衞生署藥物辦公室
藥物註冊及進出口管制部

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Dear Healthcare Professionals,

SFDA - Vitamin K1 Injection: the risk of severe allergic reactions

The China State Food and Drug Administration (SFDA) reminded healthcare professionals of safety information regarding reports of severe allergic reactions in patients treated with vitamin K1 injection, which is indicated for bleeding disorders caused by vitamin K deficiency.

The National Center for Adverse Drug Reaction (ADR) Monitoring database indicated that there were 893 reports of ADRs associated with the use of vitamin K1 injection from 1 January 2004 to 31 May 2011. Among these reports there were 328 cases (36.7%) of anaphylactic shock.

China SFDA advised healthcare professionals to check if the patients are allergic to vitamin K1 injection before the beginning of the treatment, and to stop the medication once any symptoms of allergy occur. The doctors should follow strictly the dosage regimen in accordance with the product information. In addition, manufacturers should include such adverse reactions in the package inserts in order to ensure the safe use of the products. For details, please refer to SFDA's website:

http://www.sda.gov.cn/WS01/CL0051/67933.html

In Hong Kong, there are five registered injection which contain vitamin K1. The package inserts have stated that patients with hypersensitivity to the drug are contraindicated to be used. In view of the SFDA's recommendation, the issue will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Please report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.drugoffice.gov.hk at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,

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for AD(D)