



To: International Society of blood Transfusion (ISBT)
Working Party on Global Blood Safety (WP GBS)

Montréal, December 15th, 2022

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Subject: Application for inclusion on the WHO EML and EMLc

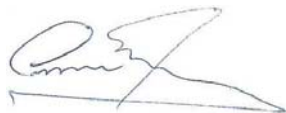
The WFH realizes the importance of Cryo-PR in the treatment of many conditions particularly in low-income countries (LIC). For some diseases, including VWD and fibrinogen deficiency, as well as various major traumas, PR-cryo clearly has an important role.

For Hemophilia A, we would like to reiterate that according to the WFH Guidelines for Management of Hemophilia (3rd edition, 2020), cryo PR could only be the last treatment choice when no other treatments are available (Plasma derived and recombinant clotting factor concentrates or bispecific antibody). Most low middle income countries (LMIC), and all upper middle-income countries (UMIC) have adequate amounts of CFCs to manage major hemophilia bleeds. However, in the LIC access to CFCs remains a challenge.

We support your effort to include Cryo – PR in the EML list but are concerned about the inclusion and use of non-pathogen reduced Cryo as we believe that its risk/benefit profile remains too high to justify its inclusion for Hemophilia patients.

Also, all cryo preparations do not address the long-term joint health of hemophilia A patients since it cannot be used prophylactically to prevent bleeding episodes, the standard of care for hemophilia A, thus does not represent a favorable benefit/risk for them. We are concerned addition of cryo to EML may encourage governments to not invest in therapies that are proven to be therapeutically more efficacious and can provide optimal management for hemophilia A patients in the long run. That said, when better treatments are unavailable, it remains an important option to manage life or limb threatening bleeding, and other major bleeding episodes in VWD, fibrinogen deficiency, hemophilia A, and traumatic bleeding.

With our best regards

A handwritten signature in blue ink, appearing to read 'Cesar Garrido', with a stylized, sweeping flourish at the end.

Cesar Garrido

President, WFH

A handwritten signature in black ink, clearly legible as 'Glenn Pierce'.

Glenn Pierce MD, PhD

VP Medical, WFH

A handwritten signature in blue ink, appearing to read 'Radoslaw Kaczmarek', with a stylized, sweeping flourish at the end.

Radoslaw Kaczmarek, PhD

Chair Coagulation Products Safety, Supply and Access Committee, WFH

A handwritten signature in black ink, appearing to read 'Alain Baumann', with a stylized, sweeping flourish at the end.

Alain Baumann

CEO, WFH