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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Recommendation to suspend the marketing authorisations for infusion solutions containing hydroxyethyl-starch

Your attention is drawn to the recommendation announced from the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) to suspend the marketing authorisations for infusion solutions containing hydroxyethyl-starch (HES). These medicines are mainly used to replace lost blood volume in hypovolaemia and hypovolaemic shock. They are used in critically ill patients including patients in sepsis or burn or trauma injuries, or patients who are undergoing surgery.

Following a review of the available evidence (data from the scientific literature and the data submitted by the companies, and took advice from a group of external experts), PRAC concluded that the benefits of infusion solutions containing HES no longer outweigh their risks. The review was triggered by the German Medicines Agency, the Federal Institute for Drugs and Medical Devices (BfArM), following three recent studies that compared HES with other products used for volume replacement called crystalloids in critically ill patients. The studies showed that patients with severe sepsis treated with HES were at a greater risk of kidney injury requiring dialysis. Two of the studies also showed that in patients treated with HES there was a greater risk of mortality.

The PRAC was of the opinion that, when compared with crystalloids, patients treated with HES were at a greater risk of kidney injury requiring dialysis and had a greater risk of mortality. The PRAC also considered that the available data only showed a limited benefit of HES in hypovolaemia, which did not justify its use considering the known risks. The PRAC therefore concluded that the marketing authorisations for these medicines be suspended.

The suspension should remain in place unless the marketing authorisation holder can provide convincing data to identify a group of patients in whom the benefits of the medicines outweigh their risks. Please refer to the following website at EMA for details.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001814.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 6 registered pharmaceutical products containing hydroxyethyl starch. The Drug Office of Department of Health has contacted the registration certificate holders of the above products for updates and details of the situation. Only 2 products are marketed in Hong Kong and they are registered by Fresenius Kabi Hong Kong Ltd: Voluven Infusion 6% (HK-50474) and Volulyte 6% Solution for Infusion (HK-58087). In view of the findings by EMA, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The Drug Office of Department of Health will remain vigilant on new safety information related to infusion solutions containing hydroxyethyl starch issued by other regulatory authorities.

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: 2186 9845 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 sincerely,

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