

GLOBAL HARMONIZATION TASK FORCE

Working Towards Harmonization in Medical Device Regulation

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ARTICLE FOR REGULATORY AFFAIRS FOCUS

May 2001

Australia Chairs the Global Harmonization Task Force (GHTF)

In January 2001, Australia (represented by the Therapeutic Goods Administration, TGA) assumed the Chair of the Global Harmonisation Task Force (GHTF) for the next 18 months.

The GHTF comprises five founding members - Canada, USA (North America), European Union (Europe), Australia and Japan (Asia-Pacific). The Chair and secretariat rotate among the three geographical regions every three years. Australia and Japan (representing the Asia-Pacific region) have responsibility from 1 January 2001 - 31 December 2003. The national regulatory authority holds the position of GHTF Chair and a national medical device industry association undertakes the Vice Chair's role.

The GHTF was conceived in 1992 in an effort to respond to the growing need for international harmonisation in the regulation of medical devices. The GHTF provides a forum in which official representatives of national regulatory bodies, working with medical device manufacturers and other organisations possessing relevant expertise, can harmonise global approaches to regulating the safety, clinical performance and quality of medical devices in ways that protect public health, promote technological innovation and facilitate international trade. The purpose of the GHTF is to encourage convergence in regulatory practices relating to these issues.

The primary manner in which the GHTF achieves its purpose is via the publication and dissemination of harmonised guidance documents on basic regulatory practices. Once endorsed as Final Documents by the GHTF, they can then be adopted/implemented by member national control authorities. To date, the GHTF has approved 15 final Guidance Documents and national regulatory authorities are encouraged to adopt these, where appropriate, into their medical device regulatory systems.

In September 2000, the GHTF established a Steering Committee, responsible for management oversight and policy setting for the organisation. The Steering Committee comprises a maximum of 24 Members, consisting of 4 government regulators and 4 medical device industry representatives from the three major geographic regions.

The GHTF Chair, Rita Maclachlan (Director of the TGA's Conformity Assessment Branch) hosted the inaugural meeting of the GHTF Steering Committee in Sydney from 28 February - 2 March 2001. The Committee was addressed by Senator the Hon Grant Tambling, Parliamentary Secretary to Australia's Federal Minister for Health and Aged Care.

Senator Tambling's responsibilities include overseeing the regulation of medical devices, medicines and food in Australia. During his address to the Meeting, Senator Tambling gave the commitment that the Australian Government is 'locked into' the GHTF processes and is very keen to have worldwide regulatory differences identified in order to minimise duplication of effort and resources.

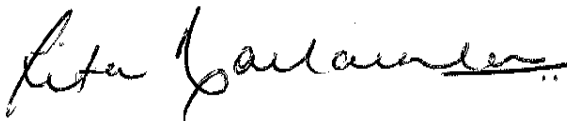
During the meeting, the major issues considered by the Steering Committee were -

- A Strategic Review of the organisation and development of a Strategic Plan for the next 5 years;
- The review of several GHTF regulatory guidance documents developed by the GHTF Study Groups;
- Founding Members' progress reports on the adoption of GHTF guidance documents into their national systems for medical devices; and
- Planning for the 9th GHTF Conference to be hosted by Australia in Barcelona, Spain from 11-16 October 2001.

The Steering Committee will further progress the outcomes achieved in Sydney at its second meeting in Brussels, Belgium from 12-13 June 2001.

GHTF Conferences are held at least every 18 months to ensure regular progress is made on GHTF activities. The Conference program includes meetings of the individual Study Groups, a Plenary Session, Area (Regional) Meetings and Special Topic Presentations. The purpose of the Plenary Session is to inform participants of ongoing GHTF activities and to serve as a forum for participants to discuss pertinent issues or present material that may be of interest to their international colleagues.

Further information on the GHTF (including the 9th Conference Program) may be obtained from the website - www.gh tf.org



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22 May 2001

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