The Hong Kong Association of the

Pharmaceutical Industry

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September CEO Luncheon

A CEO luncheon was held on 11 September with the objective to update member companies on what the Board would like to achieve in this term and the progress of some initiatives that we have started. More importantly, the Association took this opportunity to solicit inputs and feedback from CEOs on the proposed directions and strategic plan.

Dr. Sian Ng, President of HKAPI, gave the opening remarks and thanked member companies' participation. Ms. Sabrina Chan, Executive Director of HKAPI then updated members on the healthcare and pharmaceutical market environment, recent regulatory changes such as competition law, data exclusivity. For the 2012 – 2014, the focus of our directions will be on enhancing drug accessibility, drug safety, communications and drug education. The critical paths and end points for key initiatives were also shared. Results from the recent member survey on services provided were presented. Based on suggestions from member companies, further discussions on how to enhance services such as monthly survey reports and seminars will be held.

Dr. Sian Ng thanked members for attending the luncheon and providing feedback to the Board.

Mr. Roee Shahar, Vice President, gave an account of the work of the Anti-Counterfeit Taskforce.

Ms. Sabrina Chan, Executive Director, updated members on the strategic plan of the Association for 2012 -2014.

13 CEOs and representatives from member companies attended the luncheon.

Meeting with Dr. Ko Wing-man, Secretary for Food and Health

On 4 Sept, the HKAPI Board of Directors had a meeting with Dr. Ko Wing-man, Secretary for Food and Health to understand his vision, strategic directions and priorities for the healthcare policy in Hong Kong. During the meeting, Dr. Ko also shared with the Board his views on healthcare financing, public-private partnership initiatives, drug accessibility, clinical trials and patent linkage in Hong Kong.

Joint event with the Drug Office: Briefing on Pharmaceutical Product Registration and Change of Registered Particulars

In order to update our members about procedures for drug registration and change of registered particulars, a joint meeting between the Drug Office of the Department of Health and HKAPI was organized on 20 August. About 100 representatives from member companies attended the briefing.

During the meeting, Mr. Frank Chan, Chief Pharmacist, Drug Registration and Import/Export Control Division, and his team explained in details the application process for drug registration and change of particulars application as well as the latest document requirements for these two types of application. The Drug Office also shared issues commonly identified in the screening of submitted documents and a number of initiatives that will be adopted by them to further enhance the efficiency of the drug

registration process. Members also took the opportunities to clarify their queries and concerns in the drug registration process.

The Association thanked the Drug Office for working closely with the industry to facilitate drug registration and change of particulars application and welcomed the opportunities to have this kind of briefing from time to time which has enhanced our communication with the Drug Office.

Ms. Karena Lee, Pharmacist, Drug Office, presented to HKAPI members on the drug registration application process and requirements.

Ms. Christy Wong, Pharmacist, Drug Office explained the change of particulars application process.

From left to right: Mr. Clive Chan, Mr. Frank Chan, Mr. Lau Ka Wing.

Mr. Clive Chan, Senior Pharmacist (Drug Registration), answered queries from members.

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Dr. Sian Ng thanked the Drug Office for organizing the briefing on drug registration for HKAPI members.

About 100 members attended the meeting.

Visit to Macau Health Bureau and Department of Pharmaceutical Affairs

HKAPI's Board of Directors including Dr. Sian Ng, Ms. Joanne Fan, Ms. Wyeman Tan, Ms. Vicky Tse, paid a visit to Macau Health Bureau and met up with Dr Chan Wai Sin, Deputy Director on 21 September to have an update on Macau's healthcare delivery system and healthcare service enhancement. On the same day, they also had a meeting with Mr. Ivan Ng, Chief of Division of Pharmacovigilance & Pharmacoeconomics, Macau Health Bureau and his colleagues from the Pharmaceutical Affairs Section to understand the latest development in the enactment of legislation governing the pharmaceutical registration and the request to distributors to fulfill Good Distribution Practice standard.

Sharing session with the Drug Office on Pharmacovigilance

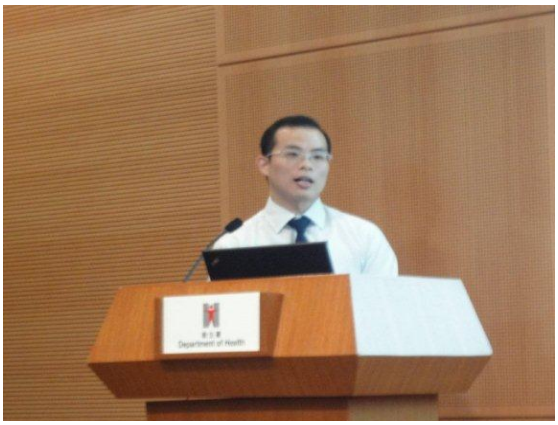
The first sharing session with the Drug Office to share our knowledge on different areas of regulatory affairs was organized on 9th August. Three speakers respectively from Merck Sharp & Dohme and Janssen were invited to talk about practice in pharmacovigilance (PV) from the perspective of international pharmaceutical companies.

First of all, Mr. Edmund Cheuk, Global Safety Country Lead – Hong Kong and Macau, Merck Sharp & Dohme (Asia) Limited discussed the roles and key responsibilities of the local pharmacovigilance officers which include compliance in the reporting of safety information, acting as a communication platform among local office, global office, health authorities and providing training on PV to internal staff. He also shared with the audience challenges faced by the industry in ensuring compliance with regulations and internal process.

In the second session, Mr. Theo Giannou, Regional Director, Pharmacovigilance, Janssen gave an overview of the structure of the global medical safety team and the key components of an effective safety system. Dr. Ellen Wei Li, Director, Single Case Safety Analysis, Janssen then presented on the reporting mechanism, the requirements and rationale in providing different types of safety reports such as Development Safety Update Report (DSUR), Periodic Safety Update Report (PSUR), latest development in the harmonization of reporting requirements in the US and EU as well as signal detection and evaluation.

The presentations are very informative and the audience is welcomed to follow up with questions to the speakers.

Ms. Linda Woo, Chief Pharmacist, Drug Office.



Mr. Edmund Cheuk, Global Safety Country Lead – Hong Kong and Macau, Merck Sharp & Dohme (Asia) Limited.

Mr. Theo Giannou, Regional Director, Pharmacovigilance, Asia Pacific, Global Medical Safety, Janssen.

Dr. Ellen Wei Li, Director, Single Case Safety Analysis, PV Analytics & Insight, Global Medical Safety, Janssen.

Sharing session with the Drug Office on the Control of Extraneous Chemicals in Drug Products

The second sharing session with the Drug office focused on the Control of Extraneous Chemicals in pharmaceutical products. Prof. Jean-Paul Fournier, retired EMA official, who has ample experience in drug development and assessing pharmaceutical dossiers, discussed in details the various EU and ICH guidelines that governing impurities in drug substances and products.

Mr. Andy Gibson, Product Quality Leader of API & Antibiotics, GlaxoSmithKline then talked about the sources of impurities and the importance of product specifications and Good Manufacture Practice in ensuring the safety and efficacy of the drug product and the exposure to certain extraneous chemicals does not bring safety concerns.

Dr. Derek Newall, Senior Director, Safety Assessment, GlaxoSmithKline further elaborated on the concepts of Acceptable Daily Intake, Tolerable Daily Intake as well as Permitted Daily Exposure and explained how these measures can be used in risk assessment, a number of product examples were used to illustrate the key points.

Prof. Jean-Paul Fournier, Retired EMA official.

Mr. Andy Gibson, API & Antibiotics, Product Quality Leader, GlaxoSmithKline.

Dr. Derek Newall, Safety Assessment, Established Product, GlaxoSmithKline.

Briefing session on the Computer System for Pharmaceuticals Registration

The Drug Office organized a briefing to HKAPI members on the Computer System for Pharmaceuticals Registration and Change of Registered Particulars application on 28 August to introduce to the industry the objectives and the main features of the new system.

It is hoped that with the online submission and payment system for pharmaceutical product registration and change of particulars application, the operational efficiency of the application procedure can be streamlined and enhanced. As a communication platform, the new system also enables applicants to keep track of requests from the Drug Office and the application status. Information captured on the drug database can also be enriched and more easily shared with the certificate holder.

After the demonstrations, members were invited to provide feedback to the system and questions were clarified. The Drug Office will organize further briefing sessions on the computer system after consolidating the feedback and suggestions from the industry.

Seminar on Growth of Competition Law in Asia Pacific: Implications for the Industry

Hong Kong's first cross-sector competition law, the Competition Ordinance was enacted in June. The prohibitions in the law will come into effect when the new Competition Commission and Tribunal are established, which is estimated to take approximately 12 months. In order to enable our members to have a better understanding on the implications of the Competition Law to the industry, we have invited our Associate Member, Baker & McKenzie to give a talk on the topic.

Ms. Clara Ingen-Housz, Partner of Baker & McKenzie, started the talk by giving an update of the Competition Ordinance highlighting the First Conduct Rule and the Second Conduct Rule. The presentation then focused on various key issues that are likely to be faced by pharmaceutical companies under the new regulatory regimes, including dealing with distributors and wholesalers, R&D agreements, IP licensing agreements. The seminar is very informative and gives advice on how to handle and meet the challenges posed by the new law.

Lunch with the Hong Kong Medical Association Council Members

HKAPI organized a lunch on 20 July to meet with the Hong Kong Medical Association Council Members elected in July 2012.

HKAPI's Participation in Conferences and Workshop

APEC Business Ethics Workshop
10-11 July
Ms. Sabrina Chan, Executive Director of HKAPI was invited by Asia-Pacific Economic Cooperation (APEC) to be the project overseer and mentor. At the first meeting of the APEC Business Ethics Workshop held in Taipei, she presented on how to align codes of business practice for the pharmaceutical sector and shared the experience of Hong Kong.

2012 ASAE Annual Meeting & Expo
12-13 August

ASAE represents more than 21,000 association executives and industry partners and their members manage leading trade associations, individual membership societies and voluntary organizations across the United States and in nearly 50 countries around the world. Ms. Sabrina Chan of HKAPI was invited by Hong Kong Tourism Board to share her experience in running an association in Hong Kong at their Annual Meeting held in Dallas, USA.

5th Annual Pharmaceutical Regulatory Summit
21-24 August

The 5th Annual Pharmaceutical Regulatory Summit, which aims to enhance collaborations between industry and authority to expedite the approval of safe and effective drugs, was held in Singapore in August. On behalf of the Association, Ms. Sabrina Chan, Executive Director presented on the Pharmaceutical Registration system of Hong Kong.