information in relation to:

(i) specific indications;
(ii) contra-indications;
(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; and, even more unlikely to have this information in Chinese.

3. METHODS OF ENTRY OF PHARMACEUTICALS TO HONG KONG

a) Reasons for Pharmaceutical Imports

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

(i) transit before exportation to countries other than Hong Kong;

(ii) manufacturing and compounding for re-export, in most cases;

(iii) registered medical practitioners or dentists for name-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 resale across the counter in the case of non-prescription drugs; and,

(vii) for sale to physicians, drug stores, dispensaries, and hospitals.

b) The Process for Registered Drug Entry to Hong Kong

There are four licences involved in the process of importing registered pharmaceuticals into Hong Kong.

These are:

(i) the **Wholesale Poisons Licence**, which is required by all parties (distributors, hospitals, doctors, pharmacies and academic institutions) that will be storing and distributing pharmaceuticals;

(ii) the **Certificate of Product Registration**, which entitles the licencee to import the pharmaceuticals for distribution;

(iii) the **Import Licence**, which enables the importer to bring a package of pharmaceutical goods into Hong Kong for sale in Hong Kong;

(iv) the **Import Licence** which enables the importer to bring a package of pharmaceutical goods into Hong Kong, for re-export; and,

(v) 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

1. The applicant is required to make application to the Department of Health. The application covers details of the organization's business registration and the organization's office and warehouse set up. If the organization is to handle pharmaceuticals under the Dangerous Goods category a qualified pharmacist will also need to be approved by the application.

2. The Department of Health will then inspect the site checking storage conditions, temperature controls and power supplies.

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 or Free Sale Certificate has a life span of 5 years and is issued by the Department of Health. It provides the holder with, in almost all cases, the exclusive right to import a particular pharmaceutical or pharmaceutical component.

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

1. The distributor applies to the Department of Health for an import licence. The application provides details of the Certificate of Product Registration, a letter of authorisation from the manufacturer, the product for import, the quantity, and a copy of the company's business registration.
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

1. The procedure is the same as that in paragraph *(iii)* above, except that neither a Certificate of Product Registration nor a letter of authorisation from the manufacturer is required.

(v) Application for an Export Licence

1. The application for an Export Licence is the same as paragraph *(iii)* above, until step four, where the licence holder deposits the pharmaceuticals with the Customs and Excise officials for export.

4. SYSTEM WEEKNESSES

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.

5. RECOMMENDATIONS

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;

b) a Free Sale Certificate from the source country; or,

c) proof of evidence of re-export such as an import licence from the country to which the pharmaceutical goods were re-exported.