BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

0

26 June 2013 | Influencers | By BioSpectrum Bureau

Founded in 1968, the Hong Kong Association of the Pharmaceutical Industry (HKAPI) has 71 members, which includes the 20 top global pharmaceutical companies. HKAPI's member companies supply over 70 percent of the prescription medicines in Hong Kong.

The association's mission is to enhance the public health of Hong Kong citizens by making innovative new drug therapies available. To accomplish this, the association makes recommendations to public health policy makers on behalf of its members.

Ms Sabrina S K Chan, executive director, Hong Kong Association of the Pharmaceutical Industry (HKAPI), Hong Kong, shares her thoughts on current challenges faced by pharmaceutical companies in Hong Kong and the changes required in regulatory approval process. Here are the excerpts:

What is the total number of members of your association? What is the eligibility to become a member of your association?
We have a total of 71 members, among which 39 are full members, 30 are associate members and two are affiliate members. In order to obtain a full membership, which is given to companies engaged in R&D of pharmaceuticals, a company should also manufacture in accordance with good manufacturing practice and quality control protocols. Companies whose business

is primarily the manufacture of generic products are excluded from membership. On the other hand, companies, which qualify as full members but do not yet have a product in the Hong Kong market, are given affiliate membership. Associate membership is extended to companies engaged in providing services to the pharmaceutical industry.

What is the size of pharmaceutical industry of Hong Kong?
The Hong Kong pharmaceutical market is around $7 billion (HK$ 55billion) and the country is trying to focus more on this industry. It is making efforts to get expertise in regulatory approval and is looking at adopting new initiatives and policy. Hong Kong has a highly ageing population and the demand of healthcare is also substantial. Therefore, the objective of the association is to expedite regulatory environment in the country.

What is the role of HKAPI when it comes regulatory norms in Hong Kong?
We have 30 associate members companies along with 38 R&D based multinational companies as our members. These firms provide services to our full members, including the Hong Kong Science Park and law firm.

We also address public safety concerns about counterfeit and unregistered drugs, sharing the international experience of manufacturing quality drugs, knowledge of good manufacturing practices (GMP) and pharmacovigilance reporting system. We also provide education to patients on healthcare and treatment options by partnering with healthcare professionals, such as doctors and pharmacists. The association has actively participated in events of the health community and presented its views to the public on different health issues such as healthcare financing, drug policy and undesirable medical advertisements ordinance amendment bill.

What are the challenges of registering a pharmaceutical product in Hong Kong?
There is not very much clarity in classification of pharmaceuticals and its definition in the law book of Hong Kong and in its dosage form and format of the product, whether it is substance or mixture of substances. For example, in vitamins and minerals some vitamins have to be registered as drugs, including vitamins A, D, E, H and K that exceed in dosage, vitamins B1, 2, 3 that are greater than 0.2 mg. In many countries of the world a special category for nutritional product may not require certificates for registering these product as pharmaceuticals.

What steps can be taken by the authority and the industry to have a better registration process?
According to the industry views, organization responsible for drug approval can overcome the challenges by creating a dedicated team for different aspects of pharmaceutical regulations. The industry has to adopt a sophisticated system instead of a simple one. There needs to be a team to specialize on pharmacovigilance and a dedicated qualified person should be appointed in Hong Kong office.

Hong Kong can also migrate to computerized system for drug registration, for import and export licensing system and allow E-submission. Besides, more concern on safety and quality and more reference documents should be required. The country needs much sufficient manpower and to take lot of new initiatives. The industry has to adopt the changes, get access to clear communications with authority and provide better training to the team to serve the initiatives.