HKAPI 香港科研製藥聯會

The Hong Kong Association of the Pharmaceutical Industry

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HKAPI's Mission Statement and Strategic Directions

Since the forming of the new Board in April, Board members have been working on reviewing the mission statement of the Association, developing a Board charter that spells out core values and objectives of the Board and formulating the strategic directions for 2016-2018.

The new Mission Statement **"*To drive the expedient access of innovative healthcare solutions for the people of Hong Kong and Macau with high ethical standards*"** broadens our scope from pharmaceuticals to healthcare solutions, from Hong Kong to Macau and recognizes the importance of upholding our industry's quality standards as well as the experience of our member companies in providing patient support programs in addition to supplying effective medicines. To achieve our mission and objectives, Taskforces will be revamped.

New HKAPI representations in Government bodies and Universities

The following Board members and the Executive Director were recently appointed to represent the industry in various Panels and Committees.

Mrs. Margaret Rumpf, President of HKAPI
Accreditation Panel Member, Department of Health, The HKSAR

Dr. Sian Ng, Vice President of HKAPI
Member, Strategic Advisory Committee, Phase 1 Clinical Trial Centre, the Chinese University of Hong Kong.

Ms. Sabrina Chan, Executive Director of HKAPI
Appointed member, High Level Steering Committee on Anti-Microbial Resistance, The HKSAR

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Member briefing on the Macau guidelines on the importation of NCE

Macau Health Bureau has recently issued some new guidelines on the importation of new chemical entity to Macau. The Regulatory Affairs Taskforce of the HKAPI has met with the Pharmaceutical Affairs Division to clarify questions raised by members and a briefing was then organized for members in May. During the briefing, members of the Taskforce shared with colleagues the scope of the new regulation, detailed documentation requirements such as CPP, expert evaluation reports, risk management report, Asian clinical trial data for import license application.

The Taskforce also reminded members the submission requirements for named-patient importation and the approval procedure for advertising materials to be used in Macau.

In the coming term, the Regulatory Affairs Taskforce will liaise more closely with the Macau health authorities to get timely update on changes in regulations.

Ms. Sabrina Chan, Executive Director of HKAPI, introduced the members of the Taskforce.

Ms. Karen Yuen, Regulatory Affairs Taskforce Lead (Left) and Ms. Elaine Tang, Taskforce member.

Members of the Regulatory Affairs Taskforce, (from left) Mr. Donald Chong, Ms. Fiona Yuen and Ms. Susanna Yim.

Over 80 members attended the briefing and clarified their questions with the Taskforce members.

Development of Trade Single Window in Hong Kong: Consultation Session for HKAPI

The Government plans to set up a Trade Single Window (SW) as a central information technology platform for the one-stop lodging of all trade documents to facilitate trade declaration and customs clearance. In order to brief all the concerned stakeholders and solicit their views on the proposal of Single Window, the Commerce and Economic Development Bureau (CEDB) organized a briefing session to members of HKAPI on 28th June. The briefing was chaired by Ms. Karen Yuen, Regulatory Affairs Taskforce Lead. Mr. James Wong, Senior Superintendent (Single Window) of the CEDB first gave a brief introduction of the operation of the SW, its benefits to the trade community and the government as well as the implementation timeline.

As most of our member companies have their distributors handling the import and export of pharmaceutical products on their behalf, representatives from our distributors expressed some of their concerns including the feasibility of pre-lodging of shipment information as some information may not be provided on time. Members also took the opportunity to clarify issues such as the platform for post-shipment amendments and the potential impacts of mis-reporting on customs clearance. Together with colleagues from the Customs and Excise Department as well as the Department of Health, CEDB clarified questions raised by members and will consolidate and take into consideration of their views and suggestions.

Ms. Sabrina Chan, Executive Director of HKAPI, thanked the CEDB for organizing the consultation session for HKAPI members.

Ms. Karen Yuen, Regulatory Affairs Taskforce Lead, chaired the briefing and facilitated the discussion.

Mr. James Wong, Senior Superintendent (Single Window) of the CEDB.

Mr. Eric Shum, Senior Systems Manager (Single Window), of the CEDB.

Mr. K.K. Tse, Staff Officer (Single Window), Customs and Excise Department.

Mr. Y.F. Yeung, Acting Senior Pharmacist (Drug Import and Export), Department of Health.

Progress of the Oncology Innovation Study Group

With the participation of 14 member companies, the Oncology Innovation Study Group (OISG) was established since 2015 with the objectives to identify the gaps on different aspects of a cancer control plan in Hong Kong from prevention, screening, diagnosis, treatment to palliative care and more importantly to provide recommendations to improve cancer care in Hong Kong.

The OISG has invited experts in oncology including oncologists, clinicians, representatives from NGOs and patient groups to join the expert panel to advise on the project approach, provide an alternate perspective from the angles of NGOs, patients, academia and clinical groups and recommend potential relevant solutions.

Good progress has been made and phases one and two of the study have been completed. Consultants were commissioned to produce a quantitative research report comparing cancer care in Hong Kong with some benchmarking countries to

identify gaps in Hong Kong as well as a final report on Hong Kong's cancer strategy based on a horizon scan of international best practices and stakeholders' interviews. In the upcoming months, the findings and recommendations of the reports will be communicated to key stakeholders including the government, Hospital Authority, healthcare professionals and patient groups.

HKAPI Office Relocation

The HKAPI is pleased to announce that we have moved to the following new office location from 1st July, 2016.

Room 906-7, 9/F., K. Wah Centre, 191 Java Road, North Point, Hong Kong
香港北角渣華道 191 號嘉華國際中心 9 樓 906-7 室

All telephone and fax numbers remain unchanged.

Board members visited the new office.

Board of Directors meeting held at HKAPI office

HKAPI Training Program for Medical Representatives

The certificate training course organized by HKAPI for medical representatives from member companies started in April. The program comprises 22 lectures which cover a wide range of practical topics including the functions and abnormality of major human biological systems, principles of pharmacology and pharmacology of different kinds of drugs including Corticosteroids, Cardiovascular and CNS Drugs. An overview of the pharmaceutical industry, regulations and healthcare services in Hong Kong are also provided in the course.

The first lecture, conducted by Ms. Sabrina Chan, Executive Director of HKAPI, focused on the pharmaceutical industry of Hong Kong and the HKAPI Code of Practice. Ms. Chan gave an overview of the key pharmaceutical regulations in Hong Kong and highlighted our mission, objectives and the work of various

Taskforces under the HKAPI. In the second session, Ms. Chan discussed in details the Association's Code of Practice and shared the latest development of code of practice and compliance in the Asia Pacific region as well as globally.

Ms. Sabrina Chan shared with students the strategic directions and the work of HKAPI.

72 medical representatives enrolled into 2016 HKAPI training program.

New HKAPI Members (Apr – Jul)

HKAPI is pleased to welcome Actelion Pharmaceuticals Hong Kong Limited which joined as Full Member, as well as New β Innovation and Nutricia Clinical Nutrition (HK) Co Ltd. which joined as Associate Member between April and July.

Actelion Pharmaceuticals Hong Kong Limited

Actelion is a leading biopharmaceutical company focused on the discovery, development and commercialization of innovative drugs for diseases with significant unmet medical needs. It has subsidiaries in over 30 countries, covering all major pharmaceutical markets worldwide. Our Mission is to strive to treat more patients with ground-breaking therapies. This mission inspires and motivates us.

Actelion's strategy is designed to create value by leveraging the Company's many strengths. These include its global leadership in the field of pulmonary arterial hypertension (PAH) therapy, a strong and effective worldwide specialty commercial organization, a highly productive discovery capability and a unique company culture that focuses on delivering innovative medicines that improve patient's lives.

New β Innovation

New β Innovation Limited is dedicated to developing advanced life-saving Hemoglobin-based Therapeutics. Our scientific experts have employed the latest technologies and innovative approaches to find health solutions for unmet medical needs.

We also have on-going collaborations with top universities worldwide on various research projects. We have successfully patented our protein preparation technology in various countries.

Nutricia Clinical Nutrition (HK) Co Ltd.

NUTRICIA is founded in 1901, based in the Netherlands, specialized for delivery of evidence-based, specific nutrition to patients of all ages, from infants to the elderly, we pioneer nutritional discoveries that help people live longer, healthier lives. We are leading in the field of advanced medical nutrition globally, our business is rapidly expanding in the world, by now our business has covered 55 countries.