Dear Healthcare Professionals,

**PRAC confirms its previous conclusion on risk of inhibitor development with factor VIII medicines**

Your attention is drawn to the European Medicines Agency's (EMA) announcement that EMA's Pharmacovigilance Risk Assessment Committee (PRAC) following a re-examination procedure has confirmed its previous conclusion of May 2017 that there is no clear and consistent evidence of a difference in the incidence of inhibitor development between the two classes of factor VIII medicines: those derived from plasma and those made by recombinant DNA technology.

Factor VIII is needed for blood to clot normally and is lacking in patients with haemophilia A. Factor VIII medicines replace the missing factor VIII and help control and prevent bleeding. However the body may develop inhibitors as a reaction to these medicines, particularly in patients starting treatment for the first time. This can block the medicines' effect, so bleeding is no longer controlled.

Due to the different characteristics of individual products within the two classes, the PRAC reaffirmed that the risk of inhibitor development should be evaluated individually for each medicine, regardless of class. The risk for each product will continue to be assessed as more evidence becomes available.

To reflect the evidence currently available, the PRAC confirmed its recommendations that the prescribing information should be updated to include, as appropriate, inhibitor development as a very common side effect in previously untreated patients, and as an uncommon side effect in previously treated patients. The warning on inhibitor development should be amended to highlight that low levels of inhibitors pose less risk of severe bleeding than high levels.

The PRAC's final recommendation will now be sent to EMA's Committee for Medicinal Products for Human Use (CHMP) for the adoption of EMA's opinion. Further details and information for patients and healthcare professionals will be published at that time.

Please refer to the following website in EMA for details:

In Hong Kong, there are 20 registered pharmaceutical products containing human coagulation factor VIII and 5 registered pharmaceutical products containing octocog alfa, i.e. recombinant factor VIII product. All of them are prescription only medicines. Related news was previously issued by the EMA, and was posted on the Drug Office website on 7 December and 21 December 2013, 8 November 2014, 16 May and 9 July 2016, and 6 May 2017. So far, DH has not received
any adverse drug reaction report related to human coagulation factor VIII and octocog alfa. DH will continue to remain vigilant on the final decisions by the EMA's CHMP on the PRAC recommendations.

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 faithfully,

(Joseph LEE)
for Assistant Director (Drug)