

Regulators' Forum

In association with the World Self-Medication Industry

5th Asia Pacific Regional Conference

Tokyo Declaration 2002

A Shared Vision

On the 15th November 2002 a Regional Regulators' Forum was held in Tokyo, Japan in association with the World Self-Medication Industry (WSMI) 5th Asia Pacific Regional conference, hosted by the Proprietary Association of Japan. The Tokyo Forum was convened by the Ministry of Health, Labour and Welfare (MHLW). The Tokyo Forum follows the successful Regulators' Forum held in Sydney in 2000, hosted by the Australian Therapeutic Goods Administration. Participants at the Forum encouraged close cooperation and collaboration in the regulation of medicines in the Asia Pacific Region. This builds on the Sydney 2000 Declaration that signalled a new significance to regional cooperation and set the scene for a more strategic approach in this area.

The Tokyo Forum was chaired by MHLW and co-chaired by TGA and it brought together regulators from eleven countries in the Asia Pacific region. The following countries were represented: Australia, China, Fiji, Indonesia, Japan, Korea, Malaysia, Myanmar, Nepal, Singapore and Thailand. Also present were representatives of the European Commission, WHO, WSMI and a consumer advocate.

Representatives of the participating countries reported on notable events in therapeutic goods regulation and on progress towards implementing the recommendations of the Sydney 2000 Declaration. The Forum generated interest among the international participants of the WSMI conference, and many were invited to observe the proceedings of the Forum.

The Forum recognized the common objectives and the mutual benefits in the enhancement of public health and safety through sharing information and collaborating on the regulation of medicines. It also signalled an intention to raise

awareness of the increasing role of self-medication in national health care policies, to encourage regional regulators to keep pace with pharmacological and pharmaceutical technologies and to foster community awareness of responsible self-medication.

A major contribution to the Forum was the discussion of the just-released Japanese MHLW's *Interim Report on the Role of Over-the-Counter (OTC) Medicines in Self-Medication*. The major theme of the interim report is to encourage OTC medicines, including traditional medicines, to be needed, trusted and used with confidence by consumers. The interim report recognizes the changing roles and expectations of OTC medicines, requirements for the appropriate use; the roles of industry, healthcare professionals and government; and sets new directions for the OTC sector in Japan.

A number of interesting contributions were made from various participating countries, as well as regional and international organizations. These included details of progress and advancements following from the Sydney 2000 Declaration as well as current issues related to health policy, and the regulation of non-prescription medicines by each of the respective regulatory authorities.

Key areas of interest and discussion included new technologies and the growing use within the region of the Internet technology. Through exchange and discussion on this issue it was recognized that the experience and thoughts of each of the participating countries demonstrated differing issues as well as benefits arising from Internet technology. It was noted that the Internet offers many benefits as well as raising many problems such as biased and/or misleading information and potential danger to consumers through the purchase of unlicensed, sub-standard or counterfeit medicines.

These issues and benefits reflected differences of geography, distribution channels and people's availability as well as accessibility to this newly developed technology. The Forum recognized that Internet technology is rapidly increasing its significance in our societies and regulatory sectors, in particular, are expected to develop appropriate measures to maximize its benefits, minimize associated risk and affect agreed controls. The need to develop appropriate standards for medicine information, was also recognized. Encouraging co-operative research may

contribute significantly to furthering this work by providing the necessary evidence base.

For these reasons the need for regular and continuing dialogue and sharing of experiences among regional regulators is paramount in meeting the principle obligation of protecting and promoting public health. The outcome of this dialogue and sharing should be pursued in subsequent fora and the development of broad collaborative guidelines should be encouraged. It was recognized that this should assist regulators to meet their primary role of protection and promotion of people's health. It was agreed that the regulatory agencies would nominate a point of contact for issues associated with the Internet. It was recognised that this would facilitate governments becoming more proactive in this area.

The Tokyo Regulators' Forum also canvassed other broad areas of interest, including the need to harmonise terminology, and that a collaborative, on-going work program would be progressed and reported on at the next Forum, planned for 2003.

The outcomes of the Tokyo Regulators' Forum herald an increased level of cooperation in the region, providing a firm basis for each country to actively participate in and influence harmonization initiatives within and beyond the region.

The Ministry of Health, Labour and Welfare of Japan and the Australian Therapeutic Goods Administration were invited to assist further developments related to issues discussed during the forum, particularly relating to the Internet, over the next couple of years. This was welcomed by all participants.

Tatsuo Kurokawa PhD
Director, Safety Division
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
Japan
Chair

Graham Peachey
Director, Trans-Tasman Group
Therapeutic Goods Administration
Australia
Co-Chair

Tokyo Regulators' Forum
15 November 2002