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

To ensure a proper system to safe-guard patients' safety
Off-label use of pharmaceuticals should be discouraged

The Hong Kong Association of the Pharmaceutical Industry (HKAPI), on behalf of its 40 member companies engaging in the research and development of novel pharmaceuticals, and providing 70% of treatment drugs in Hong Kong, does not encourage off-label use of pharmaceuticals as a core principle by supporting the registration system of Hong Kong as a proper system to protect patients safety by evaluating the pharmaceutical's efficacy, safety and quality.

Off-label use brings uncertain effects

Even though off-label use is not illegal in most countries, and can be used case by case under the clinical judgement of individual doctors[1], the industry does not encourage off-label use of any of pharmaceuticals, as a principle. It is because the approved medical indications of pharmaceuticals are based upon scientific clinical trials, including at least 3 phases of pre-registration trial and post marketing surveillance. Off-label use means that the use lacks the same assurances of safety and efficacy as an approved indication. The effects of off-label drug use on patients' health are highly uncertain. With regard to the analysis of Knight Ridder Newspapers in 2003, it was estimated that 115 million off-label prescriptions were written in 2002. Based on the FDA's data, at least an estimated 8,000 patients became seriously ill in the year following the taking of off-label drugs[2].

Clinical trial shall be in good practice and proper pharmacovigilance

The industry agreed that the Hospital Authority (HA) should further observe the developments of scientific evidence based on findings from large-scale randomized controlled studies conducted overseas, and it is encouraging to see the determination of the HA to support clinical trials in Hong Kong. However, proper pharmacovigilance and good clinical trial practice shall be observed when conducting the clinical trials. Patients should have the right to fully understand the risk involved and have the autonomy to decided whether to participate in the clinical trials or not.

Drug listing system be fair and transparent

Drug listing evaluation has to be fair and transparent. Due to the fact that the clinical trial will be done by the HA, the assessment body for the drug listing, should comprise experts within the HA system, as well as those independent from the HA system, with decision factors to be transparent to the public. During the process, scientific research

[1] Such as in UK, the General Medical Council provides detailed guidelines on Good Practice in Prescribing Medicines for doctors. http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp

[2] With regard to Knight Rider Newspapers' analysis in 2003, in the year of 2002, 115million of off-label use prescription were written. Based on the FDA data, the Knight Ridder also estimated that at least 8,000 of patients became seriously ill after taking some of drugs off-label. Alison Young and Chris Adams, "Off-label Drugs Can Do Damage"' Knight Ridder Newspapers, 11/03

findings from both overseas and local studies should be considered to assess the safety and efficacy data, and patients' safety shall be the prioritized concern, and not cost effectiveness.

In conclusion, medicines can only be used in accordance with the approved indications, and in respect of regulatory criteria related to quality, safety and efficacy for which the medicine receives marketing authorization. Supporting off-label use as clinical guidelines, systematically, without the context of individual patients' medical needs, risks jeopardizing patient safety, and undermines the authority of the medicines regulatory body whose primary mission is to protect patients. The industry does not think it is something that we should encourage or condone, not to mention the legal liability of off-label use, and the remedy for patients is a debatable topic in various countries[3]. We hope that doctors and health service providers shall consider well before off-label use of medicine.

[3] For example in Taiwan, according to Article 13 of the Drug Hazard Relief Act, an application for drug relief cannot be made in the following situations:
g. Harm caused by the use of test drugs.
h. The drug has not been used according to the indications and efficacy as shown on the drug permit.