7/18/07

DRAFT Agenda - ASEAN Enhanced Partnership
Medical Devices Capacity Building Workshop
Hanoi, Viet Nam, July 30 – 31, 2007

Sunday, July 29

6:00 – 7:30 pm **Welcome Reception**

Monday, July 30

8:30 - 9:15 **Introductory Session**

ASEAN Secretariat Speaker, Ms. Sylvia Laksmi Sardy, Standards and Conformance Unit, Bureau of Economic Integration and Finance

Host Viet Nam Government Speakers, Vice Minister of Health Dr. Prof. Nguyen Thi Kim Tien and Mr. Duong Van Tinh, Director General of Medical Device Department, Ministry of Health

ASEAN Medical Device Harmonization Activities, Dr. M.S. Pillay, Ministry of Health, Malaysia; Chair of ASEAN ACCSQ Medical Device Product Working Group, and Chair of the Asian Harmonization Working Party (AHWP)

Speaker from U.S. Embassy, Donald Nay, Senior Commercial Officer

Welcome from GHTF Chair Larry Kessler, Director, Office of Science and Engineering Laboratories, CDRH, U.S. FDA

Summary of Workshop Agenda – Stephen Berlinguette, International Trade Specialist, Office of the Pacific Basin, U.S. Department of Commerce

9:30 - 5:15 **Theme #1 – Building a Regulatory Infrastructure to Promote the Access and Use of Medical Technology**

9:30 – 10:00 The Need for Flexible Medical Device Regulatory Regimes to Address the Changing Nature of Medical Technologies; Janet Trunzo, Executive Vice President Technology and Regulatory Affairs, AdvaMed, and Vice Chair of GHTF

10:00 - 10:30 Differences Between Pharmaceuticals and Medical Devices; Michael Gropp, Vice President, Global Regulatory Strategy, Medtronic, representing AdvaMed and Eucomed

10:30 - 10:45 Coffee Break

10:45 - 12:15 Panel Discussion: Case Studies - Establishing Flexible Regulatory Regimes

Moderator: Jeffrey Gren, Director, Office of Health and Consumer Goods, U.S. Department of Commerce
Panelists:
1) Dr. M.S. Pillay, Malaysia;
2) Mr. Yew Sin Wong, Singapore;
3) Dr. Monica M. H. Wong , Hong Kong;
4) Michael Flood, Program Manager, Device Registration and Assessment, Australia TGA;
5) Laurent Selles, Deputy Head of Cosmetics and Medical Devices Unit, Enterprise and Industry Directorate-General, European Commission

12:15 - 12:30 Group Picture

12:30 - 1:30 Lunch

1:30 - 3:00 Panel Discussion - The Role of Accredited Persons/Conformity Assessment Bodies in the Regulatory Process and Establishing Confidence in Performance of Accredited Persons/Conformity Assessment Bodies

Moderator: Larry Kessler, U.S. FDA
Panelists:
1) Laurent Selles, European Commission;
2) Alfred Kwek, Regulatory Scientist and Manager, Health Sciences Authority, Singapore;
3) Yuwadee Patanawong - Thailand (invited);
4) Hwee Beng Wang – Malaysia; and
5) Paul Chan, General Manager Medical Business Unit, Asia Pacific UL International Limited

3:00 – 3:30 Challenges to Regulators Due to Changing Medical Device Technologies, Larry Kessler, U.S. FDA

3:30 - 3:45 Coffee Break

3:45 - 5:15 Panel Discussion - Addressing Medical Needs in ASEAN Countries Related to Aging Populations and the Growing Prevalence of Chronic Diseases and How these Trends will Drive the use of Medical Technologies

Moderator: Seow-Ping Goh - Johnson & Johnson Vietnam
Panelists:
1) Miang Chadaporn Tanakasemsub, Regional Regulatory Affairs Director, Asia Pacific, Bausch and Lomb
2) Ashoke Bhattacharjya, PhD, Executive Director Health Outcomes and Policy, Johnson & Johnson Medical Asia Pacific
3) Paul VanOstenberg, Joint Commission International, Managing Director for the Asia-Pacific Office (Singapore)

6:30 - 8:00 Welcome Reception

Tuesday, July 31

8:30 – 12:00 **Theme #2 - How to Grow a Medical Technology Sector at the National and Regional ASEAN Levels**

8:30 - 10:00 Panel Discussion – How Multinational Medical Device Firms Make Foreign Investment Decisions

Moderator: Janet Trunzo, AdvaMed
Panelists:
1) Michael Gropp, Medtronic;
2) Brad Hossack, Boston Scientific; and
3) Ashoke Bhattacarjya, Johnson and Johnson

10:00 - 10:15 Coffee Break

10:15 - 12:00 Panel Discussion – Case Studies – Successful Examples of Growing a Medical Technology Sector

Moderator: Brad Hossack, Boston Scientific (confirmed)
Panelists:
1) United States – Jeffrey Gren, U.S. Department of Commerce;
2) Ireland - Brad Hossack, Boston Scientific;
3) Europe - Laurent Selles, European Commission;
4) Australia, Michael Flood, Australia TGA; and
5) Singapore, Vincent Cheung, Edwards Lifesciences

12:00 - 1:00 Lunch

1:00 - 3:00 **Theme #3 - Possible Future Areas for Cooperation Under ASEAN Enhanced Partnership Relating to Medical Devices**

1:00 - 3:00 Panel Discussion - Possible Future Areas for Cooperation Under ASEAN Enhanced Partnership Relating to Medical Devices

Moderator: Michael Gropp, Vice President, Global Regulatory Strategy, Medtronic, Representing AdvaMed and Eucomed
Presentations:
1) Technology to Diagnose and Treat Primary Diseases/Infections, Pandemics, and Chronic Illness - Miang Chadaporn Tanakasemsub, Bausch and Lomb;
2) The Needs of Healthcare Providers, Seow-Ping Goh - Johnson & Johnson, Vietnam;
3) Health Insurance - Ashoke Bhattacharjya, PhD, Executive Director Health Outcomes and Policy, Johnson & Johnson Medical Asia Pacific; and
4) Integration of Information Technology, Quality and Patient Safety - Paul VanOstenberg, Joint Commission International, Managing Director for the Asia-Pacific Office, Singapore

3:30 - 3:45 Coffee Break

3:45 – 5:00 **Theme #4 – Pulling it Together and Conclusion**

3:45 - 5:00 Wrap-Up, Conclusion and Future Activities

Moderators:
Jeffrey Gren, U.S. Department of Commerce,
and
Dr. M.S. Pillay, Ministry of Health, Malaysia

Summary of Workshop

- Development of Follow-up Activities and Next Steps
- How Medical Technology Activities in the ASEAN Region Relates to Activities in Other Regions
- Topics and Timing for Future Workshops

5:00 Adjournment