香港藥學會
The Pharmaceutical Society of Hong Kong
Kowloon G.P.O. Box 73552, Yau Ma Tei, Kowloon,
Hong Kong.
Society's Fax: (852) 2376-3091
E-mail: pharmacist@pshk.hk
Websites: http://pshk.hk

25th October 2012

Dr. KO Wing Man, BBS, JP
Secretary of Health Food Bureau
18/F, East Wing, Central Government Offices
2 Tim Mei Avenue,
Tamar, Hong Kong

Dear Dr. Ko,

Regulation on Human Tissues and Monitoring of Clinics and Beauty Salon

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. I should also be grateful that you pass our humble opinion to the members of the Steering Committee of the Regulation of Private Healthcare Facilities for their deliberation.

Yours sincerely,

Mary Catherine Cheng
President
The Pharmaceutical Society of Hong Kong

c.c All LegCo Health Panel Members
Director of Health

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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 Saloons 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)