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
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BY FAX

17 December 2012

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

Dear Dr. LIANG,

European Medicines Agency 's updated advice on safer use of fibrin sealant spray applications

Your attention is drawn to the recommendations made by European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) on how to optimise the safe use of the fibrin sealants Tisseel, Tissucol, Artiss and Beriplast P (and associated names) when applied as spray during surgery, in order to reduce risk of gas embolism during spray application.

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.

Subsequent to the recommendation made by CHMP on the safe use of the fibrin sealants Evicel and Quixil in November 2012, CHMP concluded that the risk of gas embolism with Tisseel, Tissucol and Artiss (though low) could not be excluded, and thus recommended that the product information of these medicines be updated. These include:

- The product information should be updated with clear and consistent advice for healthcare professionals regarding recommended pressure and distance to use during spraying application.
- The marketing-authorisation holders for these medicines should ensure that they 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.
- The product information should include a warning that the risk of gas embolism appears to be higher when fibrin sealants are sprayed using air, as compared to CO_2, and patients should be closely monitored for signs of gas embolism.

For Beriplast P (and associated names), as the product does not require a gas-assisted spray device during application, there is no risk of gas embolism when it is used in accordance with prescribing advice and with the recommended device.

Please refer to the following EMA website for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/12/news_detail_001674.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 9 pharmaceutical products registered under the name of Tisseel, i.e., Tisseel Kit (1 ml: HK-38346, 2ml: HK-38347, 5ml: HK-38348); Tisseel Lyo powders and solvents for fibrin sealant (1ml: HK-58061, 2ml: HK-58298) and Tisseel solution for fibrin sealant (2ml: HK-58015, 4ml: HK-58014 and 10ml: HK-57908) and all are prescription-only medicines. There are 2 pharmaceutical products registered under the name of Beriplast P Combi-Set (1ml: HK-48635, 3ml: HK-48636) and all are prescription-only medicines. There is no record of pharmaceutical product registered under the name of "Tissicol" and "Artiss" in Hong Kong. This letter provides further information to Drug Office's letter to healthcare professionals dated 19 November 2012 on a similar issue released by the EMA regarding other fibrin sealants Evicel and Quixil. In view of the EMA's recommendation, the matter will be discussed with other fibrin sealants such as Evicel 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 "Reporting an Adverse Drug Reaction": 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 sincerely,

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