



18 April 2025

WHO 25th Expert Committee on Selection and Use of Essential Medicines
World Health Organization
20, Avenue Appia
1211 Geneva 27
Switzerland

Subject: World Federation of Hemophilia (WFH) Commentary on Cerus Corporation Letter in Support of the WFH C.1 Application for the WHO Model Lists of Essential Medicines 2025 Update

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Dear Members of the WHO 25th Expert Committee on Selection and Use of Essential Medicines,

This letter is provided to address the comments outlined in the Cerus Corporation letter to the Expert Committee dated 17 April 2025 on the subject – **Cerus Corporation Support for WFH's Application "C.1 Changes to listings of cryoprecipitate, pathogen-reduced cryoprecipitate, and plasma-derived clotting factor concentrates"**.

The WFH had recently held discussions with Cerus Corporation regarding the pricing information for pathogen-reduced cryoprecipitate (PR Cryo) included on page 11, Table 4 of Application C.1 Changes to listings of cryoprecipitate, pathogen-reduced cryoprecipitate, and plasma-derived clotting factor concentrates (hereinafter referred to as the Application) on the estimated cost per unit of FVIII in INTERCEPT- treated PR Cryo.

After further clarification provided by Cerus Corporation, the WFH also concluded that due to the fact that the Pathogen Reduced Cryoprecipitated Fibrinogen Complex (INTERCEPT Fibrinogen Complex, IFC) is not indicated for FVIII replacement in the United States and is approved for fibrinogen replacement with extended room temperature shelf life, the latter affects the FVIII concentration levels, making the pricing estimation not applicable in the context of FVIII unit costs. Therefore, the WFH agrees that the FVIII per IU estimated cost in Cerus Corporation produced IFC and respective reference included in Table 4 should be disregarded during the review of the Application.

Sincerely,

Glenn Pierce, MD, PhD
WFH Vice-President, Medical