

MASAC Document #287  
(Replaces Document #149)

## **MASAC RESOLUTION ON THE WORLD HEALTH ORGANIZATION ESSENTIAL MEDICINE LIST**

*The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on March 8, 2024, and endorsed by the NBDF Board of Directors on April 11, 2024.*

- Whereas, the World Health Organization Essential Medicine List (WHO-EML) presents the minimum medication needs for a basic health care system. The most efficacious, safe and cost-effective medicines for priority conditions are selected based on the current and estimated future public health relevance and the potential for safe and cost-effective treatment, and
- Whereas, in 2003, a World Health Organization (WHO) Expert Committee recommended that FVIII and FIX clotting factor concentrates (CFC) be reviewed for possible fast-track deletion from the Essential Medicine List (WHO-EML) at their 2005 meeting, and
- Whereas, following extensive submissions and testimony from the World Federation of Hemophilia and numerous other organizations including the Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation the WHO expert committee ultimately rejected this recommendation, and
- Whereas, in their decision to retain CFCs on the complementary medicine list, the WHO-EML Expert Committee noted that FVIII and FIX concentrates are lifesaving in the treatment of haemophilia and that the alternative (cryoprecipitate from whole blood donations) is less safe and more expensive, and
- Whereas, the 2023 WHO-EML reversed course and placed cryoprecipitate products that carry risks of viral infection on their core medicines list while virally-safe CFCs remained on the complementary medicine list, and
- Whereas, the evidence supporting retention of CFCs and not cryoprecipitate products on the core list are even more compelling today than when last considered in 2003 given enhanced medical knowledge and technological advancements, and
- Whereas, health equity for persons with haemophilia in countries at all income levels is far from perfect, but promoting pathogen reduced cryo (PR Cryo) and cryoprecipitate by the WHO-EML to the exclusion of plasma-derived and recombinant CFCs on the core list is moving backward, not forward, and
- Whereas, lack of inclusion of virally inactivated CFC on the core list is detrimental to patients' health and in contradiction to widely published guidelines for optimal treatment, and
- Whereas, dependence on blood components alone in the developing world will increase the risk of infectious disease transmissions such as HIV to persons with hemophilia, and
- Whereas, inaccessibility to what are the most safe, efficacious, and essential products to treat hemophilia in the developing world will lead to an increased number of deaths and disabilities, and

- Whereas, governments rely on WHO recommendations.

Therefore, MASAC recommends the WHO follow their previously well-established principles for accessibility, efficacy, and safety for many drugs, remove non- PR Cryo from the list entirely, switch PR Cryo to the complementary list and place CFCs on the core list to promote prevention of infectious disease and bleeding resulting in deaths in countries that rely upon the WHO EML for accurate information.

Furthermore, given the urgency and irreversible nature of many pathogen infections we call upon the WHO to take immediate action and not wait to correct this egregious action until the next scheduled revision of the WHO-EML in 2025.

#### References:

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- *Srivastava A, Santagostino E, Dougall A, Al. E. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia 2020; : DOI:10.1111/hae.14046.*
- *MASAC Hemophilia & Coagulation Disorder Treatments | Document 284 | NBDF.*  
<https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-284-masac-recommendations-concerning-products-licensed-for-the-treatment-of-hemophilia-and-selected-disorders-of-the-coagulation-system>
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- *Ansah JK, Kafere C, Loua A, Nkansah E, Acquah ME, Mudyiwanyama L. Regulation of blood services in Africa. Transfus Clin Biol 2021; 28: 148–53.*
- *WFH Letter to ISBT on the application for inclusion of PR-Cryo in WHO EML and EMLc.*  
<https://wfh.org/article/wfh-statement-inclusion-of-cryoprecipitate-in-the-whos-eml-and-emlc/>. 2022;published online Dec 15.

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