衞生署藥物辦公室
藥物註冊及進出口管制部
香港九龍南昌街 382 號公共衞生檢測中心三樓

2319 8458

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

電話號碼 Tel. No.:
查詢處 Enquiries (852) 2319 8458
傳真號碼 Faxline No. (852) 2803 4962
本署檔號 OUR REF.: DH DO PRIE/7-30/15

(來函請緊引此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

19 November 2012

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

European Medicines Agency recommends new advice to surgeons on safer use of fibrin sealants Evicel and Quixil

Your attention is drawn to that the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) recommended a number of risk-minimisation measures for the fibrin sealants Evicel and Quixil to minimise the risk of gas embolism when these medicines were applied as spray during surgery.

Fibrin sealants are used in a wide range of surgical procedures to help reduce local bleeding. They can be applied by dripping or spraying the solution onto bleeding tissue, where they form a fibrin clot, stopping bleeding and thereby helping the wound to heal. The solution is currently sprayed using either pressurised air or carbon dioxide (CO_2).

The review of these medicines was initiated following reports of gas embolism occurring in association with the use of spray devices that use a pressure regulator to administer these medicines. These events appear to be related to the use of the spray device at higher-than-recommended pressures and/or in closer-than-recommended proximity to the tissue surface. Following review of all available information, the CHMP concluded that the existing instructions for healthcare professionals on the use of these medicines were not sufficient to minimise the risk of this rare but life-threatening adverse effect, thus a number of new risk-minimisation measures to ensure correct use of these medicines when applied as a spray were recommended including:

- Evicel and Quixil should be sprayed using CO_2 only, instead of pressurised air, because the greater solubility of CO_2 in blood reduces the risk of embolism;
- the product information of these medicines should be updated with clear and consistent advice for healthcare professionals regarding recommended pressure and distance to use during spraying application;
- these medicines should not be sprayed in endoscopic surgery; when used in laparoscopic (abdominal) surgery, care should be taken to ensure that the minimum safe distance from tissue is observed;

- the marketing authorisation-holder for Evicel and Quixil should ensure that these products are used with pressure regulators that do not exceed the maximum pressure required to deliver the fibrin sealant, and that they contain labels stating the recommended pressure and distance.

Please refer to the following website in EMA for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/11/news_detail_001659.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 3 pharmaceutical products registered under the name of Evicel Solutions for Sealant (1ml: HK-61387, 2ml: HK-61386 and 5ml: HK-61369) and all are prescription-only medicines. There is no record of pharmaceutical product registered under the name of "Quixil" in Hong Kong. The Drug Office has not received any adverse drug reaction report in connection with the products. In view of the EMA's recommendation, the matter will be discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 3904 1225 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Ms. Pamela Li)
for Assistant Director (Drug)