HKAPI 香港科研製藥聯會

The Hong Kong Association of the Pharmaceutical Industry

Issue 4 /6 2013 **Apr-Jun 2013**

In This Issue

HKAPI Code of Practice

As an on-going commitment to provide accurate and scientific-based information on pharmaceutical products and to build professional partnerships with our healthcare professionals for the best interest of society, the HKAPI's Code of Practice has been revised and is effective on 1st April, 2013.

Major changes to the Code of Practice included:

- Extending the scope of the Code to cover subsidiaries of the Pharmaceutical companies such as the medical devices arm.
- The provision of scientific information in symposia and congresses.
- Addition of sections on relations with the general public and lay communication Media.
- Addition of sections on interaction with patients' organizations.
- Consolidating and streamlining of operating procedures.

Consultation on Implementation of Clinical Trial Certificate Application Proposal

On 31st May, the Drug Office invited HKAPI members to attend a consultation on the proposed procedures for handling clinical trial certificate applications. In the presentation, Ms. Christine Cheung, Senior Pharmacist, explained in details the definition of clinical trial that will be adopted in Hong Kong, the categorization of the types of clinical trials based on the potential risk associated with the medicine used, the corresponding evaluation which includes full document evaluation and listed scheme that will be undertaken by the authority. The proposed risk assessment approach aims to shorten the overall processing time for clinical trial certificate applications and contribute to the competitiveness of medical research and development in Hong Kong. After the briefing, Ms. Linda Woo, Assistant Director

- May CEO luncheon
- HKAPI Training Program for Medical Representatives
- Asia Partnership Conference of Pharmaceutical Associations
- New HKAPI Member (Apr-Jun)

(Drug) and Mr. Frank Chan, Chief Pharmacist, answered questions raised by members and invited them to provide further feedback and comments on the proposed mechanism and procedures.

Seminar on Track and Trace of Pharmaceutical Products

On 21st May, the Hospital Authority (HA) and the HKAPI jointly organized a seminar on the supply chain modernization process implemented by HA. The objective of the seminar is to enable members to have a better understanding of the track and trace system employed in drug distribution and medication use within HA and how members can collaborate with HA to facilitate its implementation to make the project a success, which ultimately enhances patient safety.

In her presentation, Ms. S C Chiang, Senior Pharmacist of HA, explained the key elements in the track and trace process including bar-code and Mobile Supply Chain Application as well as shared with members the challenges of the project. Ms. Chiang also updated members on the progress of the implementation status among different clusters and more importantly the second phase of the project, which extends the track and trace of batch information for drugs moving from main store to working store. Over 40 members attended the seminar and had a better understanding of the requirements of the track and trace system and the future implementation plan.

Ms. S C Chiang from the Hospital Authority talked about the progress of the supply chain modernization project.

Members exchanged views with HA colleagues on how to collaborate to enhance the track and trace of pharmaceutical products.

Contact Us

Tel: 2528-3061

Fax: 2865-6283

http://www.hkapi.hk/

info@hkapi.hk

Sharing Session on Quality Management System

This year, the Association continues to organize sharing sessions with the Drug Office to share with them regulatory practices employed by international research-based pharmaceutical companies. On 24th April, two speakers from Janssen, J&J Hong Kong Ltd. were invited to give a talk to colleagues from the Drug Office on quality management system and share their experience on inspections carried out by overseas health authorities.

Ms. Teresa Gorecki, Vice President, Global Market Quality, first gave an overview of the inspection process undertaken by the US Food and Drug Administration (FDA) and how company should respond effectively to observations listed on FDA Form 483 and further actions indicated on the establishment inspection reports such as warning letters.

In the second session, Mr. Steven Martino, Senior Director of Policy Management, Enterprise Regulatory Compliance, gave an overview on safety warning, field actions and field alerts as well as the requirements from EMEA and FDA. Quality system which includes the process of investigation, escalation, corrective and preventive actions were also discussed.

Ms. Teresa Gorecki, Vice President, Global Market Quality, Janssen, J&J Hong Kong Ltd.

Mr. Steven Martino, Senior Director, Policy Management, Enterprise Regulatory Compliance, Janssen, J&J Hong Kong Ltd.

Seminar on Effective Management of Clinical Trial Agreements and Personal Data (Privacy) (Amendment) Ordinance

HKAPI Associate Members Dechert and the HKU Clinical Trials Centre jointly conducted a seminar on the Effective Management of Clinical Trial Agreements and Personal Data (Privacy) (Amendment) Ordinance on 28th June.

Mr. Henry Yau, Managing Director of the Clinical Trials Centre at the University of Hong Kong first talked about the key success factors and some models in the management of clinical trial agreements (CTAs). A number of common issues encountered during the negotiation of the agreement, in particular, indemnity, anti-bribery requirements including the U.S. Foreign Corrupt Practices Act (FCPA), UK Bribery Act, fair market value were then discussed. Some practical strategies on expediting the conclusion of master CTAs were also shared with the audience.

In the second session, Mr. Lewis Ho, Partner of Dechert, focused his presentation on the privacy and legal liability issues of conducting clinical trials. He gave an overview on the relevant provisions of the Personal Data (Privacy) (Amendment) Ordinance (PDPO) such as the transfer of personal data exemptions to data protection principles and discussed its impact to the pharmaceutical industry. Interplay between PDPO with other existing confidentiality requirements including Code of Professional Conducts of Medical Council of Hong Kong, electronic health record system to be implemented by the Food and Health Bureau were also highlighted. Over 40 members attended the seminar and found it very useful and informative.

Mr. Henry Yau of HKU Clinical Trials Centre shared his experience in clinical trial management.

Mr. Lewis Ho from Dechert presented on the privacy and legal issues of conducting clinical trials.

Over 40 members joined the seminar.

May CEO Luncheon

A CEO luncheon was orgnaized on 9th May to share with members the structure and reviewing process of the Drug Advisory Committee to enhance communication with the Chief Pharmacist Office. 17 chief representatives attended the luncheon and found it useful in understanding the roles and process of different committees involved in the drug enlistment process and the types of information member companies can provide to better facilitate the process of application.

HKAPI Training Program for Medical Representatives

The HKAPI certification training programme for medical representatives started in April with the enrollment of 87 medical representatives from 21 member companies. The training course consists of 22 lectures and covers an extensive curriculum on different human biological systems, principles of pharmacology and pharmacokinetics, pharmaceutical technology, regulations and healthcare services in Hong Kong. The first lecture of the course focuses on the pharmaceutical industry in Hong Kong and HKAPI's Code of Practice. Dr. Sian Ng, President of HKAPI, discussed with students the recent development and the characteristics of the pharmaceutical market in Hong Kong as well as the roles of medical representatives. In the second session, Ms. Sabrina Chan, Executive Director, explained in details the Association's Code of Practice with emphasis on the recent updates and revisions.

Dr. Sian Ng gave the first lecture on the pharmaceutical industry in Hong Kong.

Ms. Sabrina Chan discussed in details the HKAPI Code of Practice.

87 medical representatives enrolled into the HKAPI training program this year.

Asia Partnership Conference of Pharmaceutical Associations

The Second Asia Partnership Conference of Pharmaceutical Associations was held on 10-12th April in Japan with the participation of 12 Pharmaceutical Associations. Ms. Sabrina Chan, Executive Director of the HKAPI attended the conference on behalf of the Association.

The theme of the conference is to expedite the launch of innovative medicines for the peoples in Asia. During the conference, member associations shared the challenges they faced and explored the solutions to these challenges. Also, the achievements of each working group were reviewed in order to set future directions. The two focus areas identified are open innovation platform and regulatory approval which includes providing more training programs to reviewers, regulatory harmonization as well as mutual recognition of documents and procedures.

Ms. Sabrina Chan presented on the challenges faced by R&D based pharmaceutical companies in Hong Kong.

12 Pharmaceutical Associations from Asia attended the Second Asia Partnership Conference.

New HKAPI Member (Apr – Jun)

HKAPI is pleased to welcome Celgene Limited, HKU Clinical Trials Centre, Howse Williams Bowers, who joined as Full Member and Associate Member in Apr-Jun 2013.

Celgene Limited

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global pharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. Celgene International Sàrl, located in Boudry, Switzerland, is a wholly-owned subsidiary and international headquarters of Celgene Corporation.

HKU Clinical Trials Centre

The Clinical Trials Centre (CTC) is a leading academic clinical research organization established in 1998 under The University of Hong Kong, dedicated to offering one-stop solutions in support of clinical research. CTC is committed to enhancing human healthcare by promoting the quality and efficiency of clinical research through ethical consideration, scientific expertise, quality assurance and education. CTC's main scope of business includes clinical research consultation, protocol development, regulatory and ethics affairs, project management, study monitoring, contract management, budget and payment management, study coordinator support, central laboratory, study drug management, data management, medical statistics, medical writing, and professional training and education. CTC's clientele includes over 150 pharmaceutical, biotechnology and medical device companies worldwide, as well as local and overseas healthcare, academic and contract research organizations. Over the years, it has facilitated over 700 sponsored clinical studies.

Howse Williams Bowers

Howse Williams Bowers is one of Hong Kong's largest independent law firms which combines the in-depth experience of its lawyers with a creative, forward-thinking approach. HWB opened for business during January 2012 with 5 partners and will have expanded to 16 partners and over 90 lawyers and staff by June 2013.

One of HWB's key practice areas is pharmaceutical and regulatory law. The company has successfully defended pharmaceutical companies facing prosecution for statutory offences. HWB have advised on drug trials, multi-jurisdictional distribution agreements, employment contracts and advertisement matters for pharmaceutical companies. HWB advises upon a

broad range of intellectual property matters and represents companies in IP-related litigation. Other core practice areas include corporate & commercial, commercial dispute resolution, insurance, employment and maritime.

The HWB partners and their teams have an excellent reputation for delivering high quality legal advice with a practical and commercial approach to solving legal issues for our clients in HK and beyond.