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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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