

**THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY
AND
THE AMERICAN CHAMBER OF COMMERCE IN HONG KONG**

Position Paper

“Pharmaceutical Patent linkage”

The Issue

The "patent linkage" issue relates to the lack of coordination between the system for pharmaceutical patent protection and pharmaceutical product registration.

Position

The HKSAR Government should take measures to safeguard pharmaceutical patent rights. Relevant Hong Kong laws should be amended to require applicants to declare the patent status of their products and to reject or revoke product registration applications based on false declarations.

Rationale

In a typical case, an applicant for pharmaceutical product registration is fully aware that its product infringes a valid patent. There is currently no power under the relevant ordinance and subsidiary legislation to require the rejection of such an application or the revocation of a product registration on the grounds of patent infringement. Instead, the relevant right holder must seek remedy through litigation.

Other jurisdictions require the applicant for product registration to check a box declaring that its product does not infringe third parties' rights. The Mainland adopted this cost-effective, self-declaration approach when its pharmaceutical laws and regulations were recently reformed. Hong Kong cannot afford to lag behind the Mainland on this issue. “Patent linkages” have long been established in the US and Canada. The EU does not have patent linkage, though its data exclusivity lasts longer than Hong Kong’s, ranging from 6 years in some countries to 10 in others. Singapore has not yet established the linkage, but it is expected to do so under the US/Singapore Free Trade Agreement.

It is the current practice of the Pharmacy and Poisons Board to issue a Certificate of Drug/Product Registration authorizing products “to be marketed for use within Hong Kong”. Because a product registered in Hong Kong may violate other legal provisions or rights and interests, this practice should be discontinued and registration certificates should simply state that the product is registered.

Hong Kong has an obligation to safeguard intellectual property rights as a signatory to the *Paris Convention for the Protection of Industrial Property* and the *Agreement on the Trade Related Aspects of Intellectual Property Rights Protection*. Hong Kong's continued failure to safeguard pharmaceutical patent rights will discourage investment by international firms and will hamper local innovation. This obviously runs counter to Hong Kong government's stated desire to make Hong Kong the capital of traditional Chinese medicine.