#### 衞生事務委員會

#### 待議事項一覽表

(截至2004年5月14日)

建議的討論日期

#### 1. 治療視網膜病變的藥物及方法

在2004年3月8日的事務委員會會議上,陳婉嫻議員 2004年第二季 建議應優先討論此議題。

#### 2. 要求醫生投購保險作為執業條件,藉以就醫療疏忽 或醫治失當向病人作出賠償

在2004年3月8日的事務委員會會議上,陳婉嫻議員 2004年第二季 建議應優先討論此議題。

#### 3. 基層護理服務

在2002年4月8日的事務委員會會議上,政府當局答 2004年第二季 應日後向委員簡介有關提供基層護理服務事官。

#### 4. 長遠醫護融資的研究

政府當局建議的議題。

2004年第二季

#### 5. 醫管局培訓及福利基金的使用情況

2003年6月27日財務委員會會議上,政府當局同意 2004年第二季 每年向衛生事務委員會匯報醫管局培訓及福利基 金的使用情況。

#### 6. 全港醫院設施的長遠規劃

政府當局建議的議題。

2004年第四季

#### 建議的討論日期

#### 7. 安樂死的立法建議

素蔡玉議員建議的議題。

2004年第四季

## 8. 調整1998年4月1日或以後受聘的醫管局職員的每月津貼

2004年3月8日事務委員會會議上,委員要求政府當局及醫管局向他們匯報醫管局如何整體上保持與公務員成本相若。

2004年第四季

#### 9. 《 吸煙(公眾衛生)條例 》的法例修訂建議

在2002年7月8日的事務委員會會議上,政府當局答應進一步評估禁煙對經濟的影響,以及可否將新成立的衞生福利及食物局轄下各部門的資源匯集,以便執行禁煙巡查工作。政府當局會在日後的會議上向委員匯報。

2004年第四季

#### 10. 《中醫藥條例》(第549章)的擬議修訂

立法會申訴部要求事務委員會跟進黃宏發議員提出的建議,即修訂《中醫藥條例》(第549章),准許中醫組就未能根據條例第92條符合替代資格要求而成為註冊中醫的人士的審核結果,進行覆檢。

2004年第四季

#### 11. 檢討公共醫院服務的收費及收費減免機制

羅致光議員建議的議題。

尚待確定

#### 12. 保障藥劑製品的專利權

羅致光議員建議的議題。詳情請參閱附錄。

尚待確定

議會事務部2 立法會秘書處 2004年5月14日



### 民主黨立法會議員秘書處

#### Secretariat of Legislative Councillors The Democratic Party

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立法會衛生事務委員會主席麥國風先生:

## 建議委員會討論藥品註冊對醫藥專利的保護

本人日前收到香港科研製藥聯會及香港美國商會來信,要求 修訂關於藥品註冊的條例,以保障醫藥產品的專利。本人建議將 此列爲事務委員會議程,日後加以討論。

隨函附上有關函件,以茲參考。

二零零四年五月五日



## The Hong Kong Association of The Pharmaceutical Industry

ROOM A, 13/F., TRUST TOWER, 58 JOHNSTON ROAD, WANCHAI, HONG KONG.

TELEPHONE: (852) 2528 3081/2 FACSIMILE: (852) 2865 6233

Thursday, 29th April, 2004

Ms. Maria Kaiser Ng Senior Solicitor for Intellectual Property Department Intellectual Property Department 24th Floor, Wu Chung House 213 Queen's Road East Wanchai Hong Kong

Dear Ms Ng,

#### Re: Hong Kong Pharmaceutical Patent Linkage Protection

Over the past two months our members have been encouraged to see the government, and your bureau/department in particular, actively consider measures to improve patent protection in Hong Kong.

It is the current practice of the Pharmacy and Poisons Board to issue a Certificate of Drug/Product Registration authorizing products "to be marketed for use within Hong Kong' regardless of whether these products violate other legal provisions or rights and interests, and we appreciate your effort to push through regulatory reform by this summer to discontinue this practice and issue registration certificates that will simply state that the product is registered.

However, we still feel strongly that Hong Kong needs to introduce patent linkage to effectively protect innovation. Please see our attached position paper, of which some of you are probably already aware. We look forward to discussing this issue with you further.

With best regards.

Yours sincerely,

Dr. Anthony Chan

President 2004-06

Member: International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Associate Member: Federation of Medical Societies of Hong Kong

# THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY AND THE AMERICAN CHAMBER OF COMMERCE IN HONG KONG

#### Position Paper

#### "Pharmaceutical Patent linkage"

#### The Issue

The "patent linkage" issue relates to the lack of coordination between the system for pharmaceutical patent protection and pharmaceutical product registration.

#### Position

The HKSAR Government should take measures to safeguard pharmaceutical patent rights. Relevant Hong Kong laws should be amended to require applicants to declare the patent status of their products and to reject or revoke product registration applications based on a false declarations.

#### Rationale

In a typical case, an applicant for pharmaceutical product registration is fully aware that its product infringes a valid patent. There is currently no power under the relevant ordinance and subsidiary legislation to require the rejection of such an application or the revocation of a product registration on the grounds of patent infringement. Instead, the relevant right holder must seek remedy through litigation.

Other jurisdictions require the applicant for product registration to check a box declaring that its product does not infringe third parties' rights. The Mainland adopted this cost-effective, self-declaration approach when their pharmaceutical taws and regulations were recently reformed. Hong Kong cannot afford to lag behind the Mainland on this issue. "Patent linkages" have long been established in the US and Canada (EU does not have patent link, though its data exclusivity lasts longer than Hong Kong's, from 6 years in some countries to 10 in others). Singapore has not yet established the linkage, but it is expected to do so under the US/Singapore Free Trade Agreement.

It is the current practice of the Pharmacy and Poisons Board to issue a Certificate of Drug/Product Registration authorizing products "to be marketed for use within Hong Kong". Because a product registered in Hong Kong may violate other legal provisions or rights and interests, this practice should be discontinued and registration certificates should simply state that the product is registered.

Hong Kong has an obligation to safeguard intellectual property rights as a signatory to the Paris Convention for the Protection of Industrial Property and the Agreement on the Trade Related Aspects of Intellectual Property Rights Protection. Hong Kong's continued failure to safeguard pharmaceutical patent rights will discourage investment by international firms and will hamper local innovation. This obviously runs counter to Hong Kong governments stated desire to make Hong Kong the capital of traditional Chinese medicine.



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The Hon. Henry Tang, GBS, JP, Financial Secretary, HKSAR

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Dr. Hon. Lo Wing-Lok, JP

Dr. Hon. David Chu Yu-lin, JP

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P.04