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- **Working Group on Implementation of Hospital Authority’s Key Initiatives**

  The Working Group on Implementation of the HA’s Key Initiatives met again on 29th May and 29th June. HKAPI have been working closely with the Hospital Authority to examine the feasibility of various procurement requirements in the areas of microbiology testing, routine sample testing, provision of Certificate of Analysis. HKAPI also helped to organize visits between the HA and all the pharmaceutical distributors in HK. We have surveyed the views of our members and communicated the results to the HA during the meetings, our discussion has led to some practical and mutually agreeable solutions. These interim solutions and future directions, as well as their implementation schedule will be communicated to members via email and at the all members’ meeting.

- **Sub-taskforce on Medical Device Regulations**

  In June, a sub-taskforce on medical device regulations was established under the regulatory affairs task force. The Medical Device Control Office plans to have the legislation on the mandatory regulatory systems enacted by the end of 2009. The sub-task force met with the Medical Device Control Office on 18 June to discuss and express the industry’s views on various issues, which included the Medical Devices Administrative Control System, responsibilities and requirements of local responsible person (LPR), Class I Medical Devices registration.

- **Briefing Sessions on Counterfeit Pharmaceuticals**

  On 27 May, two 1.5 hour briefing sessions focussing on the identification of counterfeit pharmaceuticals were organized for two groups of frontline officers of HK Customs who carry out raids and inspections at pharmacies and airmail centre respectively.

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Mr Aaron Hui, Senior Product Manager of Pfizer discussed, in detail, the supply chain of pharmaceutical products. Mr Mike Chan, Senior Product Protection Officer of Eli Lilly shared information with the officers about emerging trends in counterfeiting in the Asia Pacific and pointed out various indicators that showed the pharmaceuticals that were likely to be counterfeited. Security features of pharmaceuticals were then explained by both of them. We are also delighted to have Mr Alex Ma, Director – Asia Pacific, Pharmaceutical Security Institute (PSI) to give an overview of the functions of the PSI and the global trends in counterfeiting.

About 40 officers attended the briefing sessions and HKAPI aims to provide regular briefings of this kind in future.

Mr. Aaron Hui of Pfizer discussed the security features of their products.

Mr. Mike Chan of Eli Lilly presented on the emerging trends in counterfeiting.

Customs and Excise Department officers stationed at the Airport attended the briefing on Counterfeit Pharmaceuticals.

Frontline officers from the Customs and Excise Department attended the HKAPI briefing on Counterfeit Pharmaceuticals.
Meeting with Consumer Council and the Customs and Excise Department

To further deter convicted pharmacies from selling counterfeit drugs and increase public awareness of these pharmacies and the serious impact of taking counterfeit drugs, HKAPI had a meeting with the Consumer Council and the Customs and Excise Department on the possibility of disclosing the names of pharmacies that have been convicted of selling counterfeit drugs. The reporting channel, frequency and information to be disclosed have been discussed.

Recent Activities

On 30 June, HKAPI was invited by the International Research-Based Pharmaceutical Manufacturers Association (IRPMA) in Taiwan to speak on the successful partnership established between HKAPI’s anti-counterfeit task force and various stakeholders in combating counterfeit drugs in HK. IRPMA would like to make reference to the approach and directions HKAPI has taken and the platform that have been established with key stakeholders over the past years.

The Healthcare and Pharmaceutical Team at Richards Butler, HKAPI’s associate member, organized a seminar on 25 June to share with other member companies current legal issues that may affect the Pharmaceutical Industry. During the meeting, Ms Lisa De’Ath and Mr Bernard Murphy gave an overview of the relevant pharmaceutical regulations and ordinances and the liability for non-compliance. Key clauses in distribution agreements between manufacturers and distributors were also highlighted. Around 10 members companies attended the seminar and found it very informative.

Guidelines on evaluation of similar biotherapeutic products

WHO has recently issued the second draft on the guidelines on the evaluation of biosimilar products, comments and suggestions on this document which will be considered by the Expert Committee on Biological Standardization (ECBS) are welcomed on or before 15 July. An earlier draft (WHO/BS/08.2101) was presented to the ECBS in October 2008. Final draft for submission to the ECBS will be posted on WHO Biologicals website (http://www.who.int/biologicals/en/) for public consultation in August 2009.
Task Force on Drug Distribution Guidelines during Pandemic

As at 30th June, there were 785 human swine influenza cases in Hong Kong. The number of cases has risen continuously since the confirmation of the first human swine flu (H1N1) case which involved a 25-year-old Mexican man who traveled to Hong Kong on April 30. In view of the possibility of a more serious outbreak, a task force on drug distribution guidelines during the outbreak of a pandemic such as human swine flu, was established in May. The objective of the task force is to ensure the continued supply of drugs during the outbreak of a pandemic which is crucial to patient safety. Key issues including the frequency and mode of delivery, contingency plan to protect staff of the distributors and mutual support among distributors were discussed.

Upcoming Event: All members’ luncheon

HKAPI is organizing an all members’ luncheon on 15 July to update member companies regarding the discussion with the Hospital Authority on the initiatives they proposed after the series of drug incidents in March.

Date: 15th July 2009
Time: 12:00 – Registration and cocktails
       12:45 – Luncheon starts

Venue: Churchill Room, 26/F., The Park Lane,  
       310 Gloucester Road, Hong Kong.

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