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**CUHK Launches Pioneering Bioequivalence Studies Programme to Improve Generic Drug's Quality**

Many drugs are often made and marketed by more than one pharmaceutical manufacturer resulting in a large range of drug brands all claiming to contain the same amount of active drug. Although manufacturers may state that various brands of a medicine contain the same amount of active drug, it has been shown that this is not always the case. Such misleading claims can lead to treatment failures and toxicity. It is essential for physicians, pharmacists and others who prescribe, dispense or purchase drugs to be able to select products that have an equivalent therapeutic effect.

Bioavailability is a measure of both the rate and extent of the active drug that reaches the general circulation. Bioequivalence studies are performed to check both that different brands contain the amount of drug stated by the manufacturer and that the drug is in such a form as to be adequately and consistently absorbed and distributed around the body by the blood stream. To perform such tests, human volunteers are required. In many countries including the U.S.A. and the U.K., demonstration of bioequivalency between generic products and the original patent product is required by the pharmaceutical products registration approving authority (e.g. the Food & Drug Authority of the US).

In approving a drug product for marketing, the authority must ensure that the drug product is safe and effective. Moreover, the drug product must meet all applicable standards of identity, strength, quality and purity. To ensure these standards are met, bioavailability studies and bioequivalency data are required for all drug products. Once the brands are demonstrated to be bioequivalent, their efficacy is assumed to be similar.

Over the last few decades, the pharmaceutical industry in Hong Kong has rapidly grown to keep pace with the Hong Kong market. Many local companies produce formulations of drugs which were established in clinical practice under another brand name. Unfortunately, doubts have arisen regarding the quality of some of the local formulations. While these doubts may be unfounded, the credibility of the local industry has inevitably been questioned. Thus, independent evaluation of the bioavailability of the local formulations in comparison with their respective internationally established competitor brands is essential to maintain the credibility of the local pharmaceutical industry and enable our industry to compete effectively in the international arena. Locally, generic pharmaceutical products are used to a large extent by both private medical practitioners, hospitals and government clinics. It is essential to ensure that all patients are treated by effective yet economic medications.

Bioequivalence studies on some local generic products have already been performed, for the first time in Hong Kong, at the Prince of Wales Hospital by the Departments of Clinical Pharmacology and Pharmacy of The Chinese University of Hong Kong. There is enthusiastic support from The Chemical & Pharmaceutical Industries Council of The Federation of Hong Kong Industries and a generous foundation donation of $500,000 has been given by Pharmakon International Laboratory Limited for the establishment of the Bioequivalence Studies Programme.

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