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Legislative Council Panel on Health Services
Use of Hydrophilic Polyacrylamide Gel (PAAG) for breast augmentation purpose

Purpose

This paper seeks to give a brief account of the follow-up and investigation actions taken by the Administration in response to an incident recently reported by the Consumer Council about the adverse reactions caused by the use of Hydrophilic Polyacrylamide Gel (PAAG) for breast augmentation and, to brief Members on the measures taken by the Administration to prevent similar incidents from happening.

Background

2. In mid-April this year, the Consumer Council published in its Choice magazine an investigation report on problems caused by the abuse of PAAG injection for breast augmentation. The report cited the information provided by the Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons (HKSPRAS), which revealed that 53 women in Hong Kong had suffered from local or general adverse bodily reactions after receiving PAAG injections for various purposes including breast augmentation, and six of them ended up having their breast(s) removed. The Consumer Council expressed concern over the possible health hazard caused by this new type of injection that has become fashionable in recent years.

3. According to the same report, around 90% of these 53 women received the injections in the Mainland while the remaining 10% in Hong Kong.

PAAG

4. According to international practice, all materials used for plastic surgery (including PAAG) are classified as medical device. PAAG is a transparent, gel-like material, with a combination of 5% of polyacrylamide and 95% of water. It is a material used in plastic surgery that has been approved by authorities for the purpose of dermal filling in the European Union (EU), Canada, Australia, some Eastern European countries and the Mainland, but its use is not allowed in the USA. Our information reveals that PAAG has been

allowed for use as a breast augmentation material in some Eastern European countries and the Mainland only.

Risk Assessment

5. As a material for injection in plastic surgery, PAAG may pose two major types of health hazards. Firstly, the hazard may come from the chemical composition of the material. PAAG is mainly composed of polyacrylamide, which is a chemical formed by the polymerization of acrylamide. Polyacrylamide is non-toxic and generally used for water and sewage treatment, manufacture of cosmetic products or food packaging materials, etc.

6. While polyacrylamide is non-degradable, there may be residues of acrylamide during its production. Studies have revealed that acrylamide may be carcinogenic in animals. In recent years, scientific research has revealed that this chemical substance is also found in most food cooked at high temperature. The World Health Organisation and many developed countries have therefore stepped up study on the public health hazard of acrylamide.

7. The other hazard may lie in the injection process and the body part selected for injection. If things go awry in the injection process (e.g. disinfection procedures have not be followed), complications such as numbness, hematoma, induration, inflammation and abscess may occur at the injection site after injection.

8. A good breast augmentation material should be capable of easy and complete removal from the body after implantation. However, no medical technology now available can assure that PAAG injected into the body can be completely removed afterwards. Besides, PAAG may cause induration, which will make diagnosis of breast cancer difficult.

9. In sum, as there is little evidence about the safety and effectiveness of PAAG being used for breast augmentation, the Administration considers that PAAG is not suitable for such use. In fact, physical fitness should be viewed holistically instead of concentrating on certain parts of the body. It should be achieved through a healthy lifestyle including a balanced diet with adequate exercise rather than simply through breast augmentation. Moreover, normally a significant amount of PAAG has to be used in breast augmentation and before its injection, the administration of analgesic or anaesthetic for local anaesthesia may be required. As such, this whole process may be a medical procedure and involves a certain degree of risk. Members of the public should make sure that such procedures are done by specialists in surgery.

Follow-up Action

10. For cases documented by the HKSPRAS, the DH is currently trying to contact the patients concerned through the Society for follow-up action and further investigation. If any illegal practice (such as illegal medical practice) or breach of the Professional Code and Conduct (such as professional misconduct by medical practitioners) is found in any case, it will be referred to the relevant authority for further action.

11. In order to contact the other affected persons, and for the purpose of effective risk communication, the DH has set up a hotline to collect information from the public directly and answer public enquiry. The DH has also, by way of letters and on its website, notified all local medical practitioners and the relevant health professional bodies of the health hazards arising from the use of PAAG injection for breast augmentation, and invited them to report the relevant cases.

12. As at 21 April, the DH has received a total of 197 telephone enquiries, in which 95 people reported that they had received PAAG injections for breast augmentation. Of the 41 who said that they had experienced adverse reactions, eight said that they received their PAAG injections in Hong Kong. As it is suspected that illegal medical practice is involved in three cases, the DH has referred them to the police, together with the relevant information for follow-up action. Besides, the DH has referred a case involving professional misconduct by a medical practitioner to the Medical Council of Hong Kong for action.

13. In the Choice magazine, it was reported that "some breast augmentation advertising materials contained a claim that PAAG had been registered for clinical use with the health authorities of Hong Kong". The DH has therefore referred the matter to the Customs and Excise Department (C&ED) for investigation under the Trade Descriptions Ordinance. On 13 April, the C&ED seized some 50 bottles of substance suspected to be containing PAAG in a beauty parlour. Prosecution under the above Ordinance is being considered.

14. As information available indicates that most of the affected persons received their PAAG injections in the Mainland, and a review by the Mainland authorities of the approval for the production of PAAG for breast augmentation injection is underway, the DH has also contacted the State Food and Drug Administration and the General Administration of Quality Supervision, Inspection and Quarantine to discuss measures to strengthen the protection of public health of both places. Possible measures will include the suspension of the grant of approval for the production of PAAG and a ban on the use of

PAAG injection for breast augmentation in the Mainland, as well as a ban on its import into Hong Kong, etc.

15. It is believed that through the above measures and more public health education, the public will have a better understanding of the health hazards involved in the use of PAAG for breast augmentation, so as to achieve better protection of public health.

Statutory Regulation

16. At present, the import and use of PAAG is not subject to any direct regulation under existing legislation. Legal advice is now being sought on the introduction of legislative amendment to control the import of PAAG so that importers will be required to keep sale records on PAAG to facilitate any follow-up action by the DH if necessary. Besides, in view of the possible health hazards involved in the use of PAAG, the Administration will also consider introducing a requirement in the proposed amendment to restrict its sale to registered medical practitioners.

17. In addition, a medical devices listing system was introduced in 2004 for manufacturers, importers and wholesalers to apply for listing in a register for their medical devices that meet specific safety, efficacy and quality standards. This will facilitate the Administration in monitoring their uses and carrying out efficient recalls when necessary. The listing system has just been extended to cover Class II/III medical devices. In view of the public concern about the safety of medical devices in the wake of the PAAG incident, we are actively considering expediting the implementation of a statutory system of registration and will accord priority to the regulation of medical devices with higher risk. We will seek the views of the relevant trade accordingly.

Advice Sought

18. Members are invited to comment on the contents of this paper.

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