



**1ST ASIAN HARMONIZATION WORKING PARTY (AHWP)
TECHNICAL COMMITTEE MEETING AND WORKSHOP 2001
Berita Ubat-Ubatan December 2001**

The 1st Asian Harmonization Working Party (AHWP) Technical Committee (TC) Meeting and Workshop was held on 6th to 7th September 2001 at Subang Sheraton, in Kuala Lumpur, Malaysia. The meeting and workshop was co-hosted by the Ministry of Health Malaysia and the Association of Malaysian Medical Industries (AMMI).

Approximately 60 representatives from nine (9) participating Asian economies namely Chinese Taipei, Hong Kong China, Japan, Korea, Malaysia, Philippines, People's Republic of China, Singapore and Thailand attended the two-day event. Resource experts from Australia and United States of America (USA) which included Ms Rita Maclachlan, Chair of the Global Harmonization Task Force (GHTF), Mr Michael Gropp, member of GHTF Steering Committee, Ms Christine Nelson and Ms Judy Strojny, both from the US Food and Drug Administration (FDA) were invited as speakers and workshop co-ordinators.

In his welcoming address, Dr Clarence Tan, Chair of AHWP thanked Malaysia for kindly hosting this first AHWP Technical Committee Meeting and Workshop 2001 and commended the Organizing Committee for their efforts and initiatives. He expressed his utmost appreciation to the Global Harmonization Task Force (GHTF) for their continued strong support, collaboration and recognition, which have contributed much to the progress and success of AHWP. He said that AHWP is strongly committed to communicating and cascading the GHTF process to Asia.

Mr Mohd Zin Che Awang, Director of Pharmaceutical Services, Ministry of Health Malaysia, in his opening message, was impressed with the excellent communication and close international co-operation amongst member Asian economies, working in partnership towards development of a globally harmonized regulatory system for medical devices. He informed that Malaysia, like many other economies in the region, is currently developing a systematic regulatory framework for medical devices. Malaysia's involvement in AHWP and participation in GHTF have proven beneficial, enabling exchange of ideas and information towards formulating a suitable regulatory approach based on international harmonized concepts and principles.

It was heartening to note that there was active interaction and communication amongst participants and presenters throughout the training workshop, making the two-day get-together interesting and enjoyable. The overwhelming participation reflects enthusiasm and commitment of member economies to gain better understanding, to share ideas and experience, to establish networking, and to keep abreast of latest information on globalized approach of medical device regulatory practices.

The success of this 1st AHWP Technical Committee Meeting and Workshop 2001 serves as a stepping stone towards forging strategic regional partnership for mutual benefits, facilitating regulatory processes, eliminating technical and economic barriers, hence promoting timely international access of wide-ranging medical devices. Despite challenges ahead, with technical support from GHTF and firm commitment advocated by member Asian economies, the Technical Committee will strengthen its role to achieve the desired goals of AHWP towards the development and harmonization of medical devices regulation in Asia.

Realizing the growing need and benefits of global harmonization, as players and partners in healthcare, regulatory agencies, conformity assessment bodies, industry, consumer and trade organizations have a shared responsibility of ensuring quality, safety and effective performance of medical devices to protect public health.