衞生署藥物辦公室
藥物註冊及進出口管制部

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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,

SOLIRIS (eculizumab) - Increased risk of hemolysis or low hemoglobin with serogroup B meningococcal vaccination

Your attention is drawn to the Health Canada's announcement regarding increased risk of hemolysis or low hemoglobin with serogroup B meningococcal vaccination in patients already being treated with SOLIRIS (eculizumab). The Canadian Product Monograph of SOLIRIS has been updated to include this new safety information.

During a safety review of Bexsero, a vaccine used to protect against Neisseria meningitides serogroup B, Health Canada found more reports of serious adverse reactions with Bexsero in patients with complement mediated diseases (such as paroxysmal nocturnal hemoglobinuria [PNH] and atypical haemolytic uremic syndrome [atypical HUS]) who were being treated with SOLIRIS, than in other patients vaccinated with Bexsero. A further review of the reports with Bexsero in patients already being treated with SOLIRIS concluded that there was an increased risk of low hemoglobin, including anemia, or hemolysis. The risk was highest in patients receiving Bexsero vaccine when their predicted systemic SOLIRIS concentrations were relatively low.

SOLIRIS is a complement inhibitor indicated for the treatment of patients with PNH to reduce hemolysis, and for the treatment of patients with atypical HUS to reduce complement-mediated thrombotic microangiopathy (TMA). SOLIRIS blocks terminal complement activation; therefore patients may have increased susceptibility to infections, particularly meningococcal disease caused by Neisseria meningitidis. Consequently, all patients must be vaccinated against meningococcal infections prior to, or at the time of, initiating SOLIRIS, unless the risks of delaying SOLIRIS therapy outweigh the risks of developing a meningococcal infection.

Healthcare professionals are advised that careful consideration should be given to the timing of meningococcal vaccination relative to the administration of SOLIRIS in patients who initiate therapy and also for those receiving maintenance therapy.

- For patients stabilized on SOLIRIS and receiving maintenance therapy, and for whom additional vaccination is warranted, vaccination is only recommended when the underlying complement-mediated disease is clinically controlled with SOLIRIS, and within one week following SOLIRIS infusion, when systemic SOLIRIS concentrations are considered to be relatively high.
- All patients taking SOLIRIS must be vaccinated with a meningococcal vaccine (against serotypes A, C, Y, W135 and B) prior to, or at the time of, initiating SOLIRIS.
- Patients who start on SOLIRIS treatment less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics for 2 weeks after they are vaccinated.

Healthcare professionals are reminded to provide their patients with relevant information to increase their awareness of potential serious infections and their signs and symptoms. All patients must be monitored for early signs of meningococcal infections, evaluated immediately if infection is suspected, and treated with antibiotics, if necessary.

Please refer to the Health Canada's website for details:

http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/60752a-eng.php

In Hong Kong, Soliris Concentrate for Solution for Infusion 300mg/30ml (HK-61188) containing eculizumab is a pharmaceutical product registered by DKSH Hong Kong Limited which is a prescription only medicine; and there are four registered meningococcal vaccines, namely Meningococcal A+C Polysaccharide Vaccine (HK-36398), Mencevax ACWY Vaccine (HK-48475), Menactra Vaccine (HK-60659) and Nimenrix Vaccine (HK-62095) which are prescription only medicines; while Bexsero is not a registered meningococcal vaccine. So far, the Department of Health (DH) has received six cases of adverse drug reactions in connection with eculizumab, but none of them was associated with haemolysis after meningococcal vaccination. In view of the Health Canada announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 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 digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Joseph LEE)
for Assistant Director (Drug)