*BFAC Paper 2/06*

# First Meeting of the Business Facilitation Advisory Committee

## *Agenda Item 3 : Concerns and Proposals from the Hong Kong Association of the Pharmaceutical Industry*

### Purpose

This paper briefly sets out the major concerns and proposals of the Hong Kong Association of Pharmaceutical Industry (HKAPI) on the regulatory activities affecting the business environment of the pharmaceutical industry. Representatives of the HKAPI will stage a Powerpoint presentation at the meeting to supplement their views.

### Background

2. The Hong Kong Association of the Pharmaceutical Industry (HKAPI) was formed in 1968. Currently the HKAPI has 53 full members which are all international companies, including the world's top 20 pharmaceutical firms, engaged in the research and development of pharmaceuticals. Its member companies provide over 70% of the prescription medicines in Hong Kong. The major businesses of the HKAPI members are sales and marketing of pharmaceutical products, registration and conducting clinical trials, local distribution as well as importing and exporting of pharmaceutical products.

3. The HKAPI was formed to provide maximum information on all matters relating to the Hong Kong's pharmaceutical market to its members. Another major role of the HKAPI is to improve the relationship between its member companies and the government, all healthcare related societies and the community. The HKAPI also provides suggestions on healthcare policies to improve the overall well being of Hong Kong people.

4. In 2002, the HKAPI had raised their concerns on various problems they encountered in the registration and licensing of health and pharmaceutical products in Hong Kong and made suggestions to improve the business-friendliness of the regulatory framework of the pharmaceutical industry. Under the steer of the former Business Advisory Group, the

Administration has implemented some improvement measures to streamline the current regulatory processes. Some notable achievements cover streamlining the licensing of import and export of pharmaceutical products, acceptance of testing results of new pharmaceutical products conducted by certified laboratories, streamlining the law drafting process for approval of new drugs, and streamlining the meeting schedule of the Pharmacy and Poisons Board and its related Committees.

**Concerns and proposals of the HKAPI**

5. In their recent discussions with the Economic Analysis and Business Facilitation Unit (EABFU), the HKAPI has expressed concerns on various issues affecting the business environment of the pharmaceutical industry. Their major concerns are –

(a) delay in registration of new pharmaceutical products;

(b) lack of linkage between pharmaceutical patents and drug registration;

(c) outdatedness of the Undesirable Medical Advertisements Ordinance and related Codes of Practice on Advertising Standards issued by the Broadcasting Authority; and

(d) non-transparent drug policy concerning the Hospital Authority Drug Formulary.

Their major concerns and initial proposals to tackle the problems are set out in the ensuing paragraphs.

**Delay in registration of new pharmaceutical products**

6. The HKAPI considers that the current registration process of new drugs in Hong Kong is too time-consuming and cumbersome. It normally takes at least nine months to complete the registration of a new pharmaceutical product under the existing system. This lags far behind the standard of Singapore where a new drug already registered by benchmark agencies such as the Food and Drug Administration of the United States or the European Medicines Evaluation Agency of European Union can be registered for sale in 45 days only. The HKAPI is concerned that the delay in new drug registration will hinder the introduction of new medicine in Hong Kong and affect the industry's competitiveness in attracting investment.

7. In Hong Kong, the sale and supply of pharmaceutical products are regulated through a system of registration and classification prescribed in the Pharmacy and Poisons Ordinance (PPO) (Cap. 138). All new pharmaceutical products are required to be registered with the Pharmacy and Poisons Board (PPB), a statutory body established under the PPO, before they can be sold in Hong Kong. Applications for registration of pharmaceutical products are assessed by the PPB on the basis of their safety, efficacy and quality. The Registration Committee of the PPB examines and approves applications for registration. The manufacturers or importers of the new pharmaceutical products are required to submit valid Certificates of Pharmaceutical Product (CPP) to substantiate that their products fulfill the above criteria. The Poisons Committee determines the categorization of approved pharmaceutical products. The PPB will endorse the recommendations of both Committees. The Registration Committee, the Poisons Committee and the PPB meet in consecutive months throughout the year for product registration. Legislative amendments to the Pharmacy and Poisons Regulations and the Poisons List Regulations are necessary. The PPB is empowered to make the legislative amendments subject to the approval of the Legislative Council.

8. The HKAPI considers that some of the existing regulatory requirements are non value-added and there is scope to rationalize and streamline the following requirements/processes, hence saving the lead time required for drug registration –

(a) Instead of requiring two CPP to support a New Chemical Entity application, the Department of Health should align with the practice of other advanced countries which requires only one CPP;

(b) The Administration should consider whether the reviews by the Registration Committee, the Poisons Committee and the PPB can be held concurrently to save time;

(c) As the current legislative process usually will take about three to six months, which may be further held up during the summer recess of the Legislative Council, the Administration should review the relevant legislation to see whether legislative amendments are genuinely necessary to enhance the efficiency of the drug registration processes. It is also worth exploring whether it is feasible to replace the current positive vetting procedure (i.e. to move a motion at LegCo to amend the relevant Regulations) by the negative vetting procedure (i.e. to table an

amendment regulation at LegCo and the Regulation will come into force in 28 days if no objection is received from LegCo Members).

**Lack of linkage between pharmaceutical patents and drug registration**

9. The drug registration and patent registration are two separate systems in Hong Kong. The PPB approves registration of new drugs that are deemed to comply with the safety, efficacy and quality requirements. The PPB is not required to scrutinize whether the registration of a new pharmaceutical product would involve infringement of the patent right of another product. Patent protection is provided for by the Patents Ordinance (Cap 514). Patent registration is administered by the Intellectual Property Department. Patent owners can seek civil remedies for patent infringement. There is no criminal sanction against patent infringement. The drug registration system is maintained by the PPB in accordance with the PPO. Sale of unregistered drug is a criminal offence.

10. As Hong Kong currently has no patent linkage system to prevent patent infringement, a generic drug may obtain registration approval for marketing before the expiry of the patent of a legitimate pharmaceutical product, thus affecting the business of legitimate pharmaceutical companies.

11. According to the understanding of the HKAPI, each member of the World Trade Organisation has an obligation to instigate a mechanism to prevent and stop patent violation. Most developed countries, including China and Singapore, have either adopted a patent linkage system or implemented complementary measures to protect the patent holders. To safeguard the patent rights of legitimate pharmaceutical companies, the HKAPI considers that a drug should not be registered by the Administration unless it is clear that it does not infringe the patent of another pharmaceutical product, i.e. there should be a linkage of patent considerations with registration of drugs. In addition, the HKAPI considers that the Government should help legitimate pharmaceutical businesses in Hong Kong by facilitating them to have early knowledge of any registration application so that they can decide if there is any infringement of their intellectual property right and start prosecution or civil action early.

12. Besides, the HKAPI considers that the existing wording of the drug registration certificate may give rise to misconception that the registered drug is not patent infringing. The HKAPI considers that the Administration should expedite action to amend the wording of the certificate to make it

clear that the certificate should not be taken to mean anything more than just registration under the Pharmacy and Poisons Regulations.

**Outdatedness of the Undesirable Medical Advertisements Ordinance and related Codes of Practice on Advertising Standards issued by the Broadcasting Authority**

13. The Undesirable Medical Advertisement Ordinance prohibits the advertising of medicines, surgical appliances or treatment of certain diseases or conditions in human beings as specified in Schedule 1 and 2 of the Ordinance in order to prevent the adverse effects of improper self-medication by members of the public. Advertising of pharmaceutical products classified as Part I poison under the PPO through electronic media is further restricted by the related Codes of Practice on Advertising Standards issued by the Broadcasting Authority though these products may be advertised through the printed media. As health food and Chinese medicine may be advertised through the electronic media, the HKAPI considers it unfair to restrict the advertising of western pharmaceutical products through the electronic media.

14. As compared with the regulatory regime in the USA where companies can advertise any approved prescription drug through electronic media subject to certain conditions, the regulatory framework governing advertising of western pharmaceutical products in Hong Kong is considered outdated and restrictive. The HKAPI considers that the Administration should review the relevant legislations and codes of practice, and relax the existing regulatory framework on advertising of western pharmaceutical products to enable the public to have access to information of available products.

**Hospital Authority (HA) Drug Formulary**

15. HA is a major user of pharmaceutical products, representing 70% of the total sale of the industry. In order to list new drugs on the HA drug formulary, members of the HKAPI have been providing new pharmaceutical products for trial use by HA. However, HA generally will take prolonged time to decide whether to include the new drug on the list and the reasons for rejecting any new drugs are not provided to the industry. The HKAPI considers the situation unsatisfactory and opines that the HA should adopt a more transparent policy in this aspect.

16. Individual hospitals may maintain their own formularies which differ from the formulary of the HA Head Office. Even if a drug is listed on the drug formulary of the HA Head Office, district hospitals may not use the drug. The adoption of different formularies by the HA Head Office and district hospitals also make it difficult for the industry to predict demand and to plan the supply of their products. The HKAPI considers that to provide certainty for the industry, the HA should consider standardizing its formularies.

17. HA and the public hospitals have been carrying out regular review of utilization of drugs, resulting in change of drugs to be listed in the drug formulary. However, the industry is not consulted in the process. As the industry has no clear idea of the criteria adopted in drawing up the formulary and is unable to predict demand, it may result in supply shortage or over-stocking in inventory. As any potential change of the drug policy will have great impact on the industry, the HKAPI suggests that the drug listing procedure and criteria should be transparent and representatives of the pharmaceutical industry be consulted or involved in the process.

**Discussion**

18. Members are invited to comment on the concerns raised by the HKAPI and to suggest the way forward to address these concerns.

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