香港藥學會
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21st November 2012

Dr. Hon LEUNG Ka-Lau
Chairman,
Panel on Health Services

Dear Dr. Leung,

Regulation of- medical treatments/procedures

The recent medical incident that resulted in the death of a 46 year old woman after undergoing a high-risk beauty procedure may suggest the necessity of regulating the beauty salons that offer such services. But upon further analysis, there are loopholes in our regulatory framework that has planted such undesirable incidents.

How can the Government allow premises that processed human blood and tissue do away without a licence or inspection, when such blood or tissues after undergoing certain procedures will be infused back into the patient/client? How can one be assured that the storage condition of the human tissue and blood is suitable for human application after a period of time? In this particular medical incident, if the government has vision to have a policy on health stating that health services are not general commercial commodities and be regulated including the premises, the qualification of the person in charge and staff, and the procedures involved, the incident may have been prevented. In the UK, EU and USA, the designated Authority licenses and inspects organisations that remove, store and use tissue for human application. We should draw references to how human tissues and cells are regulated in United Kingdom[1], European Union[2] and United States of America[3],

The patient/client has consented to undergo the procedure out of ignorance of the high risk involved and also trusted the professional judgement of the medical doctor that performed the procedure. But has the medical doctor done their due diligence to protect the patient? Is the medical profession being over-empowered?

We do believe that each profession has the best knowledge for self-regulation. However, we have seen repeated cases of medical doctors not complying with the laws or good dispensing practices that it is necessary for the Department of Health to step up the inspection of medical doctors, clinics and also beauty salons that employ medical doctors. The Drug Office inspects pharmacies, medicine companies, wholesalers and licenced manufacturers over 10,000 times a year, but less than a hundred medical doctors and clinics a year. Routine inspections by concerned government departments to ensure the preparation and dispensing of drugs are performed according to

professional practice by trained staff or are under professional supervision without compromising the safety of the clients/patients, the public and the staff who are put into contact with these pharmaceutical products. The recent media report about the preparation of oncology drugs not up to Aseptic Dispensing Practices worths following up by the Drug Office under DOH.

For the protection of public health and to enhance patient safety, I attach herewith the position statement of the Pharmaceutical Society of Hong Kong for your consideration.

Yours sincerely,

Mary Catherine Cheng
President
The Pharmaceutical Society of Hong Kong

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November 21, 2012

POSITION STATEMENT ON REGULATION OF HUMAN TISSUES AND MONITORING OF CLINICS AND BEAUTY SALONS

In response to the recent serious medical incident resulting in death of a client/patient after receiving intravenous infusion by a registered medical doctor in a non-regulated premises, the Pharmaceutical Society of Hong Kong would like to make the following announcements:

1. Regulation of the processing, storage and distribution of human tissues and cells used for transplantation and human application:

(i) It is necessary to set up a regulatory framework to ensure the safety and quality of tissues and cells used for human application.

(ii) All establishments that handle, process, store tissues and cells used for human application should be required to obtain a licence from a designated Authority.

(iii) The Authority should be responsible to evaluate the suitability of the license applicant, the designated person in charge, premises and practices in relation to the licensed activities.

(iv) Suitability can be assessed through a process of inspection to ensure that the human tissues and cells are collected and processed in a way that minimises the risk to clients/patients. The collection and processing and storage must be carried out by properly trained professionals and on appropriate premises.

(v) The establishments that process and store tissues must have a system and operating procedures to allow an audit trail in case of an adverse event or incident, in particular involving human.

(vi) The designated Authority should inspect the licensed establishments every year or two based on a risk-based approach.

(vii) Reference can be drawn from regulatory framework in developed countries like UK[1], EU[2] and USA[3] .

2. Monitoring of Medical Clinics and Beauty Salon

(i) Medical doctors should be required to inform the Hong Kong Medical Council or the Department of Health the premises where they carried out their medical practices, including in the beauty salons.

(ii) There should be routine inspections at these premises by the concerned government departments to ensure all legal requirements concerning the purchase, the receipt, the dispensing, the use, the storage, the record keeping, the disposal of drugs and reporting of any adverse events are adhered to.

(iii) Routine inspections by concerned government departments to ensure the preparation and dispensing of drugs are performed according to professional practice by trained staff or are under professional supervision without compromising the safety of the clients/patients, the public and the staff who are put into contact with these pharmaceutical products.

(iv) To protect consumers, only medical doctors with accredited specialty training in the field should be allowed to perform high risk cosmetic procedures.

(v) Consideration should be given for issuances of licenses for beauty salons which perform moderate to high risk procedures. The Department of Health should conduct inspections to the beauty salons to ensure compliance to laws and regulations. Inspection frequency can be based on a risk based approach.

3. Monitoring of other premises providing treatment to patients

(i) The same set of control and regulations that govern the use and handling of pharmaceutical products in retail pharmacies should also apply to all other practice settings like treatment centers, day surgeries, ambulatory service centers, old age homes and even cosmetic and beauty salons where pharmaceutical products are used either for clinical or non-clinical purposes.

(ii) There should be a standard requirements set for these premises to comply with in order for them to continue their annual renewal of their practice pertaining to the use and handling of pharmaceutical products when these involve patients/public.

4. Revamp of advertising laws

(i) Currently, the Undesirable Medical Advertisements Ordinance, Cap. 231 prohibits the advertising of medicine, surgical appliance or treatment of certain diseases or conditions as specified in the Schedules of the Ordinance. It does not allow advertisement even if there are clinical data

and scientific based evidence. It should be revamped to reflect the change of market practice and to ensure its effectiveness in protecting the public.

(ii) For the protection of consumers, untruthful claims (such as slimming) made by the Cosmetics and Beauty Salons should be regulated.

The position paper is issued by the General Council of the Pharmaceutical Society of Hong Kong.

References

1. The Human Tissue Authority (HTA) in United Kingdom aims to ensure that human tissue is used safely and ethically, and with proper consent. It licenses and inspects organisations that remove, store and use tissue. (Source: www.hta.gov.hk)
2. The HTA gives advice and guidance about two laws – the Human Tissue Act 2004 and the European Union Tissue and Cells Directives. These were fully introduced into UK law on July 5 2007, through the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These laws ensure that human tissue is used safely and ethically, with proper consent. The HTA sets standards that are clear and reasonable, which both the public and professionals can have confidence in. (Source: www.hta.gov.hk)
3. In USA, human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product or HCT/P. The Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps under 21 CFR Parts 1270 and 1271. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. (Source: CFR - Code of Federal Regulations Title 21)

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2012 年 11 月 21 日

香港藥學會就規管人體組織及監察診所和美容中心的立場聲明書

對於近期一位顧客/病人接受由註冊醫生進行的靜脈輸液後死亡的嚴重醫療事故，香港藥學會有以下觀點。

1. 規管用於移植及應用於人體的人體組織及細胞之處理，儲存及供應

(i) 有需要成立一個管理架構以確保應用於人體的人體組織及細胞之安全及質素。

(ii) 所有負責操作、處理、儲存應用於人體的人體組織及細胞的企業需要獲得指定機構發出的牌照。

(iii) 指定機構應該負責去評定有關的牌照申請者，指定負責人、經營場所及進行活動或工序的適當性。

(iv) 適當性可以通過一連串的檢查去評估，以確保人體組織及細胞是在保障顧客/病人安全的前提下收集及處理。收集、處理及儲存的活動應在合適的處所由受專業培訓的人員進行。

(v) 負責處理及儲存人體組織的企業必須具有一個系統及操作程序去容許審核及追蹤不良的事件/事變，尤其是涉及病人。

(vi) 指定機構需要每年或每兩年檢查獲發牌的企業，檢查頻率可以根據風險評估而制定。

(vii) 可以參考先進國家,例如英國[1]，歐盟[2]和美國[3]的管理架構。

2. 監察醫生診所及美容中心

(i) 醫生應要通報香港醫務委員會或衛生署關於他們進行診治的經營場地，包括美容院。

(ii) 需要由有關的政府部門在這些經營場地進行例行的巡查，以確保有關藥物的採購、收據、配發、使用、儲存、記錄保存、藥物的棄置及不良反應事件的報告均遵守所有合法的規定。

(iii) 由有關的政府部門進行例行檢查，以確保藥物的預備及配發，是在保障顧客/病人、公眾及直接接觸該藥物的職員的安全之情況下，按照專業的規範，由經培訓的職員或在專業人士的監督下進行。

(iv) 為保障消費者，只有在該範疇接受過公認專業培訓的醫生，才會被容許去進行高風險的美容程序。

(v) 政府應要求進行中等至高風險程序的美容院申請牌照。衛生署須在美容院進行巡查，以確保法律及條例的遵從。巡查頻率可以根據風險評估而制定。

3. 監察其他為病人提供治療的經營場地

(i) 管理藥房藥物的使用及處理的同一套控制及條例，亦當應用在所有其他使用作醫療及非醫療用途的藥物之業務，例如療養中心，日間手術中心，流動的醫療服務中心，安老院，甚至美容院。

(ii) 需要為這些經營場地訂立一套標準的規定去遵守，作為每年延續它們有關藥物的使用及處理的續牌條款。

4. 廣告法例的修改

(i) 目前的不良醫藥廣告條例第 231 條禁止任何藥物、外科用具或治療某種在條例附表中指明的疾病或情況的宣傳廣告。 即使有醫學數據及有科學為基礎的證據，條例也不容許作宣傳廣告。這條例有必要根據市場的改變而進行修改，以有效地保障公眾健康。

(ii) 為了保障消費者，美容院作出的不實聲稱 (例如纖體) 必需要被監管。

此意見書是由香港藥學會委員會發出。

參考資料:

1. 英國「人體組織管理局」致力確保人體組織是被安全及道德地使用和有適當的病人允許。該局發牌及巡查給予負責清理、儲存及使用人體組織的機構。*(Source: www.hta.gov.hk)*
2. 英國「人體組織管理局」提供有關兩項法例: 《人體組織法 2004》及《歐盟人體組織與細胞標準指令》的意見及指引。這兩項法例在 2007 年 7 月 5 日通過《人體組織（人體應用質量和安全）條例 2007》完全地納入英國法例。這些法例確保人體組織是被安全及道德地使用和有適當的病人允許。英國人體組織管理局制定明確合理的標準，讓公眾和專業人士都可以信任。*(Source: www.hta.gov.hk)*
3. 在美國，用作植入、移植、輸液或轉移入接受者的人體細胞或組織，是跟一個人體細胞、組織和細胞及組織組成的產品，或 (HCT/P) 一樣受規管。生物製劑審核及研究中心根據聯邦規章典集第 21 章第 1270 及 1271 部分（21 CFR 1270 & 1271）下規管用於人體細胞、組織和細胞及組織組成的產品. 這些人體組織的例子包括骨頭，皮膚，角膜，韌帶，腱，硬膜，心臟瓣膜，來自體表及臍帶血的造血幹細胞，卵母細胞及精液。
   (Source: CFR - Code of Federal Regulations Title 21)