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Legislation of contact lens as medical device

Contact lenses for vision correction are classified under the law as a medical device but the registration is not compulsory. They can still be imported or sold without any restrictions. Under the Supplementary Medical Professions Ordinance (Cap 359), contact lens must be prescribed and supplied on prescription by registered professionals including optometrists or ophthalmologists. Unfortunately, this ordinance only govern the registered professionals and there is not law to control the selling of contact lenses through layman, non-optical store or online shop. Without regulation, the quality of contact lenses could not be assured. In addition, problem may exist if there is a recall of problematic contact lenses as there is no way to trace

Even worse, non-corrective contact lens such as cosmetic contact lens are available freely in the market. As a profession to take care of the eye health of the public, it is important to guarantee the contact lenses are prescribed by registered professionals and the contact lenses are suitable to the patients because improper use of contact lenses may result in corneal abrasion, eye infection, or even permanent decrease in vision. 1,2,3 In addition, the quality of contact lens could only be assured when they are being regulated as the contact lens has to be manufactured and stored under sterile environment to avoid contamination. Moreover, the material used for making contact lenses should allow adequate oxygen to the eyes and the pigments used for cosmetic contact lens must be non-toxic to be used.

Since 2005, the USA has classified non-corrective contact lenses as medical devices to protect public eye health. In recent years, Japan (2008), China (2012) and Canada (2016) have also done so. The UK law also governs the distribution of contact lenses, both corrective and non-corrective contact lenses should be fitted and supplied following a regulated professional's assessment of the patient's suitability. In Hong Kong, the government had started to draft amendments in legislation since Year 2000. Although

this enquiry had been raised in the Legislative Council many times (in Year 2007, 2010, 2016), there is still no much progress. In order to align with the international trend, it is a must to have legislation as soon as possible.

By putting the interest of public at the top priority, we proposed to include all types of contact lenses as a medical device and the registration should stringent as compulsory and the manufacturer must obtain a medical device licence before advertising or selling contact lens in Hong Kong. If someone distribute or import medical devices, they must apply for and obtain a medical device establishment licence (MDEL). In doing so, they are not only providing assurance that the medical devices they sell or import into Hong Kong meet the safety and effectiveness requirements set out in the regulations, but also procedures related to the distribution records; complaint handling and recalls; mandatory problem reporting; and the handling, storage, delivery, installation and servicing of contact lens to be in place to protect the public when a problem with a medical device be identified. Lastly, all contact lens much be prescribed and supplied on prescription by registered professionals. This legislation should cover all parties rather than only governing registered professionals. We are confident that including non-corrective contact lenses (cosmetic contact lenses) to be registered as a medical device compulsively will not place any additional burden on the eye care industry or healthcare systems. By contrast, harmonisation of the provisions governing supply simplifies and streamlines the burden on industry. By regulating all contact lenses, a better protect to patients will be resulted.

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