Founded in 1968, The Hong Kong Association of the Pharmaceutical Industry (HKAPI) has 51 members, including the 20 top global pharmaceutical companies. Our member companies supply over 70% of the prescription medicines in Hong Kong. Our mission is to enhance the public health of Hong Kong citizens by making innovative new drug therapies available. To accomplish this, one of our association's key roles is to make recommendations to public health policy makers on behalf of our members.

In a letter to our association dated May 4, 2006, The Hospital Authority (HA) asked for HKAPI's feedback on the Hospital Authority Drug Formulary (HADF) policy and its implementation. We are happy to provide detailed feedback in two of the three areas that were identified for review in the letter. Namely, concerning HA's,

1. proposal to change the mode of delivery for self-financed items (SFI) to provide internal dispensing at all 44 hospitals inside the HA network,
2. request for public stakeholder feedback on the Drug Advisory Committee (DAC).

We have no specific feedback in the third area concerning the mechanism of the Drug Safety Net. However, we support HA's plan to collect public feedback on the current system, and we recommend that HA consider adding critically important life-saving drugs to the four products currently on the list.

1. Mode of delivery of Self-financed items:

1.1 In principle, HKAPI supports HA's Mode of Supply proposal for SFI because it a) provides a convenient option for patient to purchase drugs immediately upon receiving a script from an HA hospital, and b) will potentially enhance increased prescription fulfillment by patients. However, we strongly urge that any profits generated from the sale of SFI be used to fund the reimbursement of additional public-sector drug expenditures within HA, as there is currently a large gap between under-funded drug expenditures and actual patient treatment needs.

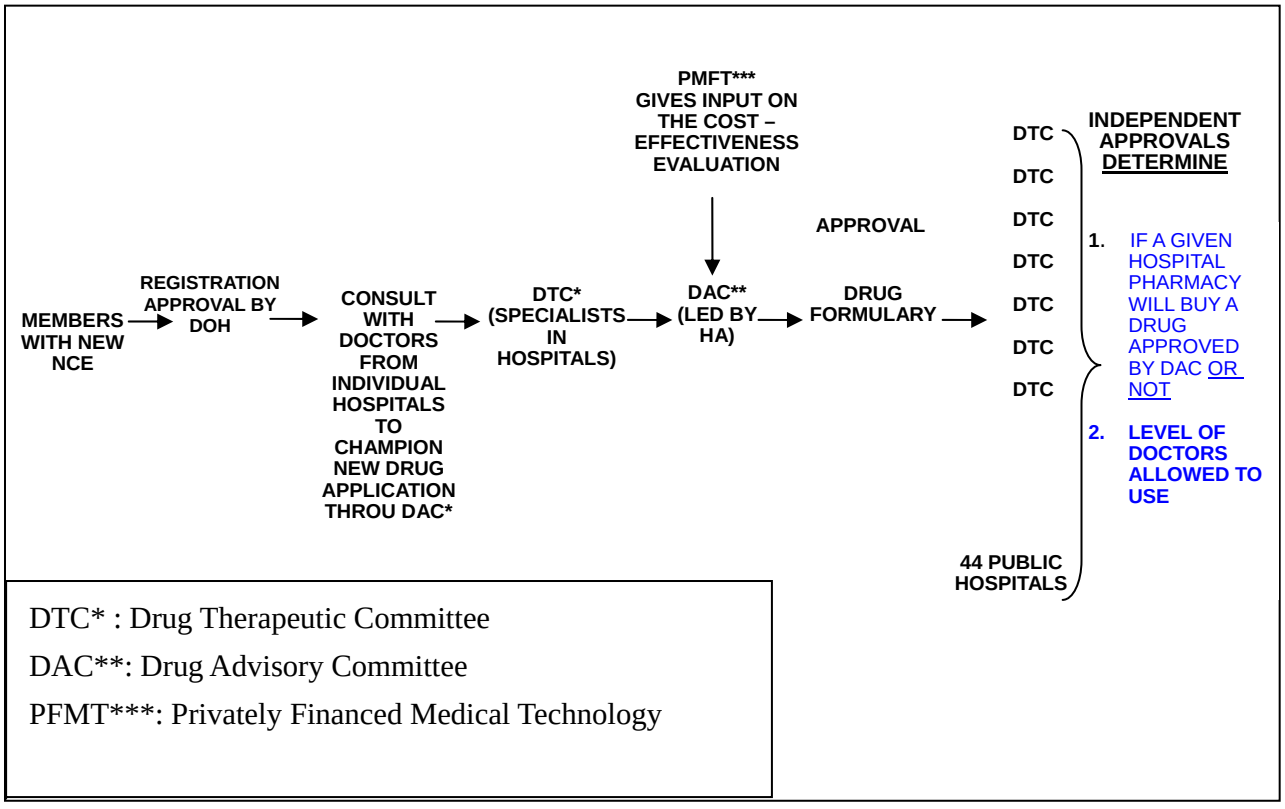
1.2 We also recognize the value that professional community pharmacies provide to patients. We urge HA to consider the use of private pharmacies inside HA institutions, through licensing or some other mechanism, to operate HA dispensaries inside the full hospital network. This approach would provide a viable way to enhance patient convenience and prescription fulfillment at HA institutions, while maintaining fair competition between the private market and the public sector. We strongly believe that it is critical to maintain fair-market economics in line with HA's "corporatization" policy.

1.3 HKAPI's member companies are the key supplier of treatment drugs to HA through a systematic tendering process. If HA's Mode of Supply proposal is implemented, we request that all contract tender proposals from HA clearly specify the estimated proportion (with actual vs. estimated sales amounts to be provided on a regular basis) of the end-user market that SFI items represent. To protect fair competition in the market, we propose a two tier pricing structure with distinct and separate drug supply pricing for SFI and non-SFI items under tender contract with HA .

2. Assessment of Drug Advisory Committee

We believe that making innovative new drugs quickly available to patients who need them is one of the best investments that HA makes in its public-sector healthcare delivery. We propose for the government to put in place a system whereby innovative new drugs can be listed in the public system, and made available to patients who need them more quickly than under the current system.

The current drug approval system is overly complicated and time consuming, resulting in substantial delays to make new drugs available to patients, and considerable loss of effective patent life for our member companies. The diagram below outlines the current approval system:



The above system of approvals includes inefficient overlapping committee roles for DOH, DAC and DTC to assess, reassess and assess again for a third time the safety and efficacy of a new drug under consideration for approval. We request HA to redefine the roles and responsibilities of the various drug approval bodies in its system (i.e. DAC and DTC) to eliminate redundancies and improve operating efficiencies. We believe that there are many areas for improvement which this can be undertaken without impacting the quality of review.

2.1 Drug Advisory Committee:

The role of DAC is to decide whether a new drug can be listed in the central formulary based on objective and scientific criteria. Currently, there is a lack of transparency in the assessment process of DAC, which includes but is not limited to:

- Criteria for selection or rejection
- How data is evaluated/interpreted
- Formal communication on reasons why a given drug may be rejected
- Role of PFMT Committee for drugs considered to be "expensive"

In order to facilitate an efficient and effective drug enlistment and review process, HKAPI proposes for HA to agree to undertake the following, to:

a) provide clear information to HKAPI and its members concerning the above four bullet items. To better allow for New Chemical Entity (NCE) drug submissions to meet the criteria and needs of HA and its DAC reviewers, we request HA to provide HKAPI members with clear criteria for drug assessment reviews under which drug applications will be evaluated. We urge that the enlistment of products onto HADF be based solely on objective clinical endpoints for safety and efficacy. Cost-effectiveness factors or other considerations should only be used to assign drugs among the various categories: general drugs, specialty drugs and SFI.

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b) allow HKAPI members companies to directly submit their own NCE applications to secure enlistment of new products on the HADF, and to be represented or present at DAC reviews of our products. As the originator companies, we are often in the best position, after investing years and substantial sums of money for global clinical development of our pharmaceutical products, to provide any supplemental information or data and to immediately answer any questions raised.

c) provide in writing an explanation why any product is rejected by the DAC within 14 days of such committee recommendation

d) allow member companies to request SFI approval only under expedited review

e) set a reasonable time period for companies to provide samples while DTC reviews are ongoing. Currently, our member companies provide substantial free samples for one year or more, while the time-consuming DTC drug evaluation process is going on throughout the HA network.

f) include patient representation on DAC, so that they, as the end users of HA drugs, can provide feedback in an open and public review setting for drugs under consideration for HADF enlistment

g) clarify the role of the PFMT committee and its influence on the drug approval process

h) provide a regular timetable of scheduled DAC reviews to our members.

2.2 Drug Therapeutic Committees (DTC):

DTCs evaluate the clinical evidence and the "cost-effectiveness' of the drug for the utilization of the drug in individual hospital. This role overlaps with the function of DAC, thus creating further barriers and time delays for the introduction of new drugs. The scheduling for these committees varies greatly from hospital to hospital. Following approval of a new drug by DAC, an additional 1-2 years is normally required to complete additional DTC assessments at all HA network hospitals. This unnecessary third review slows and limits patient access to new drug therapies.

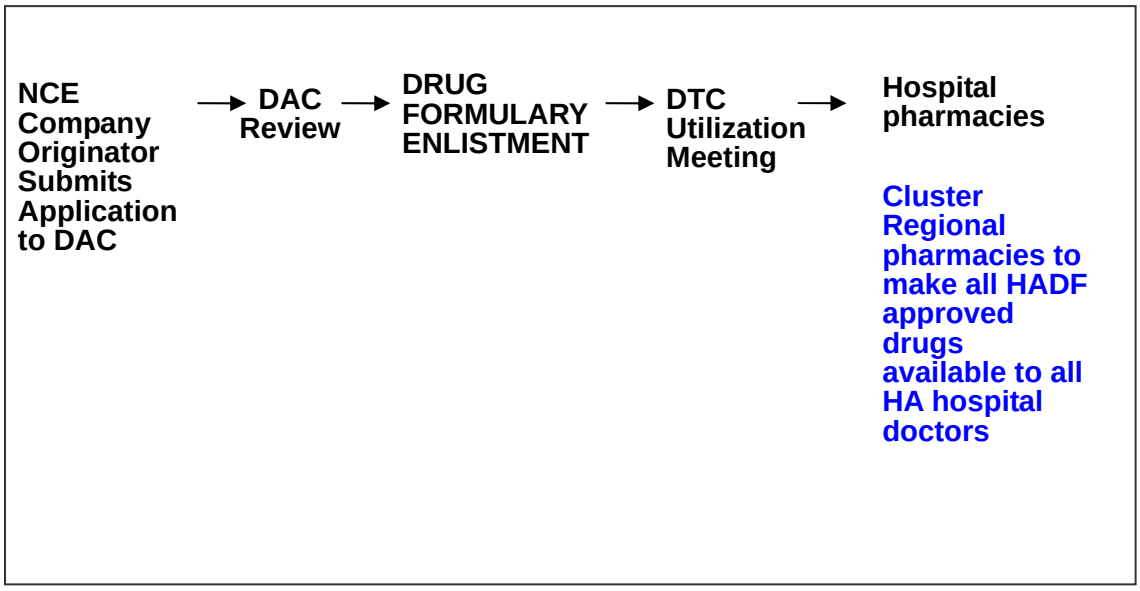
We propose that a better and more proper role of individual hospitals DTCs would be to focus on how much demand there would be for a new drug approved by DAC, and how the new drug should be stocked, utilized and by whom in a specific hospital, subject to its internal conditions and circumstances at each institution.

2.3 Cluster/individual hospitals

We support the right of all doctors of individual HAs to prescribe any drugs listed on the HADF according to their best clinical judgment. If individual hospitals and clinics have a problem to stock all needed HADF drugs at their institution, we recommend for HA to consider developing regional central pharmacies in clusters to supply all needed drugs on the HADF list, so that equitable treatment for patients with the same disease is ensured throughout the HA system.

2.4 Proposal for a new drug approval system

We propose a new drug approval system be introduced, as indicated below:



Within the new system, drug approval policy would be further enhanced by:

- Developing a clear and simplified system (including process timelines for each step in the review process) with transparency
- Establishing clear and objective, scientific criteria for the approval of new drugs
- Allowing companies to directly apply to the DAC for system-wide HADF drug listings
- Recruiting patient representatives to sit on DAC and provide feedback
- Requiring DAC to assign drugs to one of two categories
  - A) those HA will pay for or subsidize (general drug and specialty drugs with indications)
  - B) all others will be given SFI status directly and immediately
- Giving the member companies an option to ask for an SFI designation only with an expedited review process

3. Generic Substitution MUST require the explicit approval of HA doctors:

Recently, a notation has been added to all SFI prescriptions which states: "Generic Substitution Allowed Unless Otherwise Specified." HKAPI opposes the concept of 'drug or therapeutic substitution', unless specifically allowed for and explicitly approved by the prescribing doctor.

The new generic substitution statement allows uncontrolled generic substitution in the community pharmacy trade sector of non-HA approved drugs, which are not included on the HA formulary, and for which no Bio-availability and Bio-equivalence tests have been completed. We believe that this substitution policy is unsafe for patients and should be subject to further discussion and reevaluation with our organization, the pharmacy associations and HA. The current wording also encourages substitution of a product for which a valid patent may be in effect.

In summary, we support the proposal from HA to make SFI products available at HA institutions. However, we urge HA to ensure fair competition with private pharmacies. We request HA to redesign its internal review policies to enhance transparency and operating efficiencies for DAC and individual hospital DTCs (focused on new drug demand and utilization). We propose that member companies be allowed to submit NCE applications to DAC directly, and to receive written explanation for any products rejected under DAC review. Finally, we urge HA to reevaluate its current generic substitution policy to ensure that public safety is fully protected.

We would like to thank HA for allowing us this opportunity to provide our input and feedback on current key issues and opportunities. Our underlying commitment is to positively impact needed patient access to the innovative new drugs our member companies make available in Hong Kong.