Summary of Joint Commission on Commerce and Trade (JCCT)
Medical Devices Task Force Meeting
April 11 - 12, 2007

Overview

The U.S. - China Joint Commission on Commerce and Trade (JCCT) Medical Devices Task Force meeting was held in Washington, DC on April 11 - 12, 2007 as part of the JCCT Pharmaceuticals and Medical Devices Subgroup meeting.

Opening Session

The Medical Device Task Force was Co-chaired by Ms. Gao Jie, Director General, SFDA Department of Medical Device Registration, and Mr. Jay Biggs, Senior Analyst, Office of Health and Consumer Goods, U.S. Department of Commerce.

The U.S. industry delegation consisted of:
1. Nancy Travis, Vice President, Global Strategy (Asia), Advanced Medical Technology Association (AdvaMed)
2. Ed Woo, Medtronic
3. Carolyn Albertson, Director Int'l Regulatory Affairs and Affiliate Compliance, Abbott Labs
4. Lindsay Tao, Johnson & Johnson
5. Ellen Jiang, Regulatory Affairs BD China
6. Peng Cui, Manager, Regulatory Affairs, Philips Medical Systems
7. Stephen Vastagh, Director, International and Industry Programs, Medical Imaging & Technology Alliance, MITA
8. Ann Graves, Director of Regulatory Affairs, St. Jude Medical, Cardiovascular Division
9. Susan Gamble, Edwards Lifesciences

The U.S. government delegation consisted of:
1. Jay Biggs, Senior Analyst, Office of Health and Consumer Goods, U.S. Department of Commerce
2. John Stigi, Director, Division of Small Manufacturers, International and Consumer Assistance, Center for Device and Radiological Health, U.S. Food and Drug Administration (FDA)
3. Dr. Chiu Lin, Director, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, FDA
4. Stephen P. Rhodes, Director of Investigational Device Exemptions (IDE) and Humanitarian Device Exemptions (HDE) Programs, FDA
5. Anthony Cino, Trade Analyst, Office of Chinese Economic Area, U.S. Department of Commerce

The Chinese government delegation consisted of:
1. Ms. Gao Jie, Division Director, Department of Medical Device Registration, State Food and Drug Administration (SFDA)
2. Ms. Wu Liya, Division Director, Department of Policy and Regulations, SFDA

3. Mr. Wang Xiangyu, Senior Staff Member, Department of International Cooperation, SFDA

The Medical Device Task Force focused on seven key issues:
1) Clinical Trials for Medical Devices
2) In Vitro Diagnostic Regulations
3) Updates on SFDA Draft Regulations for Combination Products and Adverse Event Reporting
4) Registration and Re-registration Requirements
5) Regulation of Products With Bovine Materials
6) Medical Device Standards Issues
7) Upcoming JCCT Activities

Clinical Trials for Medical Devices

The week prior to the JCCT Medical Device Task Force meeting, SFDA asked if the U.S. side could provide an overview of how the U.S. Food and Drug Administration (U.S. FDA) regulates clinical trials for medical devices. Stephen Rhodes, the Director of Investigational Device Exemptions and Humanitarian Device Exemptions Programs at the U.S. FDA, made an in-depth presentation on this subject. Mr. Rhodes discussed U.S. medical device classification, investigational device exemptions, the responsibilities of the clinical trial investigators, the sponsors, and the Institutional Review Board. Mr. Rhodes also discussed the regulatory idea of "Least Burdensome Concept," and how the U.S. FDA applied this to the regulation of clinical trials.

SFDA indicated that this was a very timely issue, as SFDA was beginning the process of drafting their own regulations on clinical trials for medical devices. SFDA requested that U.S. FDA provide training for a single SFDA staff member on how the U.S. FDA handles medical device clinical trials. Mr. John Stigi of the U.S. FDA stated that he would try to organize this training, but that it would be conditioned upon the availability of U.S. government and industry funding. The possibility of having part of this training take place at one or more manufacturing facilities was also discussed. This proposal was included in the Subgroup Work Plan, conditional upon the availability of funding.

In Vitro Diagnostic Regulations

The U.S. delegation asked for information on SFDA's *in vitro* diagnostic (IVDs) regulations, which were released on April 3. SFDA responded that these regulations will go into effect in June 2007. SFDA also informed the U.S. delegation that blood screening and radiological markers will continue to be regulated as pharmaceuticals, but that all other IVDs will be regulated as medical devices.

In response to a question about type testing, SFDA confirmed that type testing would continue to be needed for Class II and Class III IVDs. SFDA also clarified that for Class II and Class III IVDs, instead of clinical trials, manufacturers could provide clinical data that could come from the manufacturers' own labs, as long as the data samples came from clinical trials. In response to a question about whether or not the proposed naming

conventions for IVDs had changed from the previous draft (September 2006), SFDA responded that there had not been any changes.

Updates on Draft Regulations for Combination Products and Adverse Event Reporting

In response to a question about whether or not there had been any recent updates to SFDA draft regulations on combination products, Ms. Gao Jie indicated that the September 30, 2006 Regulation 509 was the final version of the regulation, and that this document is on the SFDA website. Ms. Gao also mention that combination products is one of the issues that SFDA would like to include in the proposed medical devices seminar later during.

SFDA's response to the question about updates for Adverse Event reporting was that the January 2004 version of the regulation was the most up-to-date. Ms. Gao mentioned that Adverse Event reporting was on the SFDA legislative Work Plan for this year. SFDA was conducting a number of pilot programs on Adverse Event Reporting, and that these programs would provide information that will be taken into account as SFDA revises these regulations. Ms. Wu Liya indicated that SFDA's Medical Device Division has finished writing the draft Adverse Event Reporting regulations, and that they are currently being reviewed by SFDA's Department of Policy and Regulations for promulgation later during 2007.

Registration and Re-registration Requirements

Prior to the JCCT Subgroup meeting, the U.S. side emphasized that this was a critical issue for the medical device sector. SFDA indicated that they realized the importance of addressing the backlog of registration and re-registration issues, and Ms. Gao stated that she had endured many sleepless nights trying to decide how best to proceed. According to Ms. Gao, revision of the registration regulations is on SFDA's legislative plan for the coming year, and that revisions to medical device regulations began last year, and should be revised by the end of next year (2008).

Ms. Gao also noted that SFDA is working on a number of revisions to the administrative guidelines for registration, and that a draft would be available for comment by the end of May, with the final regulations being completed by the end of 2007. She explained that while these revisions could not go beyond the scope of the existing regulations, SFDA could simplify the administrative guidelines on how those regulations are implemented.

According to Ms. Gao, SFDA is looking at a number of ways of addressing the registration backlog problem. Options that were being discussed within SFDA included:

- Extending the review period for Class III products to 180 days
- Extending the registration license validity period from four to five years
- Exempting some product re-registrations from type-testing
- Reducing the requirements for re-registration compared with new registrations
- Reducing the requirements for re-registration due to minor changes to a product's design or manufacture (including manufacturing site changes) compared with re-registration to extend product licenses

During the Task Force meeting, SFDA made a significant announcement on the re-registration issue, which was finalized prior to the JCCT Subgroup meeting. SFDA agreed to extend the period of validity of current license for medical devices being re-registered, until the new administrative guidelines for registration are approved provided that the request for re-registration was submitted in a timely fashion; she also explained the process of documenting timeliness (Document #63.). U.S. participants agreed that this was a major change that would help address the re-registration backlog problem and the issues related to re-registering products with minor changes.

Ms. Gao also noted that, comprehensive revisions to medical device regulations (MDR), covering research and development, manufacturing, distribution, etc. began last year, and should be completed by the end of next year (2008); it is on SFDA's legislative plan for the coming year. After this comprehensive revision of the MDRs the product registration regulations will again be updated.

Regulation of Products with Bovine Materials

Dr. Chiu Lin, the Director of U.S. FDA's Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, gave a detailed presentation on U.S. FDA's regulations to control devices containing bovine materials. This presentation detailed the reasoning behind U.S. FDA's move from banning products from countries where BSE was present, to the current risk based method of addressing the types of tissues used in a medical device. U.S. industry representatives also made a presentation on some of the documentation that they receive from U.S. FDA and USDA and the level of risk protection required in order to receive these documents.

The SFDA delegation asked a number of questions about the science behind U.S. FDA's risk based approach, but there was no discussion of how this would impact SFDA's current delay in implementing the ban on medical devices containing bovine materials. U.S. DOC has proposed the week of July 23, 2007 for the industry-led and U.S. FDA led seminars that were included in the Work Plan.

Medical Device Standards Issues

AdvaMed and MITA-NEMA presented SFDA with the draft agenda for a medical device standards seminar that the associations are jointly organizing for June 4 - 6, 2007 in Beijing. SFDA responded that they did not want to include this issue on the JCCT Work Plan, but Ms. Gao would share the agenda with SFDA's Standards Division staff.

Agent Registration and Responsibilities

The identity, roles and responsibilities of agents will be clarified and revised. The goal is to focus all the responsibilities for registration, adverse event reporting, etc. on one entity, either the China office of the foreign manufacturer or its appointed agent.

Accomplishments and Next Steps

This Task Force meeting was very successful in advancing the Commerce's healthcare agenda. Accomplishments included:

- Answered questions about key provisions of the draft In Vitro Diagnostics regulation;
- Announced major changes by SFDA to extend the period of validity of current licenses for medical devices being re-registered, until the new re-registration is approved. This will help address the re-registration backlog problem;
- Raised clinical trials for medical devices as an issue of interest for SFDA;
- Confirmed that adverse event reporting have been drafted and are currently being reviewed by SFDA Department of Policy and Regulations, and will likely be promulgated later this year.
- Confirmed that SFDA was still interested in learning more about how the U.S. FDA regulates combination products.

At the conclusion of the Subgroup meeting, the 2007 Subgroup Work Plan was signed. Medical Device related activities in the Work Plan included:

- **Industry-led Seminar on International BSE Safety Regulation Approaches** - July 2007 in Beijing
- **U.S. FDA Led Seminar on Regulatory Approaches to Medical Devices Containing Bovine Materials** - July 2007 in Beijing
- **Medical Devices Task Force Meeting** - September 2007 in Beijing
- **Medical Devices Regulatory Seminar** - September 2007 in Beijing
- **Medical Devices Policy Mission** - September 2007 in Beijing, Shenyang, and Shanghai
- **Medical Device Clinical Trials Training** - Fall 2007 in Beijing (Note: due to resource constraints, the U.S. side proposed a half day workshop on this topic to be held in July 2007.
- **12th Annual JCCT Pharmaceuticals and Medical Devices Subgroup Meeting** - April 2008 in Beijing