The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

5 August 2008

BY FAX, BY EMAIL & BY HAND
Fax : 2877 5650
competition@cedb.gov.hk

Division 2 of the Commerce, Industry and Tourism Branch
of Commerce and Economic Development Bureau
The Government of the HKSAR
Level 29, One Pacific Place
88 Queensway
Hong Kong

Dear Sirs

PUBLIC CONSULTATION ON THE GOVERNMENT'S PROPOSALS FOR A COMPETITION LAW

We attach our response to the Government's "Detailed Proposals for a Competition Law – Public Consultation Paper" issued by the Commerce and Economic Development Bureau (CEDB) in May 2008.

The HKAPI is a trade association having 42 full members which are all international companies engaged in the research and development of pharmaceuticals. Our member companies provide over 70% of the prescription medicines in Hong Kong.

HKAPI appreciates the opportunity to provide its perspectives on important issues relating to proposed competition laws now raised by the CEDB and we look forward to our continued participation in the legislative process.

Yours faithfully

Sabrina Chan
Executive Director
The Hong Kong Association of the Pharmaceutical Industry

Encl

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

SUBMISSIONS BY THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY

IN RESPONSE TO A PUBLIC CONSULTATION PAPER

"DETAILED PROPOSALS FOR A COMPETITION LAW"

OVERVIEW / EXECUTIVE SUMMARY

In May 2008, the Commerce and Economic Development Bureau of Hong Kong ("**CEDB**") published for public consultation "Detailed Proposals for a Competition Law" ("the **Proposal**").

This document contains the comments of The Hong Kong Association of The Pharmaceutical Industry ("the **HKAPI**") on the Proposal. Relevant background information is provided, in the first part of this document, about both the pharmaceutical industry generally and also the specific regulatory regime within which it operates in Hong Kong, as the HKAPI considers this to be fundamental to understanding the various comments on the Proposal set out below.

At the outset, the HKAPI wishes to emphasize that it is broadly in favour of the introduction of a cross-sector competition law in Hong Kong, as set out in the Proposal. The HKAPI also appreciates the present opportunity provided by CEDB for third parties, like the HKAPI, to comment on the Proposal. That said, as set out in more detail below, the HKAPI does have some concerns about certain aspects of the Proposal, and the effect that it may have on the ability of its members to continue to operate successfully and

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

efficiently in the relevant markets in Hong Kong. These concerns may be summarised as follows:

- innovation is fundamental to the pharmaceutical industry and the proposed competition law should not be applied and enforced in such a way so as to stifle, or reduce, such innovation in the industry;

- whilst the HKAPI welcomes the Proposal that cases will be looked at on a case by case basis, the HKAPI is keen to ensure that the specific regulatory regime within which its members must operate will be taken into account in any analysis of the relevant market(s) and any alleged anti-competitive agreements and practices concerning the industry;

- at the institutional level, whilst the HKAPI welcomes the Proposal that members of the Competition Tribunal will include experts in relevant fields, including relevant commercial expertise (Proposal 16), the HKAPI is concerned that relevant industry experts should also be included in the Competition Commission, for example, an expert on the pharmaceutical industry and the relevant regulatory regime;

- that the provisions of the proposed competition law will be applied in a consistent and non-discriminatory way to all players (both public and private) active in the pharmaceutical industry;

- that the exclusions/exemptions in the Proposal will not operate in such a way as to exclude certain bodies relevant to the pharmaceutical industry (e.g. the Hospital Authority) from the scope of the future Competition Act, thus conferring on them

further competitive advantages in addition to those they already benefit from under existing regulations;

- the HKAPI is in favour of the introduction of merger control in Hong Kong, and submits that it would be most appropriate to provide for this now, rather than some time in the future;

- HKAPI is a not-for-profit organisation and it is presently unclear whether the proposed competition law will apply to such undertakings. HKAPI would like to see this point clarified in the new law.

A table containing a summary of the HKAPI's comments on each relevant part of the Proposal is set out at Annex I to these comments.

Given the special circumstances of the pharmaceutical industry, and in light of the concerns summarised above, the HKAPI considers that it may be appropriate for the Competition Commission to adopt specific guidance relating to the pharmaceutical industry clarifying the application of the proposed competition law to practices in the relevant markets (the adoption of further guidance generally by the Competition Commission is already envisaged in Proposals 25 and 27). Depending upon the content of such guidance, it may also be appropriate for the Competition Commission to adopt a specific block exemption relating to the pharmaceutical industry (Proposal 47).

In summary, HKAPI has no objection to the proposed introduction of a cross-sector competition law in Hong Kong and believes that it will help provide a "level playing field" for business. That said, the pharmaceutical industry is concerned that the existence and enforcement of such a law should neither result in further regulation of a industry that is

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

already extensively regulated nor diminish the ability of its members to compete fairly with both generic and research based manufacturers. The HKAPI would actively support any legislation designed to create a level playing field, especially as between the public and private sectors of the health industry in determining which innovative products are reimbursed by the government for patient use.

The HKAPI hopes that the CEDB will take on board these comments, and incorporate the relevant changes into the Competition Bill. Representatives of the HKAPI remain at the disposal of the CEDB to provide any additional clarification or information that may be required.

A. BACKGROUND

HKAPI & its members

1. The Hong Kong Association of The Pharmaceutical Industry ("**HKAPI**") was founded in 1968 and currently has 42 full members, which are all international companies engaged in the research and development of pharmaceuticals, including the 20 top global pharmaceutical companies. Our members supply around 70% of the prescription medicines in Hong Kong. Further information about the HKAPI, including details of its full, affiliate and associate members, can be found on its website at www.hkapi.hk.

2. The mission of the HKAPI is to ensure patients have expedient access to innovative and effective drugs to enhance better health and quality of life. HKAPI was formed to provide information on matters relating to the Hong Kong pharmaceutical market, to its members. Another major role of the HKAPI is to improve the relationship between

our member companies and the government, all healthcare related societies and the community and to expedient access for the benefit of patients. HKAPI also provides suggestions on healthcare policies to improve the overall well being of Hong Kong people. To highlight some objectives of the HKAPI as follows:

(a) to promote at all times the efficiency of the pharmaceutical industry to ensure that medicinal products of the highest quality be readily available for the prevention and treatment of human and animal disease;

(b) to make every effort to maintain and enhance the reputation of the industry and its contribution to public health and welfare, and to assist and co-operate with Government and other appropriate authorities on such matters;

(c) to promote continued activity in the development of the industry with the co-operation and assistance of the Government;

(d) to affiliate or co-operate with any organised bodies or institutions engaged in medicinal or pharmaceutical scientific research and/or having objectives similar to those of the HKAPI;

(e) to represent the views of the industry in all matters affecting the interests of members of the HKAPI and/or assist in promoting or opposing legislation affecting the industry;

3. Members of the HKAPI are all international companies or companies with international holding companies or offices in other parts of the world where competition laws already apply. Accordingly, the HKAPI and its members are

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

generally familiar with the requirements and policies of competition laws and are compliant.

4. Research-based pharmaceutical companies compete vigorously with each other. Furthermore, the availability of patent and other intellectual property protection encourages innovation and justifies the huge cost of research. The rewards offered to research-based companies under intellectual property laws encourage companies to compete with each other to offer new and improved treatments across the range of life saving to life style drugs and therapies.

5. The greatest economic challenges to the industry come from the Hospital Authority's tendering process (discussed below), pricing, parallel imports, generic substitutions and regulatory hurdles, all of which both raise costs and reduce certainties. Whilst the HKAPI believes that intellectual property right (**IPR**) and competition law can co-exist, it is keen to ensure that the proposed competition law is applied in such a way as to encourage its members to continue to invest in research and development, and therefore not to impose either unnecessary additional regulatory burdens and costs and/or further disadvantages on research-based manufacturers *vis-à-vis* generic manufacturers.

Hospital Authority

6. The Hospital Authority ("the **HA**") is responsible for the management and control of all public hospitals supplying health care services and clinical products in Hong Kong. It manages all government operated hospitals, specialist out-patient clinics and general out-patient clinics. It has some 90% of the market share of all patients in Hong Kong, according to the report of Bauhinia Foundation re. healthcare

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

financing: (see http://www.bauhinia.org/publications/BFRC-HC-FR-EN.pdf). The remaining 10% is held by the 12 private hospitals and general practice physicians in Hong Kong. The HA is, therefore, at a considerable competitive advantage in dictating the prices of suppliers given its dominant position in the market.

7. By way of contrast, (according to HKAPI data) no one pharmaceutical company has more than a 15% market share by value. Accordingly, no member of the HKAPI is in a dominant position or able to exercise any substantial degree of market power.

HOSPITAL AUTHORITY DRUG FORMULARY (HADF)

8. The HA implemented its Drug Formulary ("HADF") in 2005 in all HA operated public hospitals and clinics, i.e. the vast majority of public hospitals and clinics in Hong Kong. The HADF consists of two categories of drugs:

(a) General Drugs - Clinically approved and effective drugs with well established indications that have been widely used in the past (this represents around 85% of drugs in the HADF). Drugs from this group are provided within the standard fees and charges at public hospitals and clinics.

(b) Special Drugs - Drugs that may be used only for specified clinical situations and must be prescribed by specialist physicians if they are to be covered within the standard fees and charges. Drugs in this category are generally newer, more expensive and with variable existing practices in the HA. This category constitutes less than 15% of drugs in the HADF.

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

9. A further category of drugs are self financing items ("**SFI**"), with or without "safety net". The cost of SFI drugs with safety net are shared among the patients, pharmaceutical companies and the government, whereas the cost of pure SFI drugs are fully borne by the patient. However, there is insufficient communication as to what drugs are included as SFI and the conditions on which they will be provided to patients; indeed, patients are generally not given the option to choose a drug with such specialised medical benefits.

10. It seems clear to HKAPI that the assessment of products under the HADF is based upon considerations other than clinical safety and efficacy. In particular, the unequal supply and allocation of HADF approved drugs throughout the HA cluster hospital system results in the inequitable treatment of patients with the same disease.

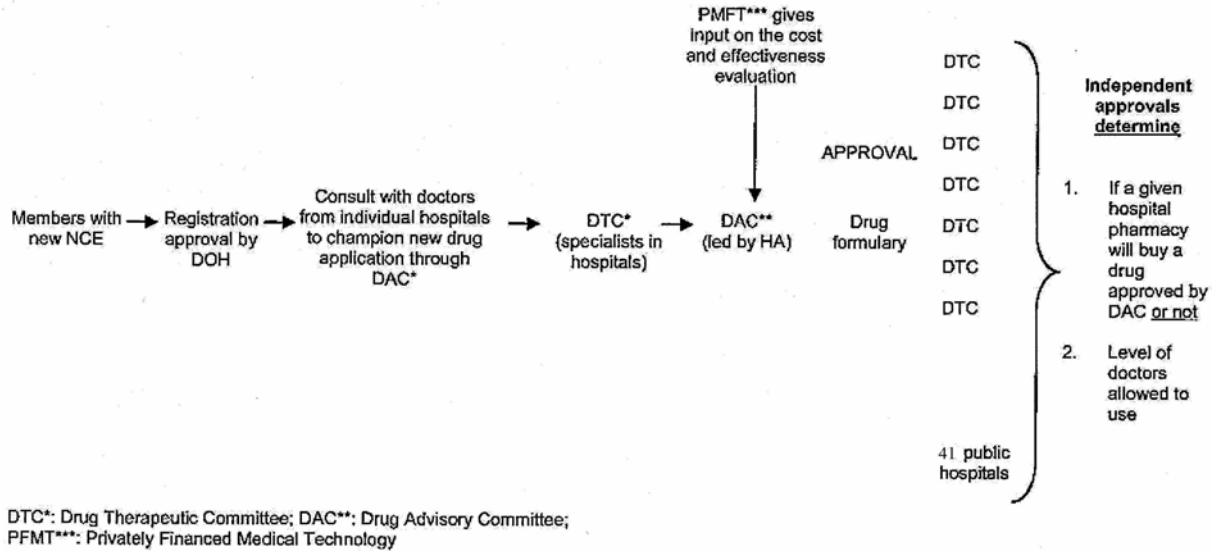
11. The unequal allocation of resources under the HA cluster system means that patients are unfairly discriminated depending upon where they live. In January 2008, the HKAPI presented a position paper on the topic of the allocation of resources among hospital clusters by the HA. The paper noted that patients with the same illness at the same stage of severity are offered different treatment because of the limited availability of new and approved drugs in a given HA hospital. A copy of the paper can be found on the HKAPI website: http://www.hkapi.hk/eng/03/03b/index.htm.

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

HA Drug Formulary Drug Approval Process

12. The current HA Drug Formulary drug approval system for supply to the HA in Hong Kong is overly complicated and time-consuming, thus resulting in substantial delays in making new drugs available to patients and considerable loss in effective patent life for member companies. The process by which drugs are selected for approval by the HA is also insufficiently communicated.

13. The current system of approval includes inefficient overlapping committee roles for the Department of Health (**DOH**), the Drug Advisory Committee (**DAC**) and the Drug Therapy Committee (**DTC**) to assess, re-assess and assess again for a third time the safety and efficacy of a new drug under consideration for approval by the HA. The diagram below contains an overview of this process.



14. Submissions made to the DAC are not (and cannot be) made directly by pharmaceutical companies, but via a doctor. The DTC process can be very slow (2 to 3 years). Information which has to be provided by the pharmaceutical

companies includes efficacy and safety tests (even though the drugs already have market authorisation), as well as cost-effective considerations, for which the companies have to provide technical data and HA budget estimates. The approval rate was only 35% for the period July 2007 to April 2008 according to the internal survey of the Association. Even after DAC approval, it is still necessary to apply to each hospital.

15. The result from the current regime is uneven and unfair access to new drug innovation across the whole HA system because of unfair resource allocations. Unequal treatment results from the need to have individual DTC reviews at each HA hospital, the lack of standardized drug formulary in all HA hospitals, the uneven allocation of resources between hospitals and the lack of recognition of specialty drugs due to lack of resources.

Summary of effect of existing regulations on the relevant markets

16. The HKAPI believes that the effect of the entire existing approval process is largely to lower prices, placing the HA at a significant competitive advantage since HA provides healthcare for 90% of the patients in Hong Kong. In particular, given its position of strength as a buyer on the relevant markets, the HA is able to dictate its terms of supply without any constraint as a result of which many unfair terms are included in contracts. For example, contracts include as much as 30% variants on the quantity of drugs to be provided over time, making it impossible for suppliers to achieve meaningful budgets and efficiencies.

17. The HA also requires companies from time to time to sign additional contracts for drug supplies in addition to and on the same favourable terms as the originally

awarded contract, taking advantage of the low prices to extend the scope of contracts.

B. COMMENTS ON THE PROPOSAL

Effect on innovation

18. Any proper analysis and policy behind the introduction of a competition law in Hong Kong should take into account all the relevant economic factors, in particular that the pharmaceutical industry is a highly regulated industry involving substantial costs and risks which need to be compensated by appropriate rewards. In this regard it is noted that the proposals include no reference to intellectual property rights. Clearly these should be expressly covered in the legislation and/or regulations/guidance, including appropriate exemptions for R&D agreements, technology transfer, patent licences, shared research programmes, multiple studies, etc.

19. Our position is that a competition law that seeks to reduce the innovative advantages gained as a result of pharmaceutical industries investment in R&D should be resisted. At the same time, we note with some concern the proposal to exempt the government and "statutory bodies". This is supposedly on the basis that the activities of the public sector will almost invariably fall under the criteria for exemptions and exclusions. Further details about HKAPI's specific concerns in this regard are set out further below; suffice to say at this point that such a result would likely also have an adverse effect on innovation in the industry.

Relationship between the proposed competition law and the existing regulatory regime relating to the pharmaceutical industry

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

20. Chapter VI of the Proposal refers to the relationship between the proposed competition law and certain existing sector-specific laws, in particular, the Telecommunications Ordinance and the Broadcasting Ordinance. No specific guidance is given on the relationship between the proposed competition law and the existing regulations that apply to the pharmaceutical industry as summarised above; while such existing regulations are not "competition" law regulations they do have a significant impact on the business practices of pharmaceutical companies and therefore how competition operates on the relevant market(s). Further, imposing additional regulations on such an already heavily regulated industry, serves to increase the burden and costs of compliance for the companies concerned.

21. The HKAPI is therefore keen to ensure that the specific regulatory regime in which its members must operate is taken into account in any investigation or review of agreements and/or practices of the industry under the proposed Competition Law. This is not a concern without basis: the European Court of First Instance has, for example, in the past criticised the European Commission for failing to take adequate account of the specific regulatory regime within which pharmaceutical companies must operate[1].

22. Further, the HKAPI notes the Proposal not to provide examples of anti-competitive behaviour in the proposed competition law itself, but for the Competition Commission to adopt separate guidelines on such issues. Whilst the HKAPI

---

[1] See, for example, the judgment of the European Court of First Instance in Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission of the European Communities*, 27 September 2006.

welcomes the proposal to look at alleged infringements of the proposed competition law on a case-by-case basis, it is also keen to ensure that any guidelines also deal with relevant special circumstances. In light of this it may be appropriate to adopt specific guidance for the pharmaceutical industry and the special regulatory regime within which HKAPI's members must operate.

The proposed institutional framework

23. The HKAPI welcomes the statements in the Proposal that the members of both the Competition Commission and the Competition Tribunal should have relevant expertise to investigate and enforce the proposed competition law. However, it appears that for the Competition Commission such expertise is limited to law, economics and SMEs (Proposal 4). On the other hand, in relation to the Competition Tribunal, Proposal 16 specifically refers to the need also to ensure relevant commercial expertise.

24. Given that the Competition Commission will be the body primarily responsible for the investigation and enforcement of the proposed competition law, the HKAPI is keen to ensure that relevant industry experts are also included in this body. The HKAPI considers that this is necessary to ensure that relevant industry considerations are properly understood and taken into account throughout the entire investigation process and without the need to appeal to the Competition Tribunal; relevant industry experts should, therefore, also be included in the case team of the Competition Commission looking at any particular case.

Non-discriminatory application of the proposed competition law

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

25. The HKAPI notes that one of the aims of the proposed introduction of a cross-sector competition law in Hong Kong is to provide a "level playing field" for business. The pharmaceutical industry broadly welcomes the introduction of such a competition law, but is concerned that the new law should be applied and enforced in such a way so as not to result in further (unnecessary) discrimination between the players in an industry that is already extensively regulated, or to diminish the ability of its members to compete fairly with both generic and research based manufacturers.

26. As indicated in the background information set out above, as a result of existing regulation in the industry, there are already significant differences between the way in which public and private sector players in the relevant markets can operate. The HKAPI would actively support any legislation designed to create a level playing field as between the public and private sectors of the health industry in determining which innovative products are reimbursed by the Government for patients' use. Currently, the HA is able to selectively exclude some of the research based pharmaceutical industry's products, thereby artificially lowering the prices of drugs in respect of which vast resources are spent by the industry for the treatment of diseases.

27. Within the meaning of the proposed competition law, the HA is an undertaking engaged in economic activity ***with a substantial degree of market power that has the purpose of effect of substantially lessening competition*** (Proposal 27 of the paper). In theory, therefore, the proposed competition law will apply to the HA as to any other undertaking in a position of substantial market power.

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

28. However, as is clear from the background information set out above, the existing regulatory regime operates so as to give HA certain competitive advantages over other players in the pharmaceutical industry in Hong Kong, including the HKAPI members. The HKAPI is keen to ensure that, in the application and enforcement of the proposed competition law, the HA will be treated in a similar way to private pharmaceutical companies and that it will not be allowed to benefit in any additional way from the introduction of the proposed competition law. In particular, as set out above, the HKAPI believes that the HA is in a position of dominance, i.e. “substantial market power”, and that certain of its practices are “abusive” activities falling within the prohibition set out in Proposal 27.

Application of exclusions and exemptions

29. As indicated above, the HKAPI notes with concern the proposal to exempt the government and "statutory bodies" (Proposal 50) from the scope of the proposed competition law. This is proposed on the basis that the activities of the public sector will almost invariably fall under the criteria for exemptions and exclusions. No definition is provided about what exactly will constitute a government or statutory body, and HKAPI is concerned that the HA may be included in such an exemption. The HKAPI notes that the HA already benefits from its special position resulting from other existing regulations and also that the HA’s role is more akin, in many respects, to that of a commercial undertaking than that of a governmental body. Accordingly, the HKAPI believes that the HA should not be considered a governmental or statutory body falling outside the scope of the proposed competition law.

30. The supposed rationale for excluding Government or statutory bodies is to help ensure that their operations are not affected by "unfounded and misconceived complaint". The proposal takes into account "the fact that Hong Kong has a relatively small public sector and that many services that are provided in other economies by the public sector are in Hong Kong provided by the private sectors". Clearly this rationale is not applicable to the HA.

31. We quote from the European Federation of Pharmaceutical Industries Association's submission dated 30 June 2008 to the European Commission in relation to the pharmaceutical sector enquiry by the European Commission:

"Although the distortion caused by national regulatory regimes was not a concern identified by the Commission in the launch of the Sector Inquiry, any empirical study of the sector that ignores this central feature of the sector will be fundamentally flawed. Indeed, it should be explicitly recognized that in circumstances where competitive conditions on both the supply and demand sides are dictated by national regulation and monopsonies [i.e. monopoly buyers]*, pharmaceutical companies are exposed to customers with tremendous market power."*[2]

32. We further adopt the EFPIA's submissions:

"The pharmaceutical industry is characterised by precisely those features which economists recognise as being strong grounds for non-intervention … Where the

[2] EFPIA (2008), "Submission to the European Commission in relation to the Pharmaceutical Sector Inquiry", p. 9

firm has engaged in substantial, high risk investment, and is enjoying the benefits of superior skill and enterprise, competition law claims should be treated with caution. The competition authorities should be particularly reluctant to interfere.[3]

"Pharmaceutical companies have no market power over pricing or conditions of supply in circumstances where competitive conditions are dictated by state regulation and monopsonies. Accordingly, national authorities have recognised that a position of dominant market power cannot arise at such circumstances."[4]

33. Given the market strength of the HA, the HKAPI submits that the HA should, likewise, not be able to benefit from the other proposed exclusions and exemptions from the proposed competition law. For example, Proposal 46 proposes to exempt agreements where the economic benefits outweigh the potential competitive harm and if they do not afford the undertaking concerned the possibility of eliminating competition in respect of a substantial part of the goods or services in question. Moreover, any such exemption would not apply to an undertaking that has a substantial degree of market power (i.e., a market share of above 40%). Given the relevant market circumstances described above, the HKAPI submits that such an exemption should not be applicable to the HA.

34. Further, Proposal 48 proposes that the conduct rules should not apply to any undertaking entrusted with the operation of services of general economic interest. HKAPI considers that this is also not applicable to the activities of the HA.

---

[3] EFPIA (2008), "Submission to the European Commission in relation to the Pharmaceutical Sector Inquiry", p. 43

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

35. Finally, Proposal 49 proposes that the Chief Executive in Council may exclude conduct from the prohibition of anti-competitive conduct if he considers that there are sound reasons of public policy for so doing. This in our submission requires a holistic approach in determining what is in the public interest, and no further details of how it will be applied are contained in the Proposal. Anti-competitive conduct that discourages innovation by the pharmaceutical industry and allows unfair competition with the private sector is clearly not in the overall public interest.

Merger regulation

36. We note the view that the CEDB considers that it is premature to put forward a firm proposal on the issue of merger regulations.

37. As indicated above, HKAPI members are already subject to competition rules in jurisdictions elsewhere and the potential anti-competitive effects of mergers are likely to have been considered already under such other rules (e.g. in the US or Europe).

38. In any event, the HKAPI considers that the provision of merger rules to clarify the allowable levels of concentration through the provision of formal "safe harbours" would be a useful inclusion. We believe it may be helpful to introduce such rules at an early stage, particularly upon the basis outlined in paragraph 25(a) of Proposal 28, whereby the Commission would only investigate a completed merger if it considers that serious competition concerns were raised.

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

The application of the Proposal to HKAPI

39. Whilst the Proposal contains a relatively wide definition of "undertaking" (consistent with other jurisdictions such as the EC), it is not clear whether it includes not-for-profit organisations. HKAPI considers that the law should generally not apply to not-for-profit organisations, though the Competition Commission should retain the flexibility to be able to apply the law on a case by case basis where relevant.

40. HKAPI itself is a non profit organisation and should not therefore be regarded as an "undertaking" subject to the conduct rules. Clarification on this issue would be welcomed.

C. FUTURE SUBMISSIONS

41. Finally, the HKAPI notes the intention to draft a Bill for consideration. We wish to have the opportunity of reviewing this document at an early stage, and to continue to be involved in the consultation process so that further submissions can be made if necessary.

42. Likewise, going forward, the HKAPI believes that the public consultation process is an important part of the legislative process and that it should also be employed in relation to the further guidance and regulations to be prepared by the Competition Commission. The HKAPI firmly believes that this is the best way to ensure that any guidance published is as helpful and comprehensive as possible.

August 2008

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

ANNEX I

Overview of HKAPI Comments on the Proposal

Proposal Number	The Proposal	HKAPI Comment
General comments on the Proposal		**Effect on innovation** Any proper analysis and policy behind the introduction of a competition law in Hong Kong should take into account all the relevant economic factors, in particular that the pharmaceutical industry is a highly regulated industry involving substantial costs and risks which need to be compensated by appropriate rewards. The proposals include no reference to intellectual property rights. HKAPI submits that these should be expressly covered in the legislation and/or regulations/guidance, including appropriate exemptions for R&D agreements, technology transfer, patent licences, shared research programmes, multiple studies, etc.

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

Proposal 4	The Commission should have a minimum of seven members, including a Chairman, appointed by the Chief Executive. At least one Commission member should have experience in SME matters. The actual number of Commission members appointed could be more than the minimum required so as to ensure that there was a sufficiently large "pool" of members to allow for the efficient conduct of the Commission's business.	**The proposed institutional framework** It appears that for the Competition Commission expertise of the members will be limited to law, economics and SMEs, whilst in relation to the Competition Tribunal members will also have relevant commercial expertise. Given that the Competition Commission will be the body primarily responsible for the investigation and enforcement of the new Competition Law, the HKAPI considers that relevant industry experts should also be included in the case team of the Competition Commission looking at any particular case.
Proposal 23	The conduct rules should apply to "undertakings", which may be defined as individuals, companies or other entities engaging in economic activities.	**The application of the Proposal to HKAPI** Whilst the Proposal contains a relatively wide definition of "undertaking" it is not clear whether it includes not-for-profit organisations. HKAPI is a non profit organisation and it considers that the law

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

		should generally not apply to not-for-profit organisations. Clarification on this issue would be welcomed.
Proposal 25	The Ordinance should not give a list of examples of anti-competitive agreements. However, the Commission should be required to issue guidelines that would give examples of the types of conduct that would commonly be considered anti-competitive.	**Relationship between the proposed competition law and the existing regulatory regime relating to the pharmaceutical industry** The HKAPI notes the Proposal not to provide examples of anti-competitive behaviour in the new Competition Law itself. The HKAPI is keen to ensure that any guidelines also deal with relevant special circumstances e.g. the existing regulatory framework applicable to the pharmaceutical industry. In light of this it may be appropriate to adopt specific guidance for the pharmaceutical industry and the special regulatory regime within which HKAPI's members must operate.
Proposal 27	There should be a general prohibition on an undertaking that	**Non-discriminatory application of the new competition law**

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

	has a substantial degree of market power from abusing that power with the purpose or effect of substantially lessening competition.	HKAPI is however concerned that the new law should be applied and enforced in such a way so as not to result in further (unnecessary) discrimination between the players in an industry that is already extensively regulated, particularly between the public and private sector players. The HKAPI believes that the HA is in a position "substantial market power", and that certain of its practices are "abusive" activities falling within the prohibition set out in Proposal 27. The HKAPI is keen to ensure that, in the application and enforcement of the proposed competition law, the HA will be treated in a similar way to private pharmaceutical companies and that it will not be allowed to benefit in any additional way from the introduction of the new competition law .
Merger Regulation, paragraphs 19 to 25	a) To introduce merger provisions whereby the Commission would only investigate a completed merger if it considered that serious competition	**Merger regulation** The HKAPI considers that the provision of merger rules to clarify the allowable levels

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

	concerns were raised; b) To introduce merger provisions as broadly described above, but to delay the enforcement of such provisions until after a review of the effect of the law; or c) not to include merger provisions in the Bill, but to reconsider whether there might be a need to add such provisions after a review of the effect of the new law.	of concentration through the provision of formal "safe harbours" would be a useful inclusion, and that it may be helpful to introduce such rules at an early stage, particularly whereby the Commission would only investigate a completed merger if it considers that serious competition concerns were raised.
Proposal 44	The Competition Ordinance should apply to all sectors, including the telecommunications and broadcasting sectors. The competition provisions in the Telecommunications and Broadcasting Ordinances that duplicate those in the Competition Ordinance should be repealed.	**Relationship between the proposed competition law and the existing regulatory regime relating to the pharmaceutical industry** No specific guidance is provided in the Proposal on the relationship between the proposed competition law and the existing regulations that apply to the pharmaceutical industry; these have a significant impact on the business practices of pharmaceutical companies and on how competition operates on the relevant market(s).

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

		Imposing additional regulations on such an already heavily regulated industry, serves to increase the burden and costs of compliance. The HKAPI is therefore keen to ensure that the specific regulatory regime in which its members must operate is taken into account in any investigation or review of agreements and/or practices of the industry under the proposed Competition Law.
Proposal 46	An agreement may be exempted from the prohibition on anti-competitive agreements if it yields economic benefits that outweigh the potential anti-competitive harm. A party to an anti-competitive agreement may apply to the Commission for an exemption if it has grounds to believe that such an exemption should be granted.	**Application of exclusions and exemptions** It is proposed to exempt agreements where the economic benefits outweigh the potential competitive harm and where there is no possibility of eliminating competition in respect of a substantial part of the relevant goods/services. Any such exemption would not apply to an undertaking that has a substantial degree of market power (i.e., a market share of above 40%). Given the relevant market circumstances described

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

		above, the HKAPI submits that such an exemption should not be applicable to the HA.
Proposal 48	The conduct rules should not apply to any undertaking entrusted with the operation of services of general economic interest, such as essential public services of an economic nature.	**Application of exclusions and exemptions** It is proposed that the conduct rules should not apply to any undertaking entrusted with the operation of services of general economic interest. HKAPI considers that this is also not applicable to the activities of the HA.
Proposal 49	The Chief Executive–in-Council may exclude conduct from the prohibition on anti-competitive conduct if he considers that there are sound reasons of public policy for so doing.	**Application of exclusions and exemptions** It is proposed that the Chief Executive in Council may exclude conduct from the prohibition of anti-competitive conduct if he considers that there are sound reasons of public policy for so doing. Anti-competitive conduct that discourages innovation by the pharmaceutical industry and allows unfair

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

		competition with the private sector is clearly not in the overall public interest and should not be able to benefit from this exclusion.
Proposal 50	The conduct rules should not apply to the government or statutory bodies. The Government would conduct a review of the issue in the light of actual experience in implementing the competition law.	**Application of exclusions and exemptions** The HKAPI notes with concern the proposal to exempt the government and "statutory bodies" from the scope of the proposed competition law. No definition is provided about the exact scope of this exemption, and the HKAPI is concerned that the HA may be included in such an exemption. The HKAPI notes the HA's role is more akin, in many respects, to that of a commercial undertaking than that of a governmental body. Accordingly, the HKAPI believes that the HA should not be considered a governmental or statutory body falling outside the scope of the proposed competition law. Further, the HKAPI believes that the rationale for this exemption, as set out in the Proposal, is not

The Hong Kong Association of the Pharmaceutical Industry
Unit A, 20/F., Times Media Centre, 133 Wanchai Road, Wanchai, Hong Kong
Tel: (852) 2528 3061/2 Fax: (852) 2865 6283

		applicable to the HA.
CHAPTER VIII	NEXT STEPS	**Future submissions** The HKAPI notes the intention to draft a Bill for consideration and would like to have the opportunity of reviewing this document at an early stage, and to continue to be involved in the consultation process so that further submissions could be made if necessary. Likewise, going forward, the HKAPI believes that the public consultation process should also be employed in relation to the further guidance and regulations to be prepared by the Competition Commission.