

Summary of Joint Commission on Commerce and Trade (JCCT)
Medical Devices Task Force meeting
April 11 – 12, 2005

Overview

The U.S. – China Joint Commission on Commerce and Trade (JCCT) Medical Devices and Pharmaceuticals Subgroup meeting was held in Washington, D.C. on April 11 –12, 2005. The Subgroup opened with a plenary session including all participants on both the medical device and pharmaceutical sides, then split up into two separate Task Forces. For the first time, both Task Forces met jointly to discuss the regulation of In Vitro Diagnostic products. The Subgroup meeting concluded with a plenary session where the signing of a Work Plan. The next meeting will be August 25 or 26 in Beijing.

Opening Session

After the Subgroup's opening plenary session, the Medical Device Task Force began its meeting. The Medical Device Task Force was Co-chaired by Mr. Chang Yongheng, Product Registration Division Director, SFDA Department of Medical Devices, and by Mr. Jay Biggs, Senior Analyst, Office of Health and Consumer Goods, U.S. Department of Commerce. Mr. Wang Lanming, Deputy Director General, Department of Medical Devices also participated in the Task Force. The Medical Device Task Force focused on five issues:

- 1) Status of accepting quality systems audits
- 2) Duplication of testing and inspection procedures
- 3) Chinese product standards for medical devices
- 4) Status of SFDA's Adverse Event Reporting system
- 5) Re-registration requirements.

Overview of SFDA Regulatory Priorities

The Medical Device Task Force began with a presentation by SFDA on last year's changes to China's medical device regulations. The SFDA medical device representatives explained there were three reasons behind the revision to the regulations: 1) accumulation of experience by SFDA in regulating medical devices; 2) knowledge gained through participation in Global Harmonized Task Force and other international meetings, and SFDA's interest in bringing China's system in line with international practice; and 3) the coming into force of China's new Administrative Supervision Law (July 2004), which requires all Chinese government departments to revise their regulations to bring them into conformity. According to SFDA, the law seeks to standardize licensing procedures based on scientific and logical criteria; reduce the number of bodies involved in licensing and simplify the licensing procedure; make Chinese administrative behavior open, fair, transparent and highly efficient; and reduce the number of items that need government licensing.

SFDA also outlined SFDA's Work Program for 2005, which includes:

- Formulate "Provisions on the Refurbished Medical Devices" (seeking to promulgate in June or July 2005)
- Formulate "Provisions on IVD (Medical Device) Registration"

- Formulate “Detailed Rules on the Technical Evaluation of National Evaluation Centers” (these are SFDA’s internal regulations for managing technical evaluation)
- Revise “Provisions on Medical Device Standardization”
- Revise Provisions on the Qualification Certification of Medical Device Certification Bodies (National Laboratories)
- Formulate “Working Procedure for Drafting the SFDA Standards”
- Formulate “Good Manufacturing Practices for Medical Devices” (QSR) (by the end of 2005)
- Formulate “Provisions on MD Adverse Events Monitoring & Reevaluation” (MDV) (seeking to promulgate in June 2005)
- Formulate “Provisions on Medical Device Recall” (seeking to announce in 2006)

SFDA emphasized that they welcome industry input as they are formulating their regulations. Draft regulations, or modifications to existing regulations, are posted on the SFDA web site, and SFDA frequently sends out a notice inviting interested parties to a discussion meeting before finalizing the draft. The time available for comment varies depending on the urgency of the situation, but it usually is more than one month. SFDA noted that the IVD regulation had already been on the web site for some time. The U.S. delegation suggested 90 days would be the minimum amount of time that should be provided for translation and full consideration of new regulations.

Quality Systems

The Chinese side agreed with the U.S. delegation on the importance of Quality Systems (QS) inspections, and at least 62 Chinese medical device firms have passed QS audits. SFDA noted that foreign manufacturers are required to undergo a Quality Systems audit for Class III products, while domestic Chinese companies are audited for Class II and Class III products. SFDA also accepts domestic and foreign manufacturers’ own QS certificate from both as a reference. SFDA explained that it is still not possible to accept third-party certification reports, because China is still developing its own system. However SFDA thinks acceptance of third-party certification reports may be possible in the future, but would have to be done on a reciprocal basis. SFDA is currently gathering information about how other GHTF countries handle this issue.

In response to industry’s request that companies that have passed QS audits be exempted from type-testing, SFDA stated that in their view type-testing is separate from the QS issue. For product registration, both type-testing and quality systems inspections are required for Class II and above. After the U.S. side noted that other countries grant registration solely on the basis of QS audits, SFDA agreed and said that China would move in this direction in the future. As described by SFDA, the current situation results in part from the need to inspect products through type-testing to ensure companies are adhering to the regulations. John Stigi of the U.S. FDA described the procedure it went through for educating small and medium sized enterprises when the U.S. switched to the use of QS audits, emphasizing that industry comments led FDA to revise its proposed regulations and incorporate flexible implementation criteria for smaller firms. U.S. FDA expressed confidence that Chinese firms could make the same transition. SFDA expressed surprise that U.S. FDA focused on more flexibility for SMEs, since SFDA’s

solution was to provide more guidance (less flexibility) in order to make sure things were done in an appropriate manner. Industry also asked about SFDA's new Good Manufacturing Practice (GMP) regulations, and were told that SFDA's new GMP regulation would be based on ISO 13485, but would have some provisions for the specific Chinese situation. SFDA hopes to have these regulations promulgated by the end of 2005, and requested that the JCCT GMP workshop in Guangzhou focus on the technical aspects of doing GMP audits, as opposed to a more theoretical discussion of GMP issues.

The U.S. delegation also encouraged SFDA to participate in the next APEC Life Science Innovation Forum Meeting in September in Korea. One of the topics of this forum will be GMP regulations. Nancy Travis of AdvaMed provided background material to the Chinese delegation.

Duplicative Testing and Inspections

The U.S. side stressed that this is still an important issue industry. The overlapping functions of SFDA and AQSIQ delays the time to market for medical devices, with no appreciable improvement in safety or health benefits. SFDA expressed appreciation for our concerns and said the situation had been reported to the State Council, and that SFDA had hoped for a result soon. According the State Council, SFDA is in charge of all medical devices. Nancy Travis of AdvaMed noted that AdvaMed had prepared a paper, which it was prepared to submit to the State Council.

Chinese Product Standards for Medical Devices

Mr. Biggs of the U.S. Department of Commerce expressed appreciation for SFDA's meeting with industry on the new pacemaker lead standard and hoped that industry comments would be taken into consideration. The U.S. delegation encouraged SFDA to follow international standards when possible.

SFDA noted that they had already streamlined its product-standard-development process by eliminating the preliminary review of the standard that used to be required before a company could begin testing against that standard. Now, the standard is submitted along with all the testing documentation, saving a step. China is working to update its standards, to require a higher level of quality.

John Stigi of the U.S. FDA noted that the U.S. and Europe take a flexible approach to the actual use of product standards. The problem with a rigid approach is that standards are always out of date, which can inhibit new technology. U.S. FDA recommended that SFDA take as its reference the GHTF's guidance document on the correct use of standards.

SFDA said the current system allowed new products to diverge from the national standard, as long as the performance values were equal to or greater than the values in the national standard. Companies could also write their own standard, as part of the registration process. While the current process is specified in the national standard law,

SFDA indicated they could be flexible in implementation in the future. In response to U.S. concerns that some companies are being forced to re-test when their standard is found to be insufficient – which would not have happened when preliminary review was part of the process – SFDA suggested that companies follow the SFDA format and ensure their values are not lower than the comparable national standard when developing their specific product standards. SFDA felt that in the past, companies relied too much on the preliminary review, and if they follow the instructions and ensure a high level of quality, there should be no problem.

The U.S. side discussed the possibility of SFDA participating in the August 8 -12 U.S. - China Standards and Conformity Workshop in Washington, DC, as part of a breakout session on medical device standards issues. SFDA expressed interest in participating in this Workshop, and asked the U.S. side to provide more details.

Joint Task Force Meeting

Because SFDA's current system treats some In Vitro diagnostic devices (IVDs) as pharmaceuticals, and some as medical devices, the Subgroup had a joint meeting of both Task Forces to discuss this issue. This joint meeting was very successful in confirming that SFDA is moving towards revising the way they treat IVDs in a manner more consistent with international norms.

Classification and Regulation of *In Vitro* Diagnostic Devices

In a special joint session including both pharmaceutical and device delegates, the U.S. side noted that most major device markets around the world regulate *in-vitro* diagnostic products as devices, not pharmaceuticals, and that China's current system imposes an inappropriate burden on *in-vitro* diagnostic device manufacturers.

Mr. Zhang Zhijun, Deputy Director General, Department of Drug Registration, responded by reviewing the history of China's regulation of such devices, which originally was the responsibility of pharmaceutical regulators. Currently, the Device Department regulates chemical diagnostic devices, and the Drug Department regulates biological devices. He noted SFDA was still in the process of transitioning all such devices to the Device Department. The process involves changing laws, regulations, and technical requirements for testing institutions. He said the three departments involved – Drug, Device, and Policy and Regulation – were cooperating together and were planning a tour to investigate international practice. After this review process is completed, the regulations and laws will be finalized. He stressed that the Drug Department would accept the final result.

Medical Device Department Deputy Director Wang expressed agreement with Deputy Director General Zhang, noting that the issue was complex. He said that SFDA would listen to outside opinions during its policymaking process. He noted that *in-vitro* diagnostic products had a special nature and stressed that SFDA would do its best to ensure their safety and efficacy in line with international practice.

John Stigi of the U.S. FDA stressed that the rest of the world uses device regulations for the pre-market review and warned that China would not be able to share reports with other countries if it elected to go the pharmaceutical route. Later, in the Medical Device Task Force, AdvaMed noted that it had prepared a paper, which it was prepared to submit to the Commission of SFDA. The SFDA medical device delegates expressed support for that approach. The U.S. side mentioned holding an informal *In Vitro* Diagnostics Roundtable on the margins of the July 11-12 U.S.-China Healthcare Forum in Beijing. Agreement was reached to include this event in the Subgroup 2005 Work Plan.

Adverse Event Reporting

In response to a request for clarification from the U.S. side, SFDA provided an overview of China's adverse event reporting system, which began in December 2002. SFDA indicated that, if a company can submit a report on the results of its adverse event monitoring, it can be exempted from type-testing for re-registration. China has started monitoring adverse events at the national and provincial levels. Currently, 22 out of 30 provinces autonomous regions and municipalities have established adverse event monitoring centers, which have authority over the city and county levels.

SFDA emphasized that the system is still under development. Under the current system, adverse events must be reported within 10 days, if there is severe harm to the patient. The hospital reports to the provincial authority, which in turn has another 10 days to report to the national center. If an event causes death, or is likely to, it must be reported immediately to the provincial center, which must immediately inform the national center. Products are listed in the key adverse event monitoring catalogue. SFDA stressed that the manufacturer should report adverse events to the authorities when they are discovered. Currently, adverse events are not reported to the manufacturer at the same time they are reported to the authorities, but the final regulations will make provisions for doing so.

SFDA explained that the provincial centers do the analysis of the events, and the role of the national center is to synthesize the reports from the regional centers. China also asks the manufacturer to conduct its own analysis of the event. In the case of a severe event, the provincial center typically invites the manufacturer to participate in the analysis.

The U.S. side noted that it takes time to undertake the proper analysis and recommend that China consider the first report a preliminary analysis. SFDA agreed that there could be a preliminary report first, with the follow-up report coming later. SFDA also noted there was a third type of report, an annual summary filed by the manufacturer, which was not limited to Class II and III devices. SFDA said that the new regulations require a report with five days for death, and 15 days for severe adverse events. If the event involves neither death nor severity, it does not need to be reported. In a later presentation, SFDA was careful to note that a *preliminary* report would have to be filed within 10 days after an event.

Re-Registration

The Chinese side agreed that type-testing should not be required for all re-registrations and described six conditions under which a product can be exempted from re-testing:

- 1) The product has not undergone structural change
- 2) The manufacturer can provide a report by a Chinese-government-recognized inspection institution, or notified body, which indicates that a company is capable of testing its own devices
- 3) If a product has undergone a structural change, and the changed part has already been tested
- 4) No adverse event and no market complaints over the four-year period
- 5) If the product has passed a random market check during the previous year
- 6) The product is approved by company's home market government authorities for sale in company's home market

The U.S. side stressed that it would be impossible to have “no” adverse events and market complaints – some are quite minor – and this should be changed to “no major” or “no serious” adverse events. The Chinese side said the criteria were being discussed internally, and some changes could be made. In a presentation to companies the following day, SFDA was careful to add the word “major” when listing the criteria for exemption.

In response to a comment that foreign manufacturers had difficulty fulfilling the second criteria because their tests and inspections were not conducted in China, SFDA said that the test certificate could come from a Notified body, which is an entity with the authority to review medical device products for approval and to perform audits. If such a body were to show the company had passed a QS audit and included a statement that the body believed the company was capable of testing its own devices, that would be sufficient.

SFDA recommended that companies begin the re-registration process at least six months ahead of time. Manufacturers would not be allowed to keep products on the market if the registration certificate were to expire. SFDA also noted that they were planning on holding annual meetings on registration issues for non-Chinese companies, similar to the one held in Wuhan (Hubei Province) in 2004.

Reimbursement Issues

The U.S. side informed SFDA that it is planning to raise the Centralized Tendering issue with the Ministry of Health, probably in meetings following the next JCCT.

Closing Plenary Session

The Subgroup closed with the Summaries of the Task Force discussions by the Task Force Co-chairs, and the signing of the Subgroup Work Plan for the coming year.

The signed Work Plan proposes the following activities:

July 2005	In Vitro Diagnostics Roundtable
July 2005	JCCT Pharmaceuticals Good Clinical Practices Workshop
August 2005	JCCT Medical Devices Good Manufacturing Practice Workshop

August 2005	JCCT Medical Devices Task Force Meeting
August 2005	JCCT Pharmaceutical Task Force Meeting
Fall 2005	U.S. – China Standards and Conformity Workshop
Spring 2006	JCCT Medical Devices and Pharmaceuticals Subgroup Meeting and Medical Device and Pharmaceutical Task Force Meetings (Beijing)

After the signing, DAS Bogosian thanked participants for the time and energy put into the Task Force discussions, and noted that real progress was made on many of the issues discussed. This was his first Medical Devices and Pharmaceuticals Subgroup that DAS Bogosian had chaired, he remarked on the bond of friendship between participants in the Subgroup, and how he hoped these bonds will grow stronger as the Subgroup participants continue working together on the issues.

Assistant Secretary for Manufacturing and Services Albert Frink brought the Subgroup to a conclusion by discussing the new position of A/S for Manufacturing and Services. He also stated that this Subgroup exemplifies a successful way two countries can work together to increase market access and opportunities for growth in the health industries between our two countries, and that he was pleased that this Subgroup in particular has been so active and successful.

Accomplishments

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

- Learning about the status of upcoming medical device regulations that are going to be promulgated during the coming year.
- Agreeing to hold a number of regulatory workshops, such as a pharmaceutical Good Clinical Practice (July 13 –15 in Beijing), medical device Good Manufacturing Practice (August 23 – 26 in Guangzhou), an IVD Roundtable (July 13 in Beijing).
- Discussions about how In Vitro Diagnostics products are regulated by the U.S. FDA and why this approach would be useful for Chinese companies as well as Chinese regulators.
- Learning about the status of SFDA's use of Quality Systems, and SFDA's rationale behind requiring re-registration of medical devices.
- An exchange of information on China's Adverse Event Reporting system, and a discussion of the importance of having manufacturers involved in the reporting system.