

**US-China Joint Commission on Commerce and Trade  
Pharmaceuticals and Medical Devices Subgroup  
Pharmaceutical Task Force Meeting  
August 29 and 30, 2006  
Beijing, China**

**Overview**

The Pharmaceutical Task Force of the U.S. – China Joint Commission on Commerce and Trade (JCCT) Pharmaceutical and Medical Device Subgroup met in Beijing, China on August 29 - 30, 2006. August 29 was devoted to a roundtable exchange on Over – the – Counter (OTC) medication regulatory frameworks in U.S. and China, while discussion on August 30 focused on increasing regulatory oversight of Chinese active pharmaceutical ingredients (APIs) and implementation of data exclusivity provisions.

Please note that this meeting built on previous meetings, notably the April 2006 10<sup>th</sup> Anniversary Meeting of the JCCT Pharmaceutical and Medical Device Subgroup and the August 2005 JCCT Pharmaceutical Task Force Meeting in Beijing, China. To access the official minutes from those meetings, click on <http://ita.doc.gov/td/health/pharmaceuticals.html>.

The U.S. Delegation to the August 2006 Pharmaceutical Task Force meeting was led by Mr. Jeffrey Gren, Director of the Office of Health and Consumer Goods (OHCG) at the U.S. Department of Commerce (DOC) and consisted of DOC and USTR officials and representatives from major U.S. pharmaceutical trade organizations. Those pharmaceutical trade organizations were Consumer Healthcare Products Association (CHPA), Generics Pharmaceutical Association (GPhA), Pharmaceutical Research and Manufacturers of America (PhRMA), and Research & Development based Pharmaceutical Association – China (RDPAC). See attachment A for a list of the U.S. delegation.

The Chinese Delegation consisted of China's State Food and Drug Administration (SFDA) officials that represented the full range of discussion topics on the agenda. They represented Department of Drug Safety, Division of Over-the-Counter Products, Department of Policy and Regulations, and Office of International Cooperation.

**Meeting Agenda**

August 29, 2006

- I. PHARMACEUTICAL TASK FORCE OPENING SESSION
- II. OTC ROUNDTABLE

August 30, 2006

- I. DATA EXCLUSIVITY
- II. BULK ACTIVE PHARMACEUTICAL INGREDIENTS AND COUNTERFEIT DRUGS
- III. PLANNING/UPDATES ON UPCOMING WORK PLAN ACTIVITIES

#### IV. PHARMACEUTICAL TASK FORCE CLOSING COMMENTS

**AUGUST 29, 2006**

##### **I. PHARMACEUTICAL TASK FORCE OPENING SESSION**

**Ms. Liya Wu** (Division Director, Department of Policy and Regulations of SFDA) facilitated the meeting.

**Mr. Wenzuo Chang** (SFDA, Director General, International Cooperation Department) Mr. Chang welcomed the U.S. delegation and provided opening remarks. He then introduced the SFDA staff and the participants from the Chinese pharmaceutical industry associations. He pointed out in his remarks that the idea of an OTC Roundtable was first raised at the JCCT Pharmaceutical and Medical Devices Subgroup meeting in March 2006, and how very quickly the idea became reality. Finally he thanked U.S. DOC for inviting such distinguished presenters for the OTC roundtable and wished it a success.

**Mr. Gren** (Director, Office of Health and Consumer Goods, DOC) Mr. Gren thanked SFDA for arranging the facilities for this roundtable, and introduced the U.S. delegation members. Mr. Gren also stated the importance of the roundtable, and that he personally looked forward to learning about the OTC industry by attending the roundtable.

##### **II. OVER-THE-COUNTER (OTC) ROUNDTABLE**

The aim of the OTC Roundtable was to create a forum for open information exchange between U.S. and China regarding OTC issues. Currently SFDA is leading several initiatives that would have tremendous impact on China's OTC regulatory environment. For example, SFDA is in the process of drafting new regulations for the classification of drugs under prescription versus OTC. There is intense interest in U.S. and other international pharmaceutical industries to see the Chinese population more empowered to self medicate. Thus this roundtable was held at an opportune time.

**Ms. Pei Liu** (Acting Director General of Department of Policy & Regulations, SFDA) Ms. Liu gave an overview of China's Drug Classification System as well as an introduction to OTC legislation in China.

**Mr. Thomas Booth** (President, Consumer Healthcare, Pfizer) Mr. Booth gave an overview of the OTC marketplace while emphasizing the importance of branding.

Topics discussed included:

- Consumer interest
- Cost-benefit
- Competitive pricing
- Role of branding
- OTC accessibility/retail snapshot

**Mr. David Spangler** (VP International Consumer Healthcare Products Association)  
Mr. Spangler gave an overview of the U.S. OTC policy and regulatory framework.

Topics discussed included:

- Legal basis for Rx and OTC classification (safety, effectiveness, labeling)
- The key role of labeling
- Regulatory paths to market: New Drug Applications, monograph categories

**Dr. David Parsons** (Director, International Regulatory Affairs GSK)

Dr. Parsons compared and contrasted the U.S. and EU frameworks.

Topics discussed included:

- Similarities in legal basis
- The key role of labeling, but with different approaches
- Regulatory paths to market: NDAs/dossiers; ingredient monographs; alternatives

**Dr. Eric Brass** (M.D., Ph.D., Director, Harbor-UCLA Center for Clinical Pharmacology; Professor of Medicine, D. Geffen School of Medicine, UCLA)

Dr. Brass spoke on Rx-to-OTC switch developments.

Topics discussed included:

- Benefits of Rx-to-OTC switches
- Key considerations in switch: labeling; self-selection/de-selection by user populations
- U.S. regulatory process for Rx/OTC switch
- Circumstances under which regulators should allow Rx/OTC switches
- "Dual status" products
- New frontiers in switch: disease management possibilities; information surrounding the physical product

**Mr. Wei Zhang** (Director General of Department of Drug Registration, SFDA)

Mr. Zhang provided closing remarks thanking participants.

**AUGUST 30, 2006**

**DAY TWO OF THE PHARMACEUTICAL TASK FORCE  
OPENING REMARKS**

**Mr. Jeffrey Gren** (DOC) – Introduced the U.S. delegation members. The timing of this subgroup meeting is very good, enabling our colleagues from the Office of U.S. Trade Representatives (USTR) to join us.

We have only three topics for this half day meeting:

- 1) Date Exclusivity and Patent Linkage;

- 2) Bulk Active Pharmaceutical Ingredients and Counterfeit Drugs; and
- 3) Planning/Updates on Upcoming Work Plan Activities.

During the March 2006 meeting we agreed to have Mark Cohen to facilitate, together with SFDA, the collaboration on certain activities for data exclusivity and patent linkage. We would like to follow up on that.

**Ms. LiLi Zhao** (SFDA) – Just some points before we proceed. SFDA pays important attention to JCCT meetings. Various departments come here to hear what U.S. have to say. We have talked so much already on DE and PL, and APIs. We hope that the U.S. side can bring up detailed cases in order to reach a deep understanding effectively. In the case of counterfeit drugs, our colleagues can explain our policies on how we regulate APIs. We hope that individual company's concerns are not talked about here.

## **I. DATA EXCLUSIVITY**

**Mr. Mark Cohn** (U.S. Patent and Trademark Office)

During the March Pharmaceutical Task Force meeting earlier this year, our industry representatives stated that they were unclear as to how Data Exclusivity provisions were implemented by SFDA.

Specifically, we have knowledge that six innovators' products have had to compete with 32 generic applications while these innovative products are still within data exclusivity periods. These innovators product should have gotten DE protection, but they did not. We still have some confusion on this issue. JCCT IPR Working Group will have a meeting in Dec. 11-12 2006 in Washington, D.C. We hope that SFDA will join that event. The December 2006 meeting may benefit SFDA by providing SFDA an opportunity to interact and discuss with China National IPR Bureau and U.S. agency experts who are expected to be present, on data exclusivity matters.

During the March 2006 Pharmaceutical Task Force meeting, we talked about seven topics (listed below). We continue to ask for further clarification on them.

- What qualifies as an New Chemical Entity (NCE)?
- What is the legal framework for generics to seek approval?
- What is the policy of DE for products approved prior to 12/2005?
- Does DE apply to bio generics?
- What is the DE procedure? Does the innovator have to apply separately for it? Or is it automatically granted?
- How is DE protection enforced? What is the relationship between DE and registration for approval by generics?
- Who can companies contact in SFDA regarding DE related questions?

We would appreciate it if SFDA can give further clarification.

**Ms. Lili Zhao** (SFDA) – I feel like that I am going back through the time tunnel. We have answered some of the questions. Do you need further explanation?

**Mr. Cohen** – We feel that we did not get much of an answer. Our industries still have questions, like, how to apply for DE protection? We still do not have adequate information on your implementation of China's DE protection. I hope that you can help us understand exactly the administrative steps we need to take. At our last conversation in March, there was no mention of an U.S. company succeeding in getting DE protection. Has there been any change?

**Ms. Zhao** – The Chinese government was apprised of TRIP plus provisions at an international conference. The Chinese government has committed to this, so do not worry if we will do it or not. I think you may have questions on detailed procedure on how to apply for DE. I would ask Mr. Ding to explain on how to get the approval.

**Mr. Jianhua Ding** (Deputy Director of Department of Drug Registration, SFDA) – I feel we have different understanding regarding DE and IPR in general. I came to the JCCT Pharmaceutical Task Force meeting in March and I wonder why more things are not resolved after so much and so long of an effort. I suggest both sides look into other country's legal systems and frameworks, and try to understand what is going on there in order to achieve mutual understanding. I visited Washington D.C. twice last year, once to attend a U.S. FDA international regulatory forum. We had very good discussions, and felt a lot of mutual understanding. Both U.S. FDA and SFDA are agencies whose prime mission is to protect public health. However, JCCT focuses on trade and this may cause certain conflict. I hope U.S. FDA can participate in future JCCT talks. Please keep U.S. and Chinese situations separate. Please try to understand the Chinese regulatory systems, and not just criticize. One point to keep in mind, for example, is that **China does not have the DE concept, but instead we use the term “undisclosed data.”**

**Mr. Gren** (DOC) – For the sake of time, we should go on. I would like the representative from USTR comment on IPR.

**Mr. Ding** (SFDA) – SFDA is not responsible for IPR. IPR should be discussed with the China IPR Bureau.

**Ms. Winter** (USTR) – I stayed an extra day for this meeting, because I feel we do not have a good, mutual, understanding on this important issue of DE, patent and IPR. I come as USTR, but I assure you that multiple agencies under U.S. Government are eager to work with you to obtain better mutual understanding of each other's systems.

**Mr. Wei Zhang** (Director General of SFDA Department of Drug Registration) – I would like to add some points on DE. I agree with Ms. Zhao. I joined SFDA and started participating in JCCT events in March 2006. On U.S.'s questions on DE, I always ask myself what caused this problem? Do we have the correct platform for the dialogue? Do we have the correct parties in the dialogue? China pays a lot of importance on DE. China has a saying: Attitude is everything. China is firmly committed to DE. We are willing to take every opportunity to participate in the discussion. Having broad interested parties to participate may help to reach common understanding. We welcome our U.S.

colleagues to give us a list of written questions. We welcome your comments and suggestions. We will see what we can do to improve our systems or ways of doing things.

**Mr. Cohen** (U.S. PTO) – I just want to know how you do it. You do not have to talk about WTO. We know you have commitment. We want to know what your procedure is. Give us a flow chart: who and where to contact. What is needed? The length of time needed for decision?

**Ms. Zhao** (SFDA) – We hope to share information that will help you to understand our systems. For instance, we do not use the term “DE,” instead we use the term “undisclosed data,” so the terms are different. You said that six companies have unfairly treated on their data protection. Please go back and ask them what and why they feel they are not protected. I am not sure that they are clear on that.

## **II. BULK ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) and COUNTERFEIT DRUGS**

**Mr. Gren** (DOC) – Let’s proceed to the next topic: API issues.

For bulk APIs we are concerned with the procedures in China, since SFDA only regulates to insure compliance with Good Manufacturing Practices if the bulk API is declared for medicinal purposes by the chemical manufacturers. If the manufacturer does not declare a medicinal use there is no regulatory control, and based upon research done by security divisions of major pharmaceutical companies with China offices, far more APIs are produced than necessary for legitimate drug production. It is clear from the research that bulk APIs produced in China are being used in counterfeit drug production, either in china or in other global locations, such as Southeast Asia, Middle East, India, Russia, and Latin America.

Counterfeit medicines are extremely dangerous to public health. It is a global issue. U.S. government is collaborating with other agencies in other countries to crack down on counterfeit drugs. For example, the APEC Life Sciences Innovation Forum is working on this. A proposal for a series of training seminars addressing the drug counterfeiting problem has been submitted to APEC.

API global trend: Currently ~40% API production is produced in China and India. Twenty years ago production was mainly in the U.S. and Europe. In the next ten to fifteen years, it is anticipated that ~80% APIs will be produced in China and India. This may not be a bad thing. This is driven by market forces – production will go where it can be done with low cost and available resources. It will be good for China. But we think that there should be infrastructure in place to regulate API production in order to stop the sale of APIs to drug counterfeiters. This will be even more important as more API production shifts to China. More and more counterfeit drugs contain API, but these APIs may not be the correct purity, concentration, etc. We hope to collaborate with China government on global activities to stop the spread of counterfeit medicines.

From the past meetings we know that SFDA has authority/responsibilities only on chemicals that are claimed to be of medicinal uses. Based upon an internet search, many companies sell bulk APIs while advertising that they can be used in the manufacture of medicines. We want to know how SFDA regulates these companies. We submitted in advance a proposal to establish a research group and to introduce a temporary regulation to augment the current oversight of APIs used in the ten most counterfeited drugs. We would like to know what SFDA thinks about our proposal.

We will meet with MOFCOM and MPS to discuss this issue as well. We bring this up here, not to criticize SFDA, but rather to seek collaboration with SFDA in finding joint agreement and resolution to this global problem.

**Mr. Zhang** (SFDA) – SFDA has a very clear understanding and attitude on cracking down on counterfeiting drugs. We have been focusing on our internal activities. SFDA would like to participate on international efforts. China has the strictest system in regulating APIs. China uses the registration system for APIs. Others have Drug Master Files or Certification of Suitability systems. China's registration system is also applicable to foreign APIs. As far as I know, U.S. has no registration requirement on APIs. We hope U.S. counterparts would consider stricter regulatory systems for APIs. We have noticed other countries have become interested in China's API regulation systems. When we met with Japan, we reached mutual understanding. Every country has to regulate well its own APIs, then things would become better globally. We learned that in the U.S., if chemicals are not claimed as for medical use, the U.S. FDA does not regulate them, although they do have some medical functions.

As for internet sales of API, we have certain regulations on website. But, it is very difficult to enforce the regulation on internet, especially some websites are owned by U.S. commercial interests.

The U.S. should also make more effort in controlling the importation of APIs. If the buyer in the U.S. does not claim the chemical is for medical use, then it should not be considered as counterfeit API. Also, if the chemicals are imported and be further treated (precipitation and so on) it may become legitimate API.

This year SFDA carried out the strictest activities to regulate the pharmaceutical market, including rectifying the market order for APIs and excipients.

We suggest not to put this API issue on JCCT. RDPAC can carry out the research on this issue, and submit a report upon completion of this research work. I agree with the second part of the U.S. proposal, i.e., introduce Chinese APIs to the U.S. through an efficient and legitimate way – maybe through an intermediate party.

**Mr. Gren** (DOC) – I am happy that SFDA is willing to participate in this global effort. It is true that after a chemical is exported to other countries, SFDA will not have any way to check or regulate if the chemical is used as an API in a drug or in a counterfeit drug. My question is if there is any way that the SFDA can regulate those chemicals that can

potentially be used for the production of counterfeit medicines, although it was not claimed for medicinal use.

**Mr. Chris Costigan** (PHRMA) – Your suggestion of conducting a research by RDPAC is very interesting. However, counterfeit drug issue should be kept under JCCT, since SFDA does have the charter to ensure public safety.

**Ms. Zhao** (SFDA) – The 2005 report by US FDA stated that there were 58 counterfeit drug cases, only one case cited in the report related to the use of APIs from China or India.

**Mr. Cohn** (USPTO) – There are three U.S. agencies responsible for matters pertaining to counterfeit drugs, FDA is one of them.

**Mr. Zhao** (SFDA) – I want to emphasize one point. If the U.S. finds a finished drug that is counterfeit, you should report this incident to the U.S. FDA. China SFDA certainly will cooperate with FDA to find the counterfeit API. Do not focus on API, but rather, focus on counterfeit drugs.

**Mr. Gren** (DOC) – Counterfeit drugs in the U.S. is far less common than in some other countries. Our point is that the counterfeit drug problem is a global problem, and we need a global effort to stop its spread.

## **V. PLANNING/UPDATES ON UPCOMING WORK PLAN ACTIVITIES**

**Mr. Gren** (DOC) – In the March 2006 meeting the topic of excipients regulations was brought up. We now ask again if SFDA is interested in visiting the U.S. to see how the excipients are regulated in the US. We think it would be good this activity be carried out in 2007.

**Mr. Zhang** (SFDA) – We are interested, and also think 2007 is a good time frame. We would appreciate help from DOC to organize the trip, in collaboration with IPEC.

**Mr. Gren** (DOC) – The next subgroup meeting will be in DC in April 2007. April 10-11, 2007. Pharmaceutical Task Force topics include: roundtable for vaccine development, follow up on OTC roundtable, a visit to U.S. pharmaceutical and chemical firms to see how companies regulate APIs.

## **VI. PHARMACEUTICAL TASK FORCE CLOSING COMMENTS**

Closing remarks were made by Mr. Zhang (SFDA) and Mr. Gren (DOC). Explored differences and reached certain understanding. Continued effort is needed and will result in better mutual understanding and benefit to the public health of both countries.

## **Attachment A**

### JCCT Pharmaceutical Task Force August 29 - 30, 2006

#### Pharmaceutical Delegation

Jeff Gren – U.S. Department of Commerce (DOC)

Audrey Winter – Deputy Assistant U.S. Trade Representative – China Affairs

Amy Celico – U.S. Trade Representative, China Office

Mark Cohen – U.S. PTO, IPR Beijing Attaché

Victoria Kao – U.S. DOC

Eric P. Brass\*, M.D. Ph.D. – Professor, U.C.L.A, representing Consumer Healthcare  
Products Association (CHPA)

Thomas M. Booth\* – Pfizer, representing CHPA

David Parsons\* – GSK, representing CHPA

Catherine A. Sohn\* – GSK, representing CHPA

David C. Spangler\* – VP International, representing CHPA

Chris Costigan – Pfizer, representing PhRMA

Cheryl Xu – PhRMA

Cathy Yang – RDPAC

Ling Ye – Hospira Inc, representing Generic Pharmaceutical Association

Jennifer Chen – Legal Director, RDPAC

\* Speakers at Aug 29 OTC Roundtable. They did not participate in August  
30 Pharmaceutical Task Force Meeting.