A.11	Cryoprecipitate (pathogen-reduced) – bleeding disorders – EML and EMLc
Draft recommendation	☒ Recommended ☐ Not recommended Justification: Add cryoprecipitate as therapeutic alternatives to coagulation factor VIII-EML and EMLc. Cryoprecipitate is a blood components contains several clotting factors has been used for decades to treat bleeding episodes in patient with clotting factors deficiency. Cryoprecipitate is proposed as a therapeutic alternative to coagulation FVIII only in settings where coagulation FVIII is unavailable or unaffordable for treatment of hemophilia A. Blood components if prepared according to WHO guidelines are safe for human use and do not need universal pathogen reduction. However, certified pathogen reduction methods could improve safety of the blood components including cryoprecipitate.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments:
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments:
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments:
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments: Blood components if prepared according to WHO guidelines are safe for human use. However, they should administered under supervision of qualified health provider staff and also require some precautions e.g. blood typing and cross matching prior to administration.

Are there any special requirements for the safe, effective and appropriate use of the medicines? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☒ Yes ☐ No ☐ Not applicable Comments: cryopercipitate should be infused only under supervision of qualified medical staff. Some laboratory monitoring test may also be required.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☐ Yes ☒ No ☐ Not applicable Comments:
Are there any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☒ Yes ☐ No ☐ Not applicable Comments: Although blood components have been add to the EML, some countries may still do not consider them as “medicine” and regulate these products differently.
Is the proposed medicine recommended for use in a current WHO guideline? (refer to: https://www.who.int/publications/who-guidelines)	☒ Yes ☐ No ☐ Not applicable Comments: