

**Second Meeting of
the Business Facilitation Advisory Committee**

***Agenda Item 2 : Administration's Response to the Concerns and
Proposals from the Hong Kong Association of
the Pharmaceutical Industry***

Purpose

This paper sets out the Administration's response in respect of the comments raised by the Hong Kong Association of the Pharmaceutical Industry (HKAPI).

2. At the meeting of the Business Facilitation Advisory Committee (BFAC) on 14 February 2006, HKAPI presented its concerns and proposals on regulatory activities affecting the business environment of the pharmaceutical industry (BFAC Paper 2/06, copy at **Annex**).

Hospital Authority's Drug Formulary

3. HKAPI indicated that there is a lack of transparency, predictability and consultation in the drug listing process, and that Hospital Authority (HA) should increase such transparency and involve the pharmaceutical industry in the process of developing/reviewing the formulary. HKAPI also commented on the structure for approving of new drugs in the HA. It suggested that to enhance the accessibility of new drugs to patients and to provide more flexibility for doctors to prescribe new drugs based on their professional judgment, the HA should consider the feasibility of revising the current drug listing mechanism by automatically including all new drugs either as general/special drugs within the Drug Formulary, drugs outside the Drug Formulary with safety net or drugs outside the Drug Formulary to be self-financed drugs.

The HA's Perspectives

4. As a responsible public organization, the HA always ensures the cost-effective use of public funds for the benefit of patients. All drug procurement procedures are conducted in a formal and fair manner according to HA guidelines. The Drug Advisory Committee (DAC) of the HA was established by the HA in 1996 as a central mechanism to study and consider the criteria for introducing new drugs in public hospitals. Members of the DAC comprises of public hospital doctors, professors and pharmacists. Applications for the introduction of new drugs by individual hospitals/clinicians will be discussed and assessed by the Committee. If required, expert panels will be formed to further examine the clinical efficacy and safety of new drugs. The DAC systematically appraises new drugs every three months and includes them into the Drug Formulary as appropriate, taking into account changes in scientific evidence, cost effectiveness, technology advances, treatment options, and scope of service provisions etc. The Drug Formulary Committee has been and will continue to update the Drug Formulary every 12 to 18 months. After a process of appraising new alternatives in relations to available drugs, new drugs are added or existing ones removed; there might as well be changes in the categories of certain drugs and the principles of their dispensing.

5. The DAC has introduced 15 new drugs since the implementation of the Drug Formulary in July last year, of which 4 are General Drugs, 7 are Special Drugs and another 4 are Self-financed items. The implementation of the Drug Formulary aims to standardize drug policy and utilization in public hospitals and clinics which in a way provides certainty for the pharmaceutical industry. However, different hospital clusters and hospitals have different mix of dominant patients, hence use of drugs within the Drug Formulary. Flexibility would need to be maintained at the hospital clusters/hospitals for drug purchasing within the Drug Formulary.

6. The HA is committed to making its operation transparent as far as practicable. It is always ready to communicate the decision and findings to the industry in an organized manner to facilitate the latter's planning. As far as the principles and the mechanism of introducing additional drugs are concerned, the HA would remain open-minded and welcome proposals on the way forward from the pharmaceutical industry and society at large.

7. It should be noted that the HA consulted widely on the implementation of the Drug Formulary. A three-month public consultation exercise took place before formal implementation of the Drug Formulary which started in July 2005. The HA has commenced a review of mechanism of the Drug Formulary in May 2006. Members of the public, including the pharmaceutical industry, have been invited to comment on the review which is on-going.

Delay in Registration of New Pharmaceutical Products

8. HKAPI commented that the current registration process of new drugs in Hong Kong is too time consuming and cumbersome and that the Administration should facilitate the industry by speeding up registration and consider measures including –

- (a) requiring only one Certificate of Pharmaceutical Products instead of two such Certificates;
- (b) holding Registration Committee, Poisons Committee and Pharmacy and Poisons Board meetings concurrently; and
- (c) replacing the positive vetting procedure in respect of new drugs with negative vetting procedure.

9. To protect public health, all medicines are required to be registered under the Pharmacy and Poisons Ordinance (PPO) (Cap. 138) before they can be sold in Hong Kong. Applications for registration of pharmaceutical products are assessed by the Pharmacy and Poisons Board (PPB) on the basis of their safety, efficacy and quality.

10. By virtue of the provisions in the Ordinance, the Registration Committee and the Poisons Committee are set up under PPB to advise PPB on registration and drug classification matters.

11. The Registration Committee is tasked to examine whether a pharmaceutical product should be registered by reviewing clinical and technical documents submitted to substantiate the safety, efficacy and quality of the product. If the Registration Committee is satisfied that a particular

pharmaceutical product should be registered, the statutory Poisons Committee will consider how the drug should be classified to ensure its sale is properly regulated. In accordance with the Ordinance, the final registration and classification decisions rest with the PPB, which is required to take into account advice from the relevant Committees.

12. The Ordinance maintains a poisons list which sets out the chemical entities contained in drugs which are subject to relevant sales control. To complete the registration process, pharmaceutical products containing new chemical entities should be entered into the poisons list and this involves a legislative process, and the law presently stipulates that positive vetting by the Legislative Council is required. This process introduces transparency and facilitates further public scrutiny of the registration process.

13. In 2005, around 3800 registration applications of pharmaceutical products were processed. 97% of these applications met the Department of Health's performance pledge, i.e. the process being completed within five months.

Holding the reviews by the Registration Committee, the Poisons Committee and PPB concurrently

14. As explained above, PPB and its two Committees are tasked with different statutory roles, hence the meetings need to be convened in a particular sequence. It is not feasible for the meetings to be held concurrently.

15. In a bid to expedite the registration process, PPB is now convened four times every year to consider registration applications. The dates of meetings of the PPB and its two Committees are made known to the trade to facilitate them in timing their drug registration applications.

16. In view of the trade's concern, the PPB is considering the following in order to speed up the registration process –

- (a) shortening the meeting cycle of PPB and its two committees;

- (b) reducing the time lapse between meetings;
- (c) re-scheduling meetings to avoid possible time lag due to breaks of the Legislative Council; and
- (d) conducting meetings upon receipt of applications for drug registration.

Replacing the current positive vetting procedure by negative vetting procedure

17. On preliminary assessment, changing the currently positive vetting procedure to negative vetting by the Legislative Council may reduce the administrative workload on the part of the Administration. However, this may not necessarily shorten the time taken to complete the legislative process. Legislative amendments are needed to bring about the proposed changes. The Administration will discuss further with relevant stakeholders before taking a decision.

Requiring only one CPP instead of two to support the application of a new drug

18. A Certificate of Pharmaceutical Product (CPP) is issued by the drug regulatory authority of a country to show that the drug concerned is registered in that country. PPB requires two CPPs (i.e. the drug concerned must have been registered in two countries) before the Registration Committee will register the new drug in Hong Kong.

19. The reason for requiring two CPPs is that there have been several cases where a new drug had received approval in only one country but had soon to be withdrawn due to the discovery of serious side effects. One recent well-known example is Wyeth's Rotavirus Vaccine, which was registered in USA but had soon to be withdrawn due to findings of bowel constriction before it had the chance of being registered in a second country. In short, it is for safety reason that two CPPs are required. Other examples in which serious side effects were detected within a short timeframe include Alosetron and Alatrovafloxacin.

The Undesirable Medical Advertisements Ordinance

20. HKAPI commented that it is unfair to restrict the advertising of western pharmaceutical products through the electronic media. As compared with the United States, the regulatory framework governing advertising of western pharmaceutical products in Hong Kong is considered outdated and restrictive.

21. The Undesirable Medical Advertisements Ordinance (UMAO) prohibits/regulates the advertisement of medicines, surgical appliances, or treatment for prevention of or treatment of certain diseases or bodily conditions as specified in Schedules 1 and 2 to the Ordinance, and those of orally-consumed products in respect of health claims specified in Schedule 4 of the Ordinance. The Ordinance is intended to protect the public from being induced by advertisements to seek improper self-medication or treatment, regardless of whether such claims are in relation to evidence-based pharmaceutical products. In other words, the Ordinance seeks to encourage people to seek proper medical consultation if they have such diseases or bodily conditions.

22. Improper self-medication or treatment may result in inadequate, inappropriate or incorrect treatment, the lack of monitoring over any therapeutic or adverse effects of treatment results, thereby endangering of the life of the patients. In determining the diseases or bodily conditions that are to be stipulated in the Schedules, a risk-based approach is adopted, balancing the risk of self-medication or delayed proper treatment and the marketing needs of the trade and product in question.

23. The Administration appreciates that drugs allowed for sale in Hong Kong have already gone through a stringent registration process. However, given the potential health risks associated with the diseases and bodily conditions specified in the Ordinance, the Administration considers that on balance, it is important to regulate relevant health claims to protect members of the public.

24. It should be noted that according to section 5 of UMAO, drug companies are allowed to advertise their products to registered medical practitioners, pharmacists, registered Chinese Medicine Practitioners, etc.

25. We do not have immediate plans to review the provisions in the UMAO at this stage.

Patent Protection of Pharmaceutical Products

26. HKAPI suggested that to safeguard patent rights of legitimate pharmaceutical companies, 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. linkage of patent considerations with registration of generic drugs.

The drug registration system and the patent protection system

27. The registration system for pharmaceutical products and the patent protection system are two separate systems in Hong Kong. The former ensures that pharmaceutical products made available in the local market are safe and efficacious and of good quality. The latter provides protection for technical innovation by granting the inventor a patent for his invention.

28. The Patents Ordinance (Cap 514) and its subsidiary legislation provide for the registration and protection of patents in Hong Kong. Our patent protection system is in full compliance with the requirements under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPs”) of the World Trade Organization (“WTO”). The patent registration system is based on formality examination which is administered by the Intellectual Property Department. An effective patent confers rights on its proprietor to prevent third parties without his consent from, among other things, making, putting on the market, using or importing or stocking a product which is the subject matter of the patent. Patent owners may institute civil proceedings in courts against infringers of their rights, and seek remedies, including an injunction restraining the defendant from any apprehended patent infringement act; an order requiring the defendant to deliver up or destroy any patent infringing product; damages in respect of the infringement; an account of the profits derived by the defendant from the infringement; a declaration that the patent is valid and has been infringed by the defendant.

29. Separately, all pharmaceutical products are required to be registered before sale in Hong Kong. The purpose of this registration requirement is to protect public health. Under the Pharmacy and Poisons Ordinance (PPO) (Cap 138), the Pharmacy and Poisons Board (PPB) was tasked to register drugs complying with the scientific criteria of safety, efficacy and quality. There is no mandate for the PPB to take patent status as one of the criteria in vetting drug applications. The rights of patent owners to civil remedies are not affected by PPB's registration of a drug which is subsequently proven to be patent infringing. It should also be noted that there is no requirement of patent linkage under TRIPs.

30. To ensure patent holders have access to drug registration information, the information on all registered pharmaceutical products are made known through the "Compendium of Pharmaceutical Products". Patent holders could check if their rights have been infringed. To facilitate protection of patent rights established channels, the above information has been uploaded onto the Department of Health's website since October 2001. A rapid search function was introduced on the website in March 2003.

31. Similar to the drug registration system in Hong Kong, those of the European Union (25 countries in total) do not take into account patent.

Patent linkage

32. "Patent linkage" generally refers to the linkage of patent with registration of generic drugs, i.e. a drug should not be registered if it may infringe the patent of another pharmaceutical product. Proposals on "patent linkage" raised by HKAPI in the past, in gist, broadly follow the directions below –

- (a) requiring applicants applying for pharmaceutical product registration to submit a certification to certify non-infringement of third parties' patent rights and to notify the patent holders of their application. If the applicant and the patent holder cannot come to an agreement, the parties may submit the disagreement to the court or to special court appointed experts who will issue an opinion;

- (b) requiring disclosure of information pertaining to applications for registration of generic drugs to patent holders upon receipt of the applications, and to suspend the application process for the purpose of ascertaining whether the drugs in question may infringe patent.

33. The Administration does not consider that registration of pharmaceutical products should be linked to the issue of patent. The drug registration system is established for protection of public health. As there is already a well-established patent protection system in Hong Kong, the drug registration system should focus on the safety, efficacy and quality aspects. In this regard, it is noted that HKAPI's proposals on patent linkage could delay the process of drug registration purely because of patent reasons, and hence affect the availability of drugs.

34. From the patent protection perspective, the proposed patent linkage would in effect give an extra patent protection for pharmaceutical products vis-à-vis other products which are equally protected under our Patents Ordinance. We see no strong reasons to provide for this given that the drug registration system has not deprived patent holders of any protection under the Patents Ordinance.

35. HKAPI requested for disclosing to the public information pertaining to drug registration applications prior to registration by administrative means previously. The PPB has considered this proposal and concluded that PPO and its Regulation contain no provision which empowers the Registration Committee to accede to the request. In light of the commercial confidentiality concerning drug information before its registration, it is a common overseas practice not to disclose drug information by the relevant authorities prior to registration of the drug concerned.

Amendment to the Certificate of Drug/Product Registration

36. The PPB recognized the trade's concern about potential misconception arising from the wording of the Certificate of Drug/Product Registration that the product concerned could be freely sold regardless of any possible patent issue and proposed legislative amendment to address the

concern. The Administration will expedite the action to amend the wording of the certificate to make clear that the certificate is meant to certify that a pharmaceutical product/substance had been registered with the PPB for the purpose of the Pharmacy and Poisons Regulations only.

37. In the interim, the PPB added an additional paragraph to the “Guidance Notes on Registration of Pharmaceutical Products”, to the effect that the applicant should be aware of the issue of possible infringement of IP rights. It also issues letters to all registered medical practitioners and to all those involved in the pharmaceutical trade and industry to remind them that the registration of a pharmaceutical product was only evidence of the product having met the requirements related to its safety, efficacy and quality and carried no implications on the patent issues. Before the legislative amendment exercise is completed, each time an application for registration of a drug is approved and the corresponding certificate of registration issued, a letter with the same reminder effect will also be issued.

Health, Welfare and Food Bureau
Commerce, Industry and Technology Bureau
June 2006

**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.

Economic Analysis and Business Facilitation Unit
Financial Secretary's Office
February 2006