恆隆貿易(香港)公司
HANG LUNG TRADING (H.K.) CO.
A DIVISION OF FULL YING INTERNATIONAL LTD.
新界屯門震寰路9號好收成工業大廈6樓19室
FLAT 19, 6/F., GOOD HARVEST INDUSTRIAL BUILDING,
9 TSUN WAN ROAD, TMTL 232, TUEN MUN, N.T., HONG KONG.
TEL : 2461 9892 FAX : 2455 6190

立法會衛生事務委員會

CB(2)1052/02-03(01)號文件

您們好! 港府現正面對龐大的財政赤字, 特別是醫療開支不斷澎脹, 全體公務員更通過減薪和市民共渡時時艱, 我們相信您一定會關注醫院管理局和政府物料公應處是否有浪費資源和是否有採取合理措施節省開支。事實上, 醫管局只須把現行的招標政策略作收改,(4.1.2 (ii)) 不但可使整個招標程序更公平合理和消除歧視,符合世貿精神, 更可讓市場機制充分發揮效力, 從而節省巨額公帑。這早已是整個醫藥行業的共識。

我們是一家本港的藥品代理商, 我們發現港府現正採用的藥品招標條件的部分條文不但違反世貿有關產地歧視的條例, 同時也違反本港的平等機會的精神。在 GSD(政府物料供應處)和 Hospital Authority 招標條件中第 4.1.2(ii)條, 有選擇性地承認某些國家政府簽發的證明文件(The Marketing Authorization) 包括中國大陸和香港等, 但是條文中不承認由其他國家政府簽發的證明文件, 包括星架坡, 臺灣, 南韓和印尼等大多數國家都不被接納。因此本港大部分的藥品供應商均被拒之門外。做成政府經常因政策(4.1.2(ii))限制, 只有少數藥廠競投, 須以大幅高於市面平均價購賣藥品, 浪費大量資源。

早於二十多年前, 印尼政府及亞州多國已按照 WHO(世界衛生組織)的建議, 實施 GMP 認證管理(Good Manufacturing Practices),嚴格規範管理制藥業, 其管理比香港和中國大陸更加嚴格。 許多的制藥廠爲此, 已作出巨大的投資, 興建新廠房及增加先進生產設備提升生產技術和品質管理, 以符合 WHO 所建議的 GMP 水平。

相反二十多年前中國大陸正在半封閉狀態, 中國政府近 1 至 2 年才開始實施 GMP 改造, 中國大陸是發展中國家, 其藥品生產技術正在起步階段, ,現正試圖和國際接軌 ,

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但至今仍有大部分未達至 GMP 水平, 製劑技術仍相當落後。至於本港制藥業也是近年才開始 GMP 改造, 至今大部分仍未達至世界衛生組織所建議的 GMP 水平, 而且大部分均爲小型藥廠, 未成氣候, 無論是在制藥科技和規模上暫時都無法和亞州多個國家相比。香港大多數都是小規模藥廠, 最多也只不過聘用 1 到 2 個有專業資格藥劑師，更不用說技術改良、研究發展。 擁有專業學位的人員比例甚低。和國際水準相差甚遠。最大的本港藥廠也只不過 1 至 2 仟萬港圓的投資。但是令人難以理解的是香港 GSD 和 Hospital Authority 根據招標條件中第 4.1.2(ii)條香港和中國大陸的藥廠均可被承認, 而像 PT KALBE FARMA 已達至國際水準的先進的大規模藥廠不被承認及歧視。過去十多年來的多次參加公開招標, 均遭受歧視及不平等待遇, 每次均被拒之門外。皆因招標條件中的 4.1.2(ii)條的條款, GSD 和 Hospital Authority 拒絕承認印尼政府(Indonesia 是 WTO 的成員國)簽發的證明文件(The Marketing Authorization)。即使我們的價格和品質都比中標者優勝都被拒之門外, 從未被在考慮之列, 也是因爲 4.1.2(ii)的條款。GSD 和 Hospital Authority 多年來一直沿用該條文, 只要翻看中標紀綠，每次能中標的都是少數的幾家公司, 結果政府採購的價格大部分都遠遠高於市場的平均價, 某些甚至是市場平均價的 1 到 2 倍。

舉例來說, GSD 於 2002 年 6 月 CETIRIZINE TABLET 的公開招標(Ref: A 4110032002), 招標結果是政府以 HK$2,580,600 FIS/HK 的價格向一家本港公司(Zuellig Pharma Ltd)購買上述藥品, 即每粒價格爲$2.04, 衆所周知, 當時市場平均價約爲每粒 $0.6-$0.7。 GSD 和 Hospital Authority 以高出市場價 2 至 3 倍購買上述產品。不但如此, 中標公司,Zuellig Pharma Ltd.在私營市場的供貨價也只是$1.3 至$1.5 之間, 價格也遠遠低於政府購買的價格。 政府是本港最大的買家, 爲何常常要大幅高于市場价購賣藥品? 問題到底出在哪里? 以上事例多不勝數, 如有須要本人可續一列舉。

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現在本港的藥品的採購和招標一直以來都是小圈子遊戲, 大部分的藥品供應商由於4.1.2(ii)條文的規定, 未能參加投標, 嚴重損害了公衆利益。

在全球一體化趨勢下, 許多歐美大型的藥廠已將生產基地移往亞州各國。因此4.1.2(ii)的條件實無存在的必要, 也防礙政府採購價廉物美的藥品, 更使政府只能從少數代理商高價購買藥品。該條文不但對衆多 WTO 成員國構成歧視, 不符合 WTO 有關禁止產地歧視的有關規定, 更嚴重損害公衆利益, 也直接歧視亞州多國, 因此港府有必要配合時代進步修改有關 4.1.2(ii)的條文, 同時承認所有 WTO 成員國簽發的 "The Marketing Authorization".

如果 G.S.D.和醫管局能收改 4.1.2(ii)條文中有關歧視部分, 便能引入競爭, 則醫管局能以市場價格購買藥物, 以每年三十億圓計算, 粗略估計醫管局最少每年能節省十億圓港幣以上。我們認爲善用資源去減省開支要比減薪好。減薪會打擊消費信心, 對本港經濟帶來負面效應。

GMP 是指世界衛生組織建議的生產和操作水平(Good Manufacturing Practices)建議中包括: 應有的生產和品質控制程式; 應有的設備, 應有的科技人員的比例。

本人希望立法會衛生事務委員會能立即跟進有關事宜。

順頌

商祺!

文國基

總經理

2003/1/18

GSD and Hospital Authority Tender

2.4 The Government may purchase from any Tenderer whose Tender has been accepted ("Contractor") any quantities over a period not exceeding 24 months, from the date of the Contract. However, the Government shall be entitled to require the Contractor to supply **additional** quantities of the Goods in excess of the Estimated Quantity specified in the Schedule at the same price as stipulated in Part V. If the excess quantities of the Goods are required by the Government, the Government may inform the Contractor by written notice at an reasonable time as agreed.

2.5 If the actual demand for the Goods **decreases** as a result of unforeseeable circumstances, the Government may by written notice serve upon the Contractor to extend the term of the Contract or to terminate the Contract before it expires.

3. Pharmacy and Poisons Regulations

Tenderers are requested to note that the Goods being offered must have been registered with the Government under Reg. 36(1) of the Pharmacy and Poisons Regulations and allowed to be imported into and freely sold in Hong Kong. **Any Tender which fails to meet the requirements above will not be accepted.**

4. Documentary Evidence

4.1 Tenderers are requested to submit COPIES OF *2 SETS (EACH SET IN SEPARATE FILE) OF THE FOLLOWING WITH THE TENDER FOR CONSIDERATION, OTHERWISE TENDERS MAY NOT BE CONSIDERED :
[*additional 7 sets of such documents may be required for evaluation after tender closing; Tenderers must submit the set of documents **within 3 working days** upon request.]

4.1.1 The Manufacturer

(i) Certified true copy of the valid Pharmaceutical Manufacturer's Licence issued by the national control authority of the country of origin indicating the manufacturer's compliance with Good Manufacturing Practices as recommended by the World Health Organization, or equivalent;
(ii) a copy of the Site Master File of the manufacturer;
(iii) detailed information on the production and quality control facilities;
(iv) qualification and experience of professional and technical personnel involved in production and quality control; and
(v) written permission from the manufacturer to allow representatives of the Department of Health and the Hospital Authority to inspect the manufacturing facilities and processes as and when required.

Tender Ref. : PT/0392/2002
File Ref. : A1/1223/2002

4.1.2 The Goods (i.e. the pharmaceutical products specified in Part V of the Tender)

(i) For those Goods manufactured in Hong Kong , a certified true copy of the Certificate of Drug/Product Registration of the product issued by the Pharmacy and Poisons Board of Hong Kong.

(ii) For those Goods manufactured outside Hong Kong, a certified true copy of the Certificate of Drug/Product Registration of the product issued by the Pharmacy and Poisons Board of Hong Kong and a certified true copy of the **Marketing Authorization*** of the Goods issued by :

(a) the national control authority of the People's Republic of China (PRC); or

(b) the national control authority of a member country of the International Conference on Harmonization (ICH) or of Australia.

(Note : The following are currently ICH member countries - Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, Netherlands, Portugal, Spain, Sweden, U.K. and U.S.A.)

***The Marketing Authorization**, as specified in 4.1.2(ii)(b), may be waived if the product is supplied by an Established Source; however, a certified true copy of the Marketing Authorization from the country of origin must be provided.

(iii) Information on the registration status of the product in any other countries.

(iv) Copies of the complete master formula, method of assay, finished product specifications, stability data with recommended shelf-life and storage condition of the product are required. Evidence showing compliance with appropriate current guidelines of the World Health Organization, where applicable, is required.

(v) A copy of the certificate of analysis of a representative batch of the product.

(vi) A copy of the bioequivalence studies report of the offered product as compared with 'Adalat Retard' brand. The bioequivalence studies must be conducted in accordance with the World Health Organization guidelines.

(vii) Information on the annual sales volume of the product in the country of origin and in other countries in the last three years.

4.1.3 The Supplier in Hong Kong

(i) Certified true copy of the relevant registrations/licences, such as the Wholesale Poisons Licence and the Wholesale Dealer's Licence to supply Dangerous Drugs.
(ii) Details of the product recall system in place.
(iii) Written permission to allow the representatives of the Department of Health and the Hospital Authority to inspect the warehouse facilities and the distribution operations.

5. Tender Sample

5.1 Tenderers are required to submit samples of 300 tablets for the item offered in original packing for evaluation, free of all costs and expenses, to the

Officer-in-charge of Samples, Procurement Division
Government Supplies Department
9/F., North Point Government Offices
333 Java Road, North Point, Hong Kong.

(Working Hours : Monday to Friday - 8:30 a.m. to 5:00 p.m.
Saturday - 9:00 a.m. to 12:00 noon)

BEFORE THE CLOSING TIME AND DATE OF THIS TENDER.

5.2 A receipt for samples duly signed by the Officer-in-charge of Samples should be obtained as proof of delivery. **TENDERERS ARE REMINDED THAT THEIR OFFERS WILL BE JEOPARDIZED IF SAMPLES HAVE NOT BEEN SUBMITTED IN ACCORDANCE WITH THE ABOVE REQUIREMENT.** Samples submitted may not be returned.

5.3 Tenderers are requested to seal their samples in such a manner that they will not become loose or cannot be replaced without breaking the seal.

5.4 A label bearing the following information should be attached to each of the samples :

(i) Tender reference number;
(ii) Company chop;
(iii) Brief description of the item;
(iv) Item number which is identical to the item number indicated in Part V; and
(v) Closing date of the Tender.

5.5 Samples may be rejected if they are not properly sealed in the manner described above.