The Hong Kong Association of the Pharmaceutical Industry

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HKAPI Code of Practice Train-the-trainer Workshop

To address the training needs of our members and to promote the newly revised HKAPI Code of Practice internally, a train-the-trainer workshop was organized on 19th August. Ms. Joanne Fan, Chair of the Code of Practice Taskforce kick-started the workshop by introducing the objectives of the meeting. Apart from ensuring the trainers have a good understanding of the Code, the Workshop also provided opportunities for the trainers to form a network to exchange views and learn from each other in the implementation of the Code. In the first session, Ms. Sabrina Chan, Executive Director of HKAPI discussed the spirit and the principles of the Code of Practice, followed by an overview of the key changes implemented in the current edition. In the second session, the participants formed into groups to discuss various cases and present their views after. The facilitators from the Code of Practice Taskforce then highlighted the key questions to be considered in each case with reference to the relevant clauses in the Code.

39 local and regional representatives from our member companies who are responsible for Code compliance attended the workshop and found the workshop very useful and the case study approach very practical.

Ms. Joanne Fan explained the objectives of the workshop and thanked all the participants for joining the event.

Ms. Sabrina Chan gave an overview on the content and key principles of the Code of Practice, and moderated the case study discussions.

- Members' briefing on Health Technology Assessment
- Anti-counterfeit Taskforce meeting
- Sharing Session with the Drug Office on electronic Common Technical Dossier

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39 representatives from 30 member companies participated in the train-the-trainer workshop.

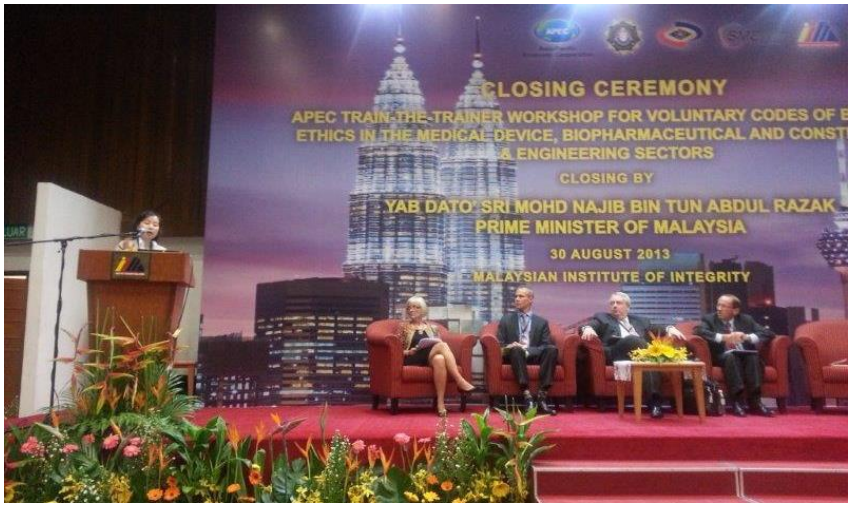
Participants presented and shared their views on different cases after group discussion.

APEC Train-the-trainer Workshop

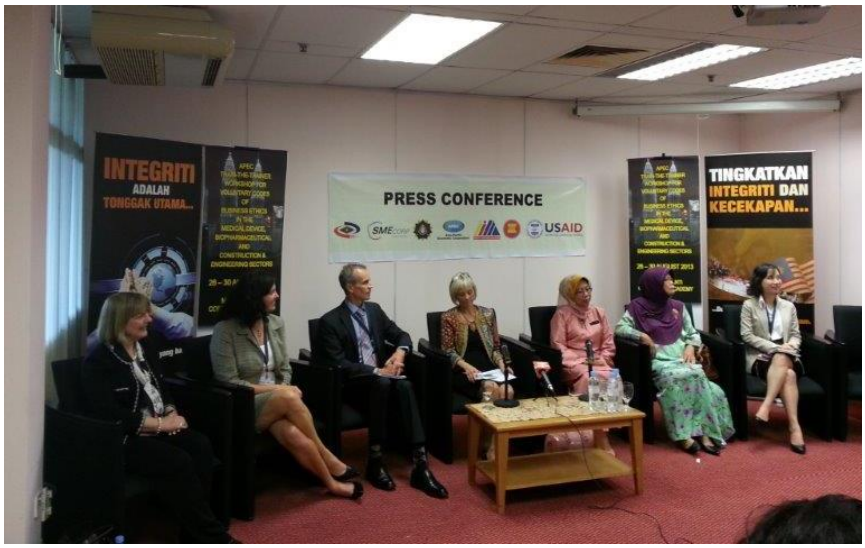
Asia-Pacific Economic Corporation (APEC) organized a five-day Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Medical Device, Biopharmaceutical and Construction and Engineering Sectors in August. The objective of the workshop is to help the region's industry associations and companies from the three sectors to build technical skills necessary to organize and manage effective and sustainable compliance programs. Ms. Sabrina Chan, Executive Director of HKAPI, is the project overseer and one of the mentors. She was invited to chair and participate in several panel discussions to share case studies and her views on effective training, key performance indicators of compliance programs. (For more details of the Workshop, please visit http://www.sprm.gov.my/apec-semai.html?&lang=en)

More than 200 participants from 24 APEC and ASEAN economies in the medical device, biopharmaceutical, and constructions and engineering sectors attended the workshop. Mr. John Kerry, Secretary of State, commended APEC of working closely with the private sector to develop codes of ethics for businesses. (http://www.state.gov/secretary/remarks/2013/10/215176.htm)

Following the Train the trainer Workshop, Ms. Chan also attended the APEC Healthcare Stakeholders Awareness High-Level Meeting: Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors in Bali to present on the importance of collaboration among physicians, hospitals and industry in ensuring a high standard of ethics in the healthcare sector.



Ms. Sabrina Chan delivered the readout from the Biopharmaceutical Sector at the closing session of the APEC Train-the-Trainer Workshop for Voluntary Codes of Business Ethics.

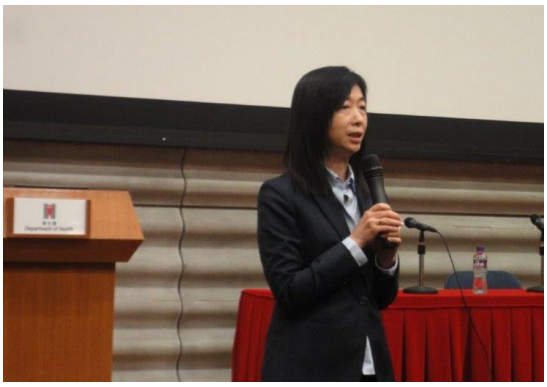


Ms. Sabrina Chan (First from the right) at the press conference of the APEC Train-the-Trainer Workshop.

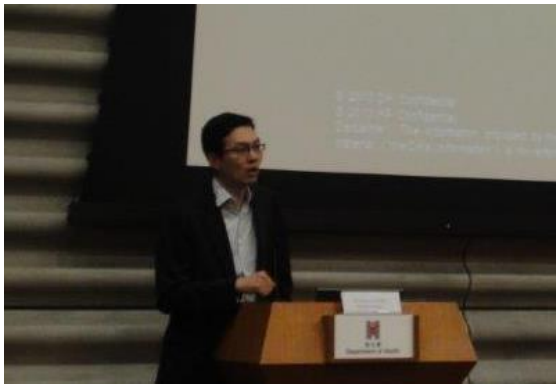
Briefing on New Computer System for Pharmaceuticals Registration and Change of Registered Particulars Guidelines

The Drug Office has been planning to launch a new computer system to enable online submission of drug registration applications, change of registered particulars applications and renewals of registered pharmaceutical products. On 13th September, the Drug Office held a briefing to update the industry regarding the progress of the computer system after incorporating some of the suggestions from the last briefing and consultation. During the briefing, how to apply for e-cert and product access control

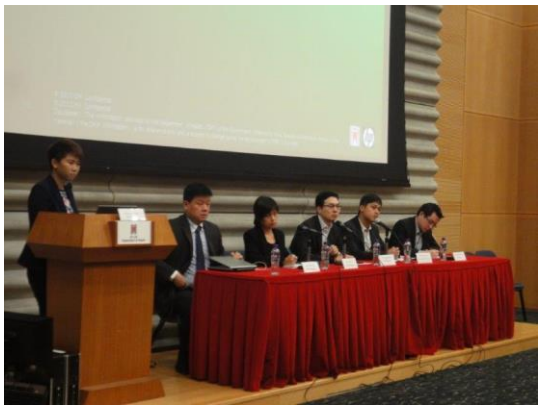
were explained, the submission of new registration application, registration renewal and change of particulars application were also demonstrated. In the second session, the Drug Office explained the regulations governing registered particulars, the new screening procedures for change of registered particulars application and some of the common issues identified in the submission. The Association thanked the Drug Office for the opportunities to have briefing sessions from time to time to update members on various initiatives undertaken.



Ms. Linda Woo, Assistant Director (Drug), Department of Health welcomed members' participation in the briefing sessions.



Mr. Frank Chan, Chief Pharmacist of the Drug Office gave a short introduction and explained the objectives of the briefing.

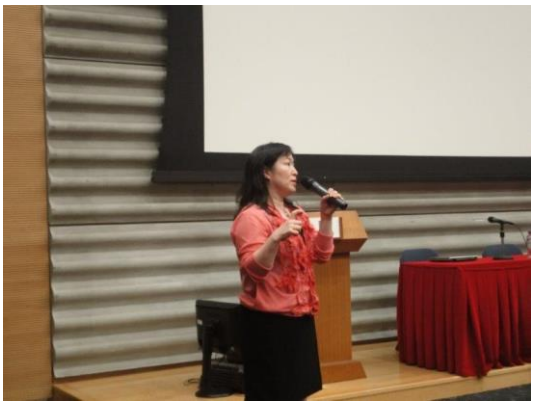


Mr. Frank Chan and his team who are working on the new computer system updated members on the progress of the development.

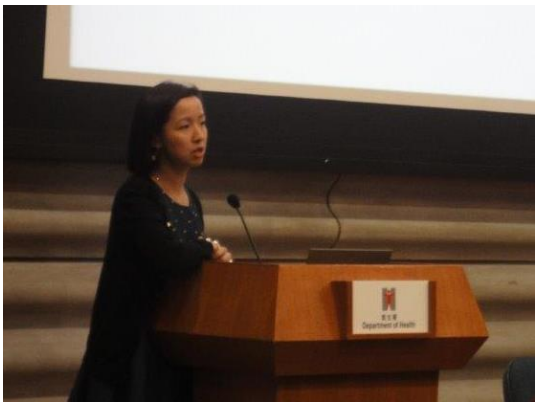
Mr. Clive Chan, Senior Pharmacist (Drug Registration) of the Drug Office answered questions on change of registered particulars applications.

Regulatory Affairs Good Practice Sharing session

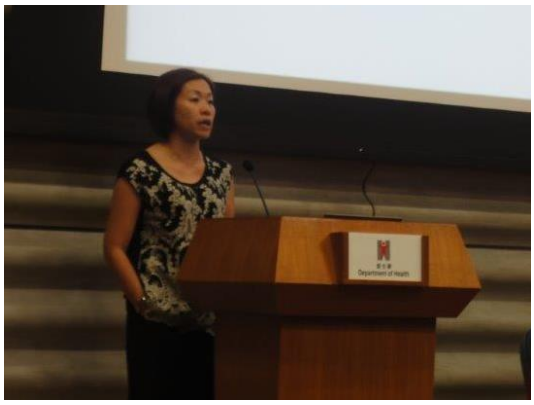
Following the Drug Office briefing, the Regulatory Affairs Taskforce also took the opportunity to have a sharing session with members on good practices in preparing NCE and change of registered particulars dossier. Members of the Taskforce shared their experience in providing commonly requested supplements and performing quality checks on the dossier that will facilitate the application review. Over 80 members attended the briefing and found the information very useful.



Ms. Annette Chiu, Chair of the HKAPI Regulatory Affairs Taskforce.



Ms. Elaine Tang, Member of the HKAPI Regulatory Affairs Taskforce.



Ms. Karen Yuen, Member of the HKAPI Regulatory Affairs Taskforce.

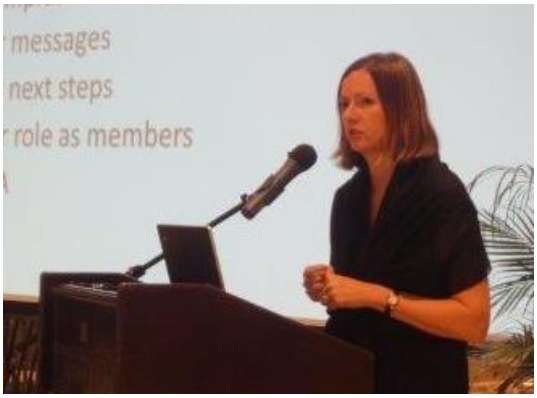
Over 80 representatives attended the Drug Office briefing and HKAPI sharing session.

Members' Briefing on Health Technology Assessment (HTA)

The Health Outcomes Taskforce, led by Ms. Sally Storey, HKAPI Board of Directors, was set up in March to work with all relevant stakeholders to ensure that any health

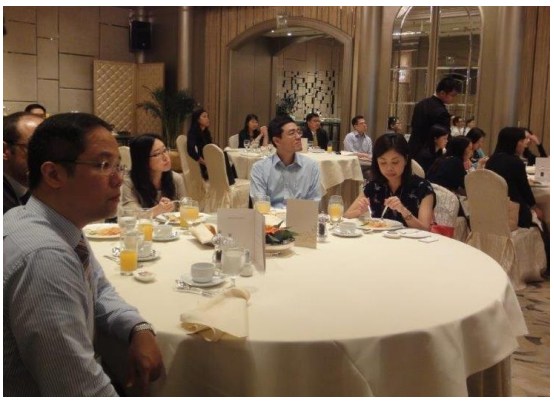
technology assessment systems introduced are simple, effective, transparent and timely in their development and implementation. A member meeting was organized on 22nd July to update members on the current development of HTA in Hong Kong and the work carried out by the Taskforce. Ms. Sally Storey first introduced the objectives of the Taskforce and the progress of the work undertaken in the past few months. Learning from other countries' experience in the development of HTA systems and the key principles of good practices in the implementation of HTA systems were also shared with members. Last but not least, the role of member companies and the upcoming roundtable meeting we are going to organize with other key stakeholders, were discussed.

Dr. Sian Ng, President of HKAPI, introduced Ms. Sally Storey and the objectives of the members' briefing.



Ms. Sally Storey presented on the current development of HTA in HK

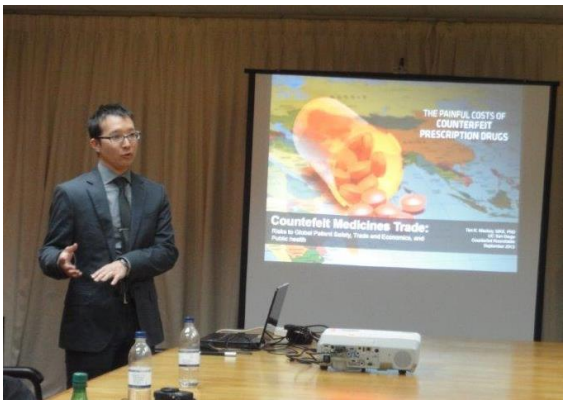
Mr. Roee Shahar, Vice President of HKAPI, thanked members for joining the meeting.



30 members attended the members' briefing on HTA.

Anti-counterfeit Taskforce Meeting

On 26th September, a roundtable discussion was organized by the HKAPI Anti-counterfeit Taskforce. We are pleased to have Dr. Timothy Mackey, Associate Professor at UC San Diego School of Medicine in the Department of Anesthesiology to share with key stakeholders the scale of the counterfeit drugs problem in America and the impact of the problem on global patient safety, public health and economics. Dr. Mackey also outlined a global policy framework that would enable cooperation and coordination to combat this global issue. During the roundtable meeting, key stakeholders involved in fighting against counterfeit medicines in Hong Kong, including the Customs and Excise Department, Department of Health, US Consulate, Hong Kong General Chamber of Pharmacies had a very fruitful discussion where the extent of the problem in Hong Kong and the strategies we employed in combating counterfeit medicine, were discussed.



Dr. Timothy Mackey presented on the costs and risks of counterfeit medicine.

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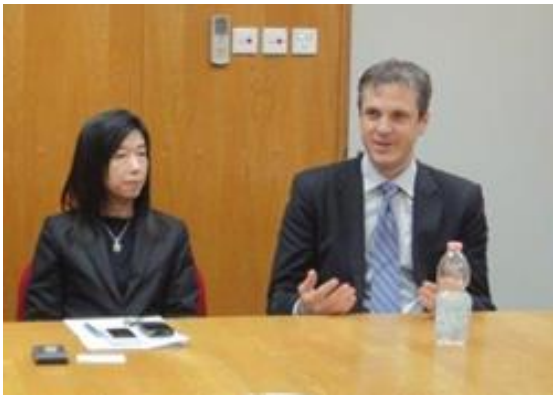
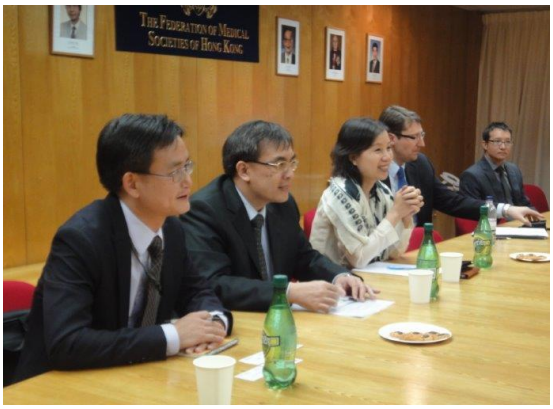


Ms. Linda Woo, Assistant Director (Drug), Department of Health and Mr. Roee Shahar, Chair of the HKAPI Anti-counterfeit Taskforce.



Mr. C. K. Chan from Customs & Excise Department (Second from the left)

Mr. Sam Hui from Hong Kong General Chamber of Pharmacies (Left).

Sharing session with the Drug Office on electronic Common Technical Dossier

A sharing session on electronic Common Technical Dossier (e-CTD) was organized with the Drug Office on 17th July using web conference. Two speakers, Ms. Elizabeth Bricard, Global Regulatory Operations from Sanofi and Ms. Eileen Ang, Head of Regulatory Affairs, Asia Pacific from GSK were invited to share their knowledge and experience in using e-CTD in other Asian countries.

Ms. Elizabeth Bricard first introduced the concepts, structure and technical requirements of e-CTD submission through a video demonstration. A comparison with Non-eCTD electronic submission (Nees) was also made. In the second session, Ms. Eileen Ang discussed the Asean CTD format and shared with the audience the implementation status of electronic submission in various Asia Pacific countries including Singapore, Malaysia, Korea and Taiwan.