The Hong Kong Association of the Pharmaceutical Industry
香港科研製藥聯會

Thank you for inviting The Hong Kong Associations of the Pharmaceutical Industry (the Association) to comment on the proposal of the Patents (Amendment) Bill 2007. Under the Proposal, **a compulsory license for a pharmaceutical product may be granted if Hong Kong finds itself, and the Chief Executive-in-Council declares it to be, in a state of "extreme urgency" which threatens public health.** The Association generally finds the proposal to be in line with both the WTO's recommendations and the Doha Declaration of August 2003.

The Association is concerned, however, about the lack of clarity on the details for implementing the Proposal. Specifically, there is no concrete mechanism or objective criteria to **define what constitutes a state of "extreme urgency". There have been recent examples in other countries where local governments have defined "extreme urgency" arbitrarily and with prejudice against rightful patent holders.**

To ensure clarity and fairness, the Association requests that:

a. **The Hong Kong Government benchmark its Avian Flu Responsive Alarm System as an example of how to put objective measures and a clear definition around key processes in a state of "extreme urgency."**

b. **An independent statutory body be established, with a balanced membership, to advise the Chief Executive-in-council prior to any state of "extreme urgency" being declared. An important role for this body would be to reference recommendations and guidance from other international health bodies.**

c. **Clarity is provided in the Proposal about how and when normal economic activities would be restored after a "state of urgency" has been resolved. Care should be taken to ensure no long-lasting damage occurs to Hong Kong's commercial principles, including protection of intellectual property rights. Details should be provided in the Proposal concerning how long generic drugs, which infringe a valid patent, can be stocked and sold during and after a "state of urgency", and who will be exempted from liability for infringing patents and for how long.**

   The Association proposes that the government centralize the purchase, usage, stocking and distribution of affected drugs during a period of "extreme urgency," so that these drugs can be effectively distributed to patients most in need and prevent any possible irrational stocking of drugs due to speculation or panic by the public.

d. **Bio-equivalence and Bio-availability* data be required for all generic products affected by a "Compulsory License," so that this process does not give rise to inferior quality generic products being used, which may lead to harmful effects for patients.**

**Bioequivalence ensures that generic medicines are therapeutically equivalent to the original branded product, while Bio-availability shows how quickly and effectively the active ingredients act on the body. A lot of regulatory bodies in the world put 75% of bio-equivalence/bio-availability compare to the original branded drug a criterion for generics registration.*

Thank you once again for the opportunity for our Association to comment on this important Proposal.

With best regards,

Sabrina Chan
Executive Director
The HKAPI