

For Discussion
on 10 April 2006

Legislative Council Panel on Health Services Monitoring the Safety of Contact Lens Solution

Purpose

This paper outlines the work of the Department of Health (DH) in monitoring the safety of contact lens solution and gives a brief account of the follow-up actions taken by DH in response to the recent public concern over the safety of a brand of contact lens solution.

Monitoring of contact lens solution

2. As contact lens solution is not intended for diagnosis, prevention or treatment of diseases, and does not carry such claims, it is not a pharmaceutical product. Consistent with many places around the world, contact lens solution is classified as a medical device⁽¹⁾ in Hong Kong. The regulation of medical devices in Hong Kong is undertaken by the Medical Device Control Office (MDCO) under DH. One of its key responsibilities is to keep track of information about problematic medical devices for the protection of the users' health through making regular visits to the websites of overseas regulatory bodies, such as the US Food and Drugs Administration and the Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. and by maintaining liaison with manufacturers and suppliers. The DH has also established an effective notification mechanism under which relevant information (e.g. safe use of medical devices) is disseminated promptly to medical institutions and organisations such as the Hospital Authority, private hospitals and medical bodies, which may be users of such devices. The DH also maintains close liaison with local manufacturers and distributors so that information on safe use of medical devices can be conveyed to users as soon as possible and a swift recall of products can be conducted where necessary. Depending on the use condition of the medical devices and severity of the incidents, the DH will make public announcements by way of press releases and press conferences to safeguard public health.

⁽¹⁾ The general definition of medical device is made with reference to the recommendations of the Global Harmonization Task Force (GHTF). The GHTF was formed in 1992, comprising representatives from regulatory authorities and the trade in countries such as the U.S.A., European Union, Canada and Australia, etc .

3. In addition, the MDCO has set up a website (www.mdco.gov.hk) specifically for disseminating information on medical devices, including educational information for the public, the trade and the healthcare professionals. The Office also works to raise public awareness of medical devices and the importance of their proper selection through posters, pamphlets and open seminars.

4. Contact lens solution is regulated by the Consumer Goods Safety Ordinance (Cap. 456) as a consumer goods. According to the Ordinance, if the Commissioner of Customs and Excise reasonably believes that a consumer goods is unsafe, and may cause serious injury to its users, the Commissioner can order its supply be suspended by the suppliers and those already in the market be immediately recalled in a reasonable manner.

Monitoring of microbial keratitis

5. Keratitis is an eye condition in which the cornea of the eye is inflamed. It is not uncommonly seen especially among contact lens users. Patients with keratitis commonly present with eye pain, redness, foreign body sensation, and sometimes fear of light. The condition may or may not have an infective cause. Contact lens-related microbial keratitis is usually caused by bacteria and fungus. Improper lens hygiene practice, such as wearing the lens overnight, smoking and wearing the lens continuously for a long time had been reported previously to be associated with increased risk of contact lens-related microbial keratitis.

6. In February this year, the Ministry of Health of Singapore (Singapore MoH) reported in a press release seven cases of local fungal corneal infections found in January 2006, which represented a marked increase over the monthly average of one to two cases. It was found that the patients were users of contact lens. The Singapore MoH announced later that of the 39 cases of fungal corneal infections reported since last May, 34 patients had used a multi purpose contact lens solution of the same manufacturer.

7. Since last year, the Centre for Health Protection (CHP) of Hong Kong has been undertaking surveillance on contact lens-related microbial keratitis cases which required hospitalization. The number of fungal keratitis cases admitted to public hospitals shows a monthly average of two to three cases.

8. In response to the cases reported in Singapore, the CHP immediately contacted the manufacturer concerned with a view to seeking the latest information. CHP also investigated possible correlation between the product and fungal keratitis cases. The sterility tests performed by the CHP on samples of the products bought locally were negative for fungal infections, indicating there was no micro-organism in the samples.

9. On the other hand, DH has also followed closely developments in Singapore and held teleconferences with Singapore MoH to exchange information. DH has also made direct contact with other places and organisations, including the USA, UK, Germany, Macau and the World Health Organisation, to find out whether there were any cases of fungal keratitis infections among contact lens users. So far, no surge of microbial keratitis cases has been detected.

10. In response to the incident, DH has also met with representatives of the manufacturer, microbiological experts, ophthalmologists, optometrists, the Customs and Excise Department and the Consumer Council to discuss the situation in Hong Kong. DH advised the manufacturer to look into the problem and take necessary measures to protect local consumers. The manufacturer subsequently decided to voluntarily suspend the sale of the contact lens solution in Hong Kong. Despite the negative result of the bacterial and fungal culture undertaken by CHP on some product samples, DH considers the supply suspension was a prudent and precautionary measure, having regard to the fact that cases of fungal keratitis in both Singapore and Hong Kong have been detected among contact lens users using the solution. The manufacturer has also set up a hotline and conducted more in-depth tests of the product. It has also made an offer to its clients for an exchange of the solution for other products.

11. The CHP has written to all local doctors to inform them of the situation. Doctors are advised to be more vigilant when they treat cases of fungal keratitis and refer the cases to ophthalmologists for follow up actions. At the same time, the CHP has requested optometrists and ophthalmologists to step up their efforts to educate their clients about correct use of contact lens and contact lens solutions.

12. DH has also set up a hotline to answer public enquiries and issued press releases to provide guidance to the community on the correct use of contact lens so as to prevent contact lens-related keratitis.

13. Although there is no evidence showing that the recent fungal keratitis cases found in Hong Kong are caused by contamination of contact lens solution in the course of its production, the DH, in light of the public concern over the issue, has stepped up its surveillance on fungal keratitis cases that are possibly related to contact lens solutions and keeps a close watch on the use of the product in other countries through the MDCO. The DH will continue to monitor developments of the case closely and inform the public where necessary in a timely manner.

Advice Sought

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

Health, Welfare and Food Bureau
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