EUROPEAN BLOOD ALLIANCE

EBA response to the 2026 review of EMA Union List of Critical Medicines

Overview

Several immunoglobulins provide treatment for patients suffering from different immunological conditions, most of which have no alternative treatments.

These Plasma-Derived Medicinal Products (PDMPs) must be administered to these patients at regular intervals to treat their conditions, and the unavailability of this medicine can have serious implications for the health of patients.

In the 2026 annual review of the Union list of critical medicines (the List), the draft circulated by the European Medicines Agency's (EMA) Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) for stakeholder consultation, human normal immunoglobulin for intravenous (IVIg) and subcutaneous (SCIg) use is proposed for removal from the List. The 2023–2025 Union lists included these medicines.

EBA firmly believe that if confirmed, the removal of these immunoglobulins from the List would be severely detrimental to European patients, to the resilience of the supply of these critical medicines, and to European self-sufficiency, as stated in Regulation (EU) 2024/1938 (SoHO Regulation), with regards to these products.

These medicines should remain on this Union List of Critical Medicines

According to the List methodology[1], critical medicines will be selected based on a risk assessment considering their relevance to public health, or "medicinal product criticality":

- the therapeutic indication of the medicine (criterion 1), and
- the availability of appropriate alternatives (criterion 2).

With regards to therapeutic indication, EBA considers that Immunoglobulins (IVIg and SCIg) should be classified as High Risk with regards to Primary Immunodeficiencies (PID), Secondary Immunodeficiencies (SID) and auto-immune diseases. For many patients with these conditions, these PDMPs are "used to treat patients with general life-threatening acute conditions, specific life-threatening acute conditions, or irreversibly progressive conditions", as specified in the methodology.

As for criterion 2, we would again argue that most of the indications are to be considered as High risk because in many case "no appropriate alternative is available".

Therefore, we firmly believe that therapeutic immunoglobulin products meet both criticality criteria and should remain on the Union List of Critical Medicines.

Beyond the criticality assessment

There are additional issues specific to immunoglobulins that further underline their criticality including supply complexity, regulatory support, and the efforts currently being deployed by many Member States to limit third-country dependency and secure patient access.

Human normal immunoglobulin, either for intravenous use or for sub-cutaneous use have been the subject of recurrent, historical critical shortages in several Member States, with potential criticality already highlighted above due to the lack of readily available alternatives.

[1] https://www.ema.europa.eu/en/documents/other/methodology-identify-critical-medicines-union-list-critical-medicines_en.pdf

PDMPs like IVIgs and SCIgs rely entirely on donated human plasma, making their supply chain very different from products with synthesised starting materials. There is currently no available substitute starting material. The production of PDMPs is a lengthy process – usually taking around 6 to 12 months from donation to delivery through complex and interconnected production pathways. The intricate balance between the collection of human plasma and the production time of Immunoglobulins requires a complex management of this unique supply chain.

It is therefore not sufficient to assess the supply of Immunoglobulins at a given time point. Growing needs of immunoglobulins in some countries, market conditions and the geopolitical context all contribute to their supply risks at a given moment. The criticality of and access to these products needs to be assessed over a long-term perspective and planning must include potential for major fluctuations.

The geopolitical factor is particularly sensitive in this respect. The United States provides around 70% of the world's plasma for PDMPs, and around 30% of Europe's. Pandemics, geopolitical tensions, and economic instability can trigger shortages, which would significantly impact patient care.

The demand of PDMPs is also growing yearly with improved diagnosis capacity and as medical discoveries expand their use beyond rare congenital diseases to protect people with secondary immune deficiencies, including cancer patients receiving aggressive chemotherapy, CAR-T patients, and organ transplant recipients.

Finally, it is worth stressing that in the recently adopted Regulation (EU) 2024/1938 (SoHO Regulation), the EU legislators recognised this supply tension on several recitals, such as

Recital (64), which reads "As there is a need to ensure the availability of SoHO for medical treatments, Member States and the Union should support the establishment of public donation facilities and promote the voluntary and unpaid donation of SoHO, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union."

as well as

Recital (65), which states that "To increase European self-sufficiency in terms of SoHO, Member States should be urged to increase their collection capacity and donor base for critical SoHO, in particular plasma, by developing non-profit and public plasmapheresis programmes."

Impact on Member States and on European self-sufficiency

Member States recognise this strategic and critical nature of immunoglobulin, and not only as co-legislators in the SoHO Regulation. Many of them are investing accordingly in plasma collection programmes, systems of clinical governance and in other parts of the PDMPs supply chain. For example, countries like Belgium, Denmark, Germany, Sweden, Spain, Italy, France and the Netherlands, to name a few, have been making very substantial investments in plasma programmes to increase the collection of plasma for PDMPs by the public sector.

A decision to remove these PDMPs from the Union List of critical medicines would significantly undermine these national efforts to secure patient access to these products and to strengthen national and European self-sufficiency, as well as their resilience to possible shortages.

Considering all the elements mentioned above, EBA supports retaining immunoglobulins on the Union List of Critical Medicines.

November 2026