17 April 2025

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

Subject: Support for World Federation of Hemophilia Applications for the WHO Model Lists of Essential Medicines 2025 Update

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

We, the clinicians from hemophilia treatment centres, responsible for clinical management of people with hemophilia, von Willebrand Disease and other bleeding disorders, are sending this joint letter in support of the three applications submitted by the World Federation of Hemophilia for the 2025 update of the WHO Model Lists of Essential Medicines (EML).

We recognize the importance of WHO EML as a guiding model for national selection and financing of essential medicines and stress the critical need for updating the EML to reflect current international clinical practice guidelines for management of hemophilia and von Willebrand disease. In this regard, we are alarmed by the inclusion of pathogen reduced and non-pathogen reduced cryoprecipitate as core medicines in the 2023 EML as therapeutic alternatives to FVIII clotting factor concentrates (CFCs), while the same virally safe plasma-derived CFCs remain on the complementary list. Non-pathogen reduced cryoprecipitate exposes people with hemophilia, von Willebrand Disease and other bleeding disorders to a significant risk of transmission of bloodborne infections, including HIV, and hepatitis B and C viruses.

Notably, also cryoprecipitate (neither pathogen-reduced nor non-pathogen reduced) cannot be used for prophylactic treatment, which is the standard of care for people with hemophilia. Prophylaxis can be provided with administration of plasma-derived and recombinant clotting factor concentrates (CFCs) and Factor VIII mimetic bispecific antibodies.

We therefore endorse WFH's recommendations outlined in the following applications:

- **C.1 Changes to listings of cryoprecipitate, pathogen-reduced cryoprecipitate, and plasma-derived clotting factor concentrates,** recommending the following revisions to EML and EMLc: to remove non pathogen-reduced cryoprecipitate; limit the use of pathogen-reduced cryoprecipitate to evidence-based indications outside the treatment of hemophilia A and von Willebrand Disease; move the listings of plasma-derived Factor VIII and Factor IX concentrates for treatment of hemophilia A and B respectively to the core list; and remove FIX complex (also known as prothrombin complex concentrate - PCC) as an alternative to FIX concentrates for treatment of hemophilia B.

- **A.23 Recombinant coagulations factors – haemophilia**, recommending inclusion of recombinant Factor VIII and Factor IX concentrates for treatment of hemophilia A and B respectively in the core list of EML and EMLc
- **A.12 Emicizumab – haemophilia A,** recommending inclusion of Factor VIII mimetic bispecific antibody, emicizumab, for treatment of hemophilia in the core list of EML and EMLc for treatment of hemophilia A.

We reiterate our commitment to provide high quality clinical care for people with hemophilia and other bleeding disorders to improve their health outcomes and quality of life. We urge the WHO 25th Expert Committee on Selection and Use of Essential Medicines to put patient safety and improved health outcomes first and approve these critical revisions to the EML to better reflect the current international clinical practice guidelines.

Sincerely,

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