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By email: mssgsecretariat@ema.europa.eu

Subject: IGH statement – 2026 annual review of the Union list of critical medicines (ULCM)

Dear Members of the MSSG,

As a patient organisation representing people living with von Willebrand disease and haemophilia A and B, we strongly support the continued inclusion of plasma-derived coagulation factors VIII and IX on the European Union list of critical medicines (ULCM). From a patient perspective, these therapies continue to meet the core criteria of criticality because they are used to treat severe, lifelong and potentially life-threatening bleeding disorders, and because uninterrupted access remains essential for patient safety and continuity of care.

Haemophilia is associated with a risk of severe bleeding, including intracranial haemorrhage, internal bleeding and progressive joint damage. Delayed or inadequate treatment can result in irreversible disability, loss of mobility, reduced quality of life and, in some circumstances, death. Reliable access to clotting factor replacement therapy is therefore not simply desirable; it is fundamental to maintaining health and preventing avoidable harm.

We recognise that recombinant factor products and other innovative therapies have expanded treatment options considerably. However, the existence of alternative products should not automatically be interpreted as evidence that plasma-derived products are no longer critical. Patients are managed individually, and treatment decisions are influenced by various factors such as clinical history, tolerability, physician judgement, national treatment pathways and reimbursement frameworks. Stable patients should not be compelled to switch therapies because of supply disruptions. The practical availability and suitability of alternative treatments should therefore be assessed from the perspective of individual patients, not solely on the basis of their authorisation.

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We also note the planned inclusion of von Willebrand factor-containing therapies, including von Willebrand factor and coagulation factor VIII in combination (ATC B02BD06) and von Willebrand factor alone (ATC B02BD10). Their inclusion is an important and welcome development, as it would help ensure that the range of therapies required for the management of von Willebrand disease is appropriately reflected within the ULCM. This would strengthen the consistency of the list and better acknowledge the needs of patients affected by inherited bleeding disorders.

Although removal from the ULCM would not necessarily trigger immediate legal consequences, it could reduce regulatory attention to the specific circumstances associated with plasma-derived coagulation factors. Maintaining their inclusion would support continued assessment of vulnerabilities and reinforce the importance of safeguarding supply for a small but highly vulnerable patient population. We encourage the EMA to consider potential supply vulnerabilities and the experiences of haemophilia treatment centres and patient organisations before deciding on the proposed removal.

We also draw attention to the WHO's 2025 Model List of Essential Medicines, in which plasma-derived factor VIII and factor IX concentrates were moved from the complementary to the core list. Although the WHO and EU lists have different purposes and assessment criteria, this recent decision underlines the continued importance of these medicines for patient care. We believe this should be considered in the present review.

Source: WHO Model List of Essential Medicines, 24th edition, 2025; WHO Expert Committee report, Technical Report Series 1064, 2026.

For these reasons, we respectfully urge the members of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to retain human plasma-derived factor VIII and human plasma-derived factor IX preparations, as identified in the consultation under ATC codes B02BD02 and B02BD04, respectively, on the Union list of critical medicines. The severity of the underlying diseases, the ongoing need for uninterrupted treatment and the limitations of real-world interchangeability of plasma-derived therapies together provide a strong justification for their continued classification as critical medicines.

Yours sincerely,
Onlineveröffentlichung ohne Unterschrift
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