HKAPI 香港科研製藥聯會

The Hong Kong Association of the Pharmaceutical Industry

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Briefing Session and Meeting of the Bills Committee on the Pharmacy and Poisons (Amendment) Bill 2014

A Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 was set up in March for the Legislative Council members to examine the clauses of the Bill. The proposed amendments to the Pharmacy and Poisons Ordinance arise as a result of some recommendations made by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong to tighten regulatory measures to safeguard drug quality and patient safety. The Department of Health organized a briefing to the industry on 14th April to provide an overview of the key proposed amendments which spans across the entire supply chain, including the regulations for manufacturers, wholesalers, retailer of pharmaceutical products and pharmacists.

On 20th May, the Bills Committee invited the HKAPI to express our views on the Pharmacy and Poisons (Amendment) Bill. The Association supports the legislative amendments put forward by the Food and Health Bureau and agrees that the proposed changes are in line with international standards and practices which can enhance the supply chain of pharmaceutical products from manufacturing, wholesaling, retailing as well as distribution to further protect patient safety. For instance, the requirement of providing written order when purchasing pharmaceutical products is in line with the Good Distribution Practice developed under the WHO and European Commission. Proper documentation can minimize the errors in delivery, wastage arises from wrong orders and hence enhancing drug and patient safety.

Similarly, the proposed amendment which requires each licensed manufacturer to employ at least one Authorized Person (AP), whose responsibility is to certify that each batch of pharmaceutical products manufactured has complied with the Good Manufacturing Practice, also tightens up existing requirements. To qualify as an AP, the person must have at least 3 years' experience in manufacturing pharmaceutical products in accordance with the GMP in addition to the

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qualifications in scientific disciplines.

All these proposed amendments will improve the overall standard of pharmaceutical products supplied in Hong Kong and it is timely to update the Pharmacy and Poisons Ordinance now.

Briefing Session on the Draft Code of Practice for Wholesale Poisons Licence Holders

The Pharmacy and Poisons Board of Hong Kong is conducting a consultation to collect views from stakeholders on the draft Code of Practice for Wholesale Poisons Licence (WPL) holders, which aims to set out the roles and responsibilities of the holders of WPL and the minimum standards in the distribution of pharmaceutical products. The Department of Health has organized a number of briefing sessions on the content of the draft Code, highlighting requirements on the storage facilities for the storing of pharmaceutical products, the procurement, supply, transportation as well as documentation and record of all transactions of pharmaceutical products. Members attended the briefing took the opportunities to clarify requirements such as temperature and humidity monitoring and written order.

Seminar on Counterfeit Medicine Trends and Best Practice in Reporting Suspected Cases

The HKAPI Anti-counterfeit Taskforce, a multipartite platform linking Customs and Excise Department, Department of Health, the Consumer Council, professional associations and the industry to combat counterfeit medicine, has organized a seminar for members on 20th June to share with them the latest counterfeit situation in Hong Kong and in the region.

Ms. Sabrina Chan, Executive Director of HKAPI, started the seminar by introducing the objectives and members of the Anti-counterfeit Taskforce and gave an overview of the strategies in fighting against counterfeit medicines in Hong Kong. Mr. Matthew Mak, Assistant Superintendent, Intellectual Property Investigation Bureau of Customs and Excise Department presented on the current situation of counterfeit medicines in Hong Kong and enforcement actions at various levels including cross border stoppage, cooperation with Hong Kong Post, mainland enforcement authorities and international cooperation to tackle counterfeit medicines. After an update of the recent development in Hong Kong,

Mr. Samson Chiu, Director of Asia Pacific Region, Pharmaceutical Security Institute (PSI) discussed regional trend in counterfeit medicines, the support provided by PSI in initiating enforcement actions with the authorities and the challenges they face in combating the counterfeit issue.

Last but not least, Mr. Ivan Ho, Member of the Anti-counterfeit Taskforce shared with member companies the procedures and best practice in identifying and reporting suspected counterfeit medicines cases to the authorities and HKAPI.

Ms. Sabrina Chan from HKAPI introduced the objectives and recent work of the HKAPI Anti-counterfeit Taskforce.

Mr. Matthew Mak from Customs and Excise Department gave an update on the counterfeit situation in Hong Kong.

Mr. Samson Chiu from PSI presented on the regional trend of counterfeit medicines.

Mr. Ivan Ho from the Anti-counterfeit Taskforce shared with members the best practice in reporting suspected counterfeit cases.

Masterclass on European Union Regulatory Affairs

On 23rd May, the HKAPI and the University of Hong Kong invited expert speakers from the Organization for Professionals in Regulatory Affairs (TOPRA) to provide a one-day training on European Regulatory Affairs to our members and the

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pharmacists from the Drug Office. The training started with an introduction of the objectives of the organization by Ms. Lynda Wight, Executive Director of TOPRA. Mr. Bob Clay, Consultant of Highbury Regulatory Science Limited, then gave an overview of the key systems and players in the European Union (EU) legislative framework and the drug approval procedures in EU. As a very experienced assessor in the UK regulatory agency, Ms. Sue Harris shared with the participants the common pitfalls in EU submissions and illustrated with a lot of examples on how to avoid them and work effectively with the regulatory authority.

In the afternoon sessions, Mr. Clay discussed the new development in EU regulatory affairs in the areas of clinical trials, pharmacovigilance, paediatric regulation framework as well as the new initiative of Early Assess to Medicine Scheme. Last but not least, Ms. Harris talked about the herbals and traditional medicines regulations in EU and the experience in their registration.

A wealth of knowledge and experience was shared during the training and members found the course very useful and they gained a better understanding on their regulatory affairs work.

Group photo of representatives from TOPRA, HKAPI and the Drug Office.

Ms. Lynda Wight, Executive Director, TOPRA introduced the aims and objectives of TOPRA.

Mr. Bob Clay, Consultant, Highbury Regulatory Science Limited.

Ms. Sue Harris, Unit Manager, Product Lifecycle Assessment Team, MHRA.

The training was organized under the HKAPI Regulatory Affairs Taskforce, led by Ms. Annette Chiu (Left).

Members took the opportunity to raise questions to the expert speakers.

HKAPI Training Program for Medical Representatives

The HKAPI certification training programme for medical representatives started on 3rd April this year with the enrollment of 79 medical representatives from 20 member companies. The training course comprises 22 lectures and covers an extensive curriculum on key human biological systems such as digestive system, circulatory and respiratory system, principles of pharmacology and pharmacokinetics, pharmaceutical technology, pharmaceutical regulations and healthcare services in Hong Kong. Ms. Sabrina Chan, Executive Director of the HKAPI, delivered the first lecture of the course which focuses on the pharmaceutical industry in Hong Kong and HKAPI's Code of Practice. An overview of the healthcare service environment including the public and private healthcare sector, the recent development in the pharmaceutical market, key regulations related to clinical trials, drug registration and enlistment were discussed. In the second part of the lecture, the HKAPI's Code of Practice, the Prevention of Bribery Ordinance and the global trend in the development of code of conduct governing the pharmaceutical industry were explained in details.

Ms. Sabrina Chan gave the first lecture on the pharmaceutical industry in Hong Kong.

79 medical representatives enrolled into the training program this year.

Seminar on ASEAN Economic Community - Spotlight on the Pharmaceutical Industry

HKAPI Associate Member Baker & Mckenzie organized a seminar on ASEAN Economic Community (AEC) and key harmonization issues with a focus on the pharmaceutical industry on 9th April.

The seminar began with Dr. Deunden Nikomborirak, Research Director, Thailand Development Research Institute presented on the latest development of AEC, its impact on ASEAN countries and their trade partners as well as the opportunities and challenges for investment. In the second session, a panel discussion focused on ASEAN pharmaceutical harmonization process and product registration submission requirements was moderated by Ms. Peerapan Tungsuwan, Partner of Baker & McKenzie. Panelists included Baker & McKenzie AEC Pharmaceutical Taskforce members: Ms. Prim Uditananda, Regulatory Affairs Manager; Mr. Ren Jun Lim, Associate and Ms. Minh Ha Vu, Senior Regulatory Practitioner. The panelists discussed the current status of the implementation of ASEAN Common Technical Requirements (ACTR), ASEAN Common Technical Dossiers (ACTD) and the Medical Device Directive. Country specific submission requirements and the impact of the harmonization of technical dossiers were also highlighted.

About 40 representatives from our member companies attended the seminar and the seminar has enriched their knowledge and understanding on the AEC and the registration submission requirements in ASEAN countries.

Ms. Isabella Liu, Partner, Baker & McKenzie gave a welcome address and chaired the seminar.

Dr. Deunden Nikomborirak, Research Director, Thailand Development Research Institute discussed the key AEC harmonization issues.

Panel discussion moderated by Ms. Peerapan Tungsuwan, Partner, Baker & McKenzie.

About 40 members attended the seminar.

Asia Partnership Conference of Pharmaceutical Associations

The third Asia Partnership Conference of Pharmaceutical Associations (APAC) was held on 10th - 11th April in Japan, Ms. Sabrina Chan, Executive Director of the HKAPI attended the conference on behalf of the Association. APAC aims to develop a strategic roadmap for collaboration among industry, academia and government with the mission to expedite the launch of innovative medicines for peoples in Asia.

During the conference, pharmaceutical associations around Asia worked together to address the challenges of regulatory convergence and made recommendations on how to speed up approval of innovative drugs in Asia as well as developing a pan-Asia drug discovery open innovation platform.

Seminar on Written Order Solution and FDA UDI updates

With the proposed requirement of placing orders of pharmaceutical products in written form in the Code of Practice for wholesalers and retailers and the recent update in U.S. Food and Drug Administration’s regulations on Unique Device

Identifiers (UDI), the Association invited GS1 Hong Kong to give a talk on the written order solution and the latest development in the regulations of UDI.

Mr. K C Leung, Assistant Training Manager of GS1 Hong Kong, explained the details of the UDI regulations which require manufacturer of medical devices to develop UDIs for all devices and place it on label as well as submitting the information to FDA's Global Unique Device Identification Database to enable the public to search for standardised information for applications such as electronic health records and devices registries.

In the second part of the seminar, Mr. Steve Tse, Solutions Manager – ezTRADE of GS1 Hong Kong shared the experience of a solution platform in electronic ordering process and demonstrated how the platform can be extended to cope with the written order requirements while minimizing the impact on the current business work flow.

Mr. K C Leung from GS1 Hong Kong presented on the regulation and the compliance requirements of UDI.

Mr. Steve Tse from GS1 Hong Kong demonstrated the functions and workflow of the written order solution.

Ms. Anna Lin, Chief Executive of GS1 Hong Kong further elaborated on the written order solution.

Around 40 full and associate members attended the seminar.

New HKAPI Members (Apr – Jun)

HKAPI is pleased to welcome CUHK Clinical Research Management Office & Phase I Clinical Trial Centre and Linklaters who joined as Associate Member in Apr-Jun 2014.

CUHK Clinical Research Management Office & Phase I Clinical Trial Centre

Faculty of Medicine of the Chinese University of Hong Kong (CUHK) is internationally reputable on cutting-edge medical research. Clinical Research Management Office (CRMO) is a joint office of New Territories East Cluster (NTEC) and CUHK to enhance the quality standard, efficiency and compliance of conducting clinical trials. Phase I Clinical Trial Centre of CUHK is located at Ward 11EF of the Prince of Wales Hospital. The centralized state-of-the art facilities as well as experienced research personnel strengthen the capacity, compliance and patient safety in early-phase studies.

Linklaters

As one of the leading global law firms, Linklaters undertakes the most important and challenging assignments for the world's leading companies, financial institutions and governments, helping them to achieve their objectives by solving their most complex and important legal issues.

We have been long established in Asia, with offices in Beijing, Shanghai, Hong Kong, Tokyo, Singapore, Seoul and Bangkok, and approximately 350 lawyers. Hong Kong houses our Asia regional headquarters, with lawyers practising Hong Kong, English and US law.

Our Asia offices combine local and international staff providing the benefit of local language skills, cultural awareness as well as familiarity with local business practices and the regulatory environment within each jurisdiction. Our ability to overlay our international experience provides our clients with a thorough understanding of the commercial risks present in each Asian jurisdiction.

We promote the sharing of expertise across our network, ensuring that clients receive a consistent level of service irrespective of location or the lawyers involved. Few firms match our commitment of ensuring our clients in Asia receive the highest global standards of service and expertise.