

IMDRF

International Medical Device Regulators Forum

Media Statement

Successful Launch to the IMDRF

Good progress and a commitment to advancing regulatory convergence and public health marked the inaugural meeting of the International Medical Device Regulators Forum (IMDRF), held in Singapore from 28 February to 1 March 2012. Regulators from Australia, Brazil, Canada, Europe, Japan, and the United States of America were joined by regulatory observers from China and the Russian Federation and by the World Health Organization for the purpose of putting the new Forum into operation and planning the transition of several key items from the Global Harmonization Task Force.

Notable outcomes of the meeting included confirmation of initial membership, the adoption of a Terms of Reference and robust workplan, agreement on the elements of an operating procedures document and a constructive dialogue with stakeholders.

The Forum's chair, Dr. Larry Kelly, conveyed a number of key messages to the approximately 100 participants in the public session on day two of the Forum, including the value of GHTF documents, the importance of establishing strong partnerships with affiliate organizations, a commitment to transparency and the vital role industry and other vested stakeholders will play in contributing to the development of new work items and the overall success of the new Forum. Dr. Kelly noted that the Terms of Reference foresees the expansion of the Management Committee to other regulators, with criteria to be established in operating procedures.

The chair ended the public session by thanking participants for their comments and underscoring the Management Committee's commitment to achieving concrete deliverables within a 18 month period on priority work items with a view to progressing regulatory convergence and to promoting access to safe and effective medical devices globally.

The appended Outcomes Statement provides a more detailed description of the inaugural meeting, including adopted new work items.

The next meeting of IMDRF will take place in Sydney, Australia on 25 to 27 September 2012. The Open Stakeholder Session will be held on 26 September.

For further information, please contact imdrf.secretariat@tga.gov.au.

Singapore

March 2012