# First China and Asia-Pacific Symposium on 'Technical Requirements for Approval and Registration of Pharmaceutical Products in China and Asia-Pacific Region'

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On 1l–13 January 1998, the First China and Asia-Pacific Symposium on 'Technical Requirements for Approval and Registration of Pharmaceutical Products in China and Asia-Pacific Regions' was held in the New Wing of the Hong Kong Convention and Exhibition Centre, the same site where festivities for the 1 July 1997 Hand-over were held. In attendance were approximately 160 local/foreign academics, government officials, pharmaceutical companies from Asia-Pacific, Europe and the United States, in addition to a variety of other representatives who share the world's interest in the potential of the Chinese market. The symposium was a true reflection of world players coming together for a common cause.

The meeting was co-organized by: several departments of the Ministry of Health (MOH), PRC (International Health Exchange Center, Bureau of Drug Administration, Center for Drug Evaluation); the Hong Kong SAR Government Industry Department, the Hong Kong University of Science and Technology (Biotechnology Research Institute, Drug Delivery Technology Center, TCM Safety Information Center); and the North American Medical Association Foundation, Hong Kong. Due to the overall effect of China's open policy coupled with the sustained economic growth of the Asia-Pacific region, stringent drug controls are needed to insure that the highest standards of safety are met by incoming products. The goal of the symposium was to provide for the development of comprehensive, updated information concerning technical requirements for drug registration. It is imperative for pharmaceutical companies to obtain current, accurate data regarding the products they distribute. The symposium provided an invaluable opportunity for those in attendance to establish regional networks, exchange information and thus to further the development of the pharmaceutical industry in China.

Within the two days of the symposium, various aspects of drug registration in China as well as the rest of the world were discussed. Nine speakers from China gave thorough coverage of their regulations — topics which included: the basic organizational structure and administration of the Bureau of Drug Administration of the MOH, drug importation administration in China, and the procedures and precautions in new drug evaluation. Those who spoke on behalf of other countries touched on the topics of: drug regulations in South America, Japan, Canada, the European Union, India; what drives the need for change in regulations; new registration systems being implemented, patents, and pre-clinical toxicological research for new medicine, amongst a few other topics that helped frame and develop interaction between speakers and audience participants.

The symposium program commenced with Professor Shao Ming-Li (Director of the Bureau of Drug Administration) giving a detailed description of the organizational structure and administrative regulations of the bureau, which highlighted the procedures that needed to be taken to obtain a successful application. Professor Shao included in his talk: administration of the domestic new drug evaluation, clinical trial administration, and the administration of the drug manufacturing plants. Mr. Ding Jian-Hau from the Bureau of Drug Administration, MOH, provided the audience with the importance of the Drug Administration Law of the People's Republic of China. In order to

ensure the quality of imported drugs, the MOH must enforce the regulations pertaining to the provision of information on product packaging outlining the contents. This aspect of drug regulation is important in the prevention of fake products, products that did not pass the control test, smuggling, products with false test reports or registration certificates from finding their way into the drug market. Furthering this talk was Professor Wang Zi-Hou (director of the Drug Evaluation Center, MOH), who provided insight on the application procedures and precautions involved in the drug registration process. In addition to the many talks given by the various attendants on regulations, policies and new developments in other areas of importance, the purpose of the symposium was to provide a forum for international discussion and exchange of information. Additional consultations were held in the morning of 13 April, where experts, speakers, and participants met for individual consultations. These sessions were aimed at allowing those with personal and company concerns with respect to China to receive special care and consideration on these matters. The expertise of the MOH would otherwise not be as accessible.

Concluding remarks reinstating the symposium's importance were given by Professor Zhao Tong-Bin, director of the International Health Exchange Center. Representatives from all over the world gathered at the First China & Asia-Pacific Symposium on 'Technical Requirements for Approval & Registration of Pharmaceutical Products in China & Asia-Pacific Regions' to exchange ideas, attempt to alleviate concerns and develop new thoughts. Opportunities such as this are the basis upon which future global development in the pharmaceutical industry as well as biotechnology will be rooted. There is a need for support and commitment to the development of networks of understanding and progress globally — people must involve themselves and continue to look ahead to the future. Opportunities such as this symposium must continue to be available.

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The organizers, advisors and speakers who attended the symposium banquet.