August 15, 2016

David Page
Canadian Hemophilia Society (CHS)
301-666, rue Sherbrooke Ouest
Montréal (Québec) H3A 1E7

Dear David Page:

Bayer Inc.
2920 Matheson Blvd. East
Mississauga, ON L4W 5R6
Tel. 905-282-5550
www.bayer.ca

I want to inform you that Bayer has initiated a withdrawal of 19 lots of its hemophilia A drug Kogenate FS that currently meet potency requirements, but have been identified as being at risk of falling below potency specification prior to shelf life expiry.

It is important to note that potency is normally expected to decline over time. During routine product testing, stability data for specific lots of Kogenate FS indicated that the product's potency was declining during its shelf life at a greater pace than normal. The probable cause of the reduced potency has been identified and corrected, and only certain lots produced before November 2015 are affected. In July, Bayer recalled 2 lots that had fallen below potency specification. Since then, testing has been completed and 19 lots that currently meet potency requirements, but are at risk for falling below specification before expiry will be withdrawn.

In Canada, potency specification for Kogenate FS is based on greater than or equal to 80% of nominal potency. The testing done in July indicated that potency values of the 19 lots being withdrawn ranged between 85% to 104% of the nominal value.

Bayer is working closely with Health Canada and Canadian Blood Services (CBS) to ensure an efficient withdrawal process that minimizes any disruption to supply and inconvenience to patients. The withdrawal is being conducted in coordination with CBS to the level of the hospital.

At Bayer, patient safety is our highest priority and as such we closely monitor potential safety signals of our products. The safety profile of Kogenate FS is continuously monitored by the Pharmacovigilance department. Based on data that have been reviewed for Kogenate FS, no

safety observations or signals have been detected by Bayer's drug safety group which would be indicative of a low potency type product issue. The current health risk assessment does not indicate an appreciable risk for patients for the affected lots.

Kovaltry is not impacted as the manufacturing process is different.

Bayer is committed to providing our patients safe and effective therapy. Should you have any questions regarding this withdrawal, please contact me at 905-282-5310 or by e-mail at shurjeel.choudhri@bayer.com. You may also contact Chrisoula Giannaris, Head Medical & Scientific Affairs, Hematology & Oncology at 905-282-5446.

Yours sincerely,

Shurjeel Choudhri, MD, FRCPC
Senior Vice-President & Head, Medical & Scientific Affairs
Bayer Inc.

cc: Craig Upshaw