

Summary of Joint Commission on Commerce and Trade (JCCT)
Medical Devices Task Force meeting
September 18, 2006

Overview

The U.S. – China Joint Commission on Commerce and Trade (JCCT) Medical Devices Task Force meeting was held in Beijing, China on September 18, 2006.

Opening Session

The Medical Device Task Force was Co-chaired by Mr. Wang Lanming, Deputy Director General, SFDA Department of Medical Devices, and by Mr. Jay Biggs, Senior Analyst, Office of Health and Consumer Goods, U.S. Department of Commerce.

The U.S. industry delegation consisted of:

1. Ed Woo - Medtronic
2. Susan Gamble - Edwards Lifescience
3. Michael Gropp - Abbott
4. Regina O'Meara - Beckman Coulter
5. Karen Long - Roche
6. Carolyn Albertson - Abbott
7. Roberta Lipson (morning session) and Jimmy Ip (afternoon session) – AmCham

The U.S. government delegation consisted of:

1. Jay Biggs - U.S. Department of Commerce
2. John Stigi - U.S. Food and Drug Administration
3. Anthony Cino - U.S. Department of Commerce
4. Richard Craig - U.S. Embassy
5. Shuyu Sun - U.S. Embassy

The Medical Device Task Force focused on five key issues:

- 1) Product Testing and Use of Standards
- 2) Registration and Re-registration Requirements
- 3) In Vitro Diagnostic Draft Regulations
- 4) Regulatory Updates
- 5) Upcoming JCCT Activities

Product Testing and Use of Standards

The U.S. delegation began by noting the voluntary character of international standards, and difficulties inherent with implementing mandatory national standards, as China is trying to do. The U.S. delegation raised two examples of how mandatory SFDA standards were causing delays in the registration process for medical devices. U.S. manufacturers, explained how the implementation of new a SFDA rule on electromedical devices now requires the full test report of all 110 tests under China's GB9706.1 regulation. This regulation is based upon an outdated version of IEC60601-1988. Most multinational medical device manufacturers are conducting tests in accordance with the

revised IEC standard, which are not being recognized by Chinese testing labs, due to a strict interpretation of the GB regulation.

The U.S. delegation asked SFDA to issue policy guideline for test labs that would allow data generated from previous standard to be used, to allow manufacturers to voluntarily select those parts of the standard that are applicable, and show compliance to only those parts which apply to the product. The delegation noted that this approach was in line with GHTF guidance on standards.

SFDA's response was that they should have used the most up to date standard when drafting their GB standard. However, drafting these regulations takes time, and there is also a legal requirement that SFDA's standards be in line with the ; this takes time to draft and finalize. In the meantime, SFDA is still legally required to use the current standard. SFDA indicated that they would try to speed up the revision of GB9706, and mentioned that the Shanghai Evaluation Center had been tasked with drafting guidance documents that would address some of the concerns that industry raised. SFDA also noted that they did not have final authority to approve standards, final authority rests with the National Standardization Center. SFDA asked industry to summarize the differences between GB9706 and the newly revised IEC60601 in a clear table to help them gain support for updating the GB standard as soon as possible.

Biocompatibility Testing

The U.S. delegation also raised concerns about biocompatibility testing requirements for registration and re-registration. During the March 2006 Task Force meeting, the U.S. delegation noted that some of SFDA's evaluation centers were requesting certain biocompatibility tests be done locally, instead of accepting the ISO 10993 based test results submitted by manufacturers. At that time, the SFDA representative from the Medical Device Evaluation Center responded that it was still possible to accept data and test results from manufacturers in developed market, and that requiring companies to re-do biocompatibility testing was ineffective. The U.S. delegation noted that manufacturers were still being asked to do biocompatibility tests locally. The U.S. delegation also noted that U.S. industry was going to organize a workshop on this issue for SFDA later in the week in Jinan, China. SFDA indicated they would be sending a number of staff to this training event and also noted that SFDA was in the process of drafting guidance on how to review and accept biological evaluation rational instead of requiring biological testing. The U.S. delegation thanked SFDA for its willingness to participate in this workshop. The U.S. delegation also asked SFDA to consider:

- Exempting biocompatibility requirement for product renewal unless clear market experience demand otherwise;
- Issuing guidance on review and acceptance of biocompatibility evaluation rational instead of mandatory testing, (this is in line with international practice);
- Issuing guidance on the designation of the responsible party (namely the Evaluation Center vs. Test Labs) and their qualification to perform review and acceptance of biocompatibility evaluation rational;
- Organizing expert panels to provide recommendation that help standardize who the responsible party is for the biocompatibility reviews.

SFDA thanked the U.S. delegation for their proposals, and noted that among the regulatory issues that SFDA was considering revising during the coming year was how to handle registration, and whether or not re-registration was even necessary (NOTE: Ms. Gao mentioned that this had not been discussed among the SFDA participants at the Task Force Meeting). Ms. Gao also stated that this would mean that 'in the near future, your issues with biocompatibility will not be an issue under the new procedures.'

Ban on Importation of Medical Devices Containing Bovine Material

Mr. Biggs thanked SFDA for meeting with Mr. Wineland of the USTR on August 24, to discuss SFDA's new policy on medical equipment products that contain the tissues of bovine and sheep from countries and regions that have reported incidents of Bovine Spongiform Encephalopathy (BSE). The U.S. delegation expressed appreciation for the fact that IVD reagents are exempted from this ban, and that SFDA indicated an openness to evaluating these regulations on the basis of scientific fact. Susan Gamble of the U.S. delegation gave a brief presentation on how U.S. manufacturers address safety concerns for medical devices that contain bovine materials.

Following the presentation, Mr. Biggs noted that SFDA's new policy demands the immediate recall of products with bovine materials in 2007, and proposed a follow up meeting between SFDA and U.S. FDA staff to discuss how to regulate bovine and ovine products in a manner that allows safe products onto the market. John Stigi of the U.S. FDA indicated that the person responsible for BSE issues for the U.S. FDA is Dr. Chiu Lin, the Director of FDA's Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

SFDA responded that this discussion was more of an academic or technical discussion rather than a regulatory JCCT issue. She also noted that the new regulation (Announcement 407) was an attempt to provide some flexibility for bovine products, by NOT basing the classification final products, but by where source materials are coming from.

Registration and Re-registration Requirements

The U.S. delegation raised concerns about the recent slowdown in the registration and re-registration process, and new mandatory testing requirements. Roberta Lipson, Chair of the AmCham Medical Device Forum, presented the results of a survey of members regarding the length of registration delays, as well as the associated cause of the delay. AmCham received responses from 13 companies on 144 kinds of products. Of the delays noted, 68 were for initial registration, and the others were for re-registration. The reasons for the delays included:

- 17 delays due to testing
- 49 delays due to interpretation of GB 9706.1
- 36 delays due to problems accepting Biocompatibility test results
- 34 due to administrative process problems

SFDA responded that they were aware that this has been a long standing problem, and that the reasons were due to a combination of lack of staff, new standards/procedures, and improper filing of registration paperwork by manufacturers.

SFDA also stated that manufacturers should take advantage of the “Unit System” where only the most advanced model in a particular class of products needs to be tested. AmCham responded that the problem with this system is that the newest model of a product is usually the most advanced, so that manufacturers would still have to register new devices.

Re-registration

Mr. Biggs began the discussion of medical device re-registration requirements by mentioning that during the March 2006 Medical Device Task Force meeting, SFDA noted that one of the SFDA Medical Device Division’s goals for the year was to further strengthen SFDA’s quality systems regulations. A key aspect of these regulations that U.S. industry would like SFDA to address is a shift to greater reliance on quality systems to replace the need for extensive re-registration requirements. Mr. Biggs noted that allowing companies to use quality systems as an alternative to the costly re-registration process would be a strong incentive for domestic Chinese manufacturers to more quickly adopt quality systems, which would also allow SFDA staff to develop a comfort level in analyzing quality systems while Chinese manufacturers begin adopting this process.

Mr. Biggs also asked a follow-up to an April 05 Task Force discussion of exemptions to re-registration that are contained in Article 14 of Decree 16 “Measures for the Administration of Medical Device Registration.” Mr. Biggs noted that based on Article 14 of this measure, products could be exempted from re-registration if they met 5 criteria. Mr. Biggs asked if SFDA were actively granting waivers based upon Article 14 exemptions. SFDA’s response was that waivers were rarely granted, but that during the coming year and a half, Decree 16 will be revised. An amendment to Decree 16 is already in place and SFDA was already soliciting public comment. The SFDA delegation also mentioned that the amendment was rather comprehensive, and may include looking at utilizing post market surveillance [instead of re-registration]. SFDA also noted that the amendment will also re-evaluation the medical device registration process, but will have to take into consideration the need to have greater decentralization than in the U.S. system. John Stigi of the U.S. FDA suggested that while SFDA re-evaluates its registration requirements, that it give as high a priority as possible to implementing Quality Systems program.

SFDA agreed that Quality Systems and post market surveillance are the weak links in SFDA’s current regulatory scheme, and indicated that they would be working to issue the proposed regulations on these topics in the near future. SFDA also noted that although they would like to intensify the numbers of inspections of local and foreign manufacturers, SFDA lacked the resources to do so. SFDA also stated that the Quality Systems regulations had not been issued at a high enough level.

In Vitro Diagnostic Draft Regulations

The U.S. delegation raised concerns that SFDA's classification scheme and naming convention are not harmonized with other major countries.

In response to questions about the classification scheme, SFDA indicated that there would be three classes of IVD devices:

Class A

- antigen/antibody tests
- Diabetes tests
- Human Genes used for genetic testing
- Blood Typing/cross matching products
- Narcotics and Toxins test
- Targeting IVD

Class C

- Reference testing for clinical trials
- Reagents used for treating samples

Class B

- Products not covered under Class A or C

The issue of type-testing requirements for both Class II and Class III are not appropriate and should only be required for blood screening products. SFDA's response was that the current draft of the IVD regulations for blood screening and RIA products are still treated as pharmaceuticals, because these products were still under the purview of the Pharmaceutical Law. SFDA also mentioned that the need for type-testing is under internal discussion debate, and that in the case of IVD's type-testing may not be needed because IVDs do not have the same safety issues as other medical devices.

The U.S. delegation also raised a question about the requirements for qualifying reagents used in clinical trials. SFDA's response was that clinical trials are required for all Class A and Class B IVD devices based on the draft guidance. The difference is number of cases/ samples for each. SFDA also indicated that the use of clinical literature as an alternative to clinical trials was also being discussed internally.

The U.S. delegation suggested that industry would prefer to have the "official" common name and then the trade name behind it.

SFDA responded that, the draft IVD regulation will have new naming requirements based on international naming conventions, and that the new naming requirements for IVD's are part of a pilot program to address safety concerns with pharmaceuticals. SFDA also noted that, in accordance with Chinese law and practical considerations, these products must use Chinese names. Other labeling requirements in Provision #10, include that

trade name size should not be twice the size of the common name, and the trade name should not have any implied therapeutic meaning.

Regulatory Updates

In response to a question about media reports that SFDA was in the process of revising a number of regulations, some of which were alluded to earlier in the meeting, SFDA indicated that there were going to be numerous revisions during the coming year and a half, and that SFDA would welcome U.S. industry's input on these issues. According to SFDA, the remainder of 2006 would be spent identifying rules and regulations that need to be addressed, and that this effort will take place simultaneously by a number of groups [note: these groups are mainly Provincial Food and Drug Administration officials]. Since medical device regulations originate from the State Council, SFDA is limited to providing recommendations. The State Council has already approved the plan to amend the MD regulations. Once amended, other rules and regulations will need to be changed as well.

Some of the key issues that SFDA mentioned were:

- Regulations on IVD reagents
- Use of Quality Systems for manufacturing medical device
- Adverse Events reporting

In addressing these regulatory issues, SFDA would take into consideration the need to balance centralization and de-centralization, re-registration requirements and measures to streamline the re-registration process. SFDA also indicated that they were considering whether or not it would be feasible to allow some low-risk products to only require record-keeping, while utilizing audits for high risk products.

By the end of 2006, SFDA hoped to have input from interested groups on all of the proposed amendments. In 2007, SFDA would work on preparing draft amendments, with the intent of having the drafts ready to be shared publicly. SFDA indicated that it would probably take another year to finalize these regulations. Other topics that SFDA would be addressing included:

- Regulatory approaches for combination products
- U.S. FDA approach to providing Investigational Device Exemptions for high-risk products
- Clinical trials for medical devices. SFDA is interested in what pre-conditions should be required before allowing a manufacturer to begin clinical trials. SFDA was specifically interested in whether or not they could rely on country of origin approval, instead of requiring Good Clinical Practice documentation.
- U.S. and European approaches to medical device classification

Upcoming JCCT Activities

The U.S. delegation proposed holding the next JCCT Pharmaceuticals and Medical Devices Subgroup meeting in Washington, D.C. during the week of April 9, 2007 [Subsequently, the proposed dates were changed to April 11-12]. In light of the large number of revisions that provincial SFDA officials will be drafting, the U.S. delegation suggested that it might be more practical to have AmCham members take the lead in

organizing smaller seminars on some of these topics in conjunction with provincial officials involved with drafting a particular regulation. SFDA welcomed U.S. input on these regulations, and reiterated the value that they had received from previous JCCT workshops. SFDA also mentioned that they would like to send an official to the US to study with the FDA, but to do so they would need financial support from the U.S. government or industry.

Accomplishments

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

- Clarified questions about key provisions of the draft In Vitro Diagnostics regulation, and expressed industry concerns regarding some provisions such as naming requirements.
- Set the stage for additional follow up to address SFDA's concerns about medical devices containing bovine or ovine materials.
- Learning about the status of a number of upcoming medical device regulations that are going to be promulgated during 2007.
- Agreeing to broaden the scope of our Task Force's technical assistance efforts to include more training programs conducted by AmCham members.
- Expressed industry concerns about the increasing use of mandatory standards, and confusion within the Chinese regulators as to how these standards are enforced.