Medicine Shortage Communication

<date>

Beriglobin (human normal immunoglobulin), 2 mL and 5 mL solution for injection in pre-filled syringe: supply shortage and cessation of marketing (discontinuation)

Dear Healthcare Professional,

CSL Behring GmbH <affiliate to include country specific information to reflect global or local company name> is notifying healthcare professionals about the marketing-cessation (discontinuation) of Beriglobin (human normal immunoglobulin) in all EU/EEA markets. As a result, this discontinuation will lead to shortages and non-availability of Beriglobin.

Overview of situation

- **CSL Behring GmbH stopped manufacturing of Beriglobin in August 2024 and has since decided to stop marketing of Beriglobin in EU/EEA markets due to commercial reasons.**
- **Beriglobin may be critical for people at increased risk of serious hepatitis A disease and who require post-exposure prophylaxis with anti-hepatitis A immunoglobulins as there are no authorised alternatives for this indication in the EU/EEA.**
- **The shortage affects all of the EU countries where the product was marketed or imported.**
- **The shortage is not due to any safety, efficacy or quality concerns with Beriglobin.**

Mitigation measures

In order to manage the shortage and discontinuation, the marketing authorisation holder is engaging with the European Medicines Agency and the National Competent Authority on mitigation measures.

Healthcare professionals should consider the following mitigation measures:

- No new patients should be prescribed Beriglobin for those indications for which there is an alternative treatment.
- Existing stocks of Beriglobin should be reserved for patients for whom there is no alternative treatment.
- When switching patients to alternative products, healthcare professionals should follow the medicine's dosing recommendations in the relevant summary of product characteristics (SmPCs).

In addition, for the situations below, healthcare professionals may consider the following options, where this in line with their local and national guidance and clinical judgment:

- For patients with primary and secondary immunodeficiencies who are currently on Beriglobin consider switching to alternative formulations of normal human immunoglobulins.
- There are no alternative immunoglobulin medicinal products authorised in the EU/EEA for pre- or post-exposure prophylaxis of hepatitis A:
    - For pre-exposure prophylaxis against hepatitis A, EU-authorised vaccines may be used
    - For post-exposure prophylaxis, follow recommended approach in your country
- <For patients with radiation-induced oral mucositis, consult relevant guidelines for information on how to manage this condition.>

For additional information related to the shortage consult EMA's shortage catalogue, your country's shortage register or your national competent authority (NCA). <Please note that NCAs do not issue clinical guidance.> <For clinical guidelines contact relevant local or national learned societies.>

Background on the shortage

Beriglobin may be critical for vulnerable groups, including individuals with chronic liver disease, with chronic hepatitis B or C, immunocompromised individuals, cancer patients or other conditions that make them more susceptible to serious hepatitis A disease.

Beriglobin may be also recommended in situations where the vaccine is contraindicated or may not yield protective immunity.

The approved indications or their wording may differ between countries; in addition, some countries may import the product for individual patients according to national procedures.

Beriglobin is indicated for subcutaneous administration as replacement therapy in adults, children and adolescents (0-18 years) with:

- Primary immunodeficiency syndromes with impaired antibody production.
- Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia (CLL), in whom prophylactic antibiotics have failed or are contra-indicated.
- Hypogammaglobulinaemia and recurrent bacterial infections in multiple myeloma (MM) patients.
- Hypogammaglobulinaemia in patients pre- and post-allogeneic haematopoietic stem cell transplantation (HSCT).

Beriglobin is indicated for intramuscular administration for Hepatitis A prophylaxis in adults, children and adolescents (0-18 years); it is used as:

- Pre-exposure prophylaxis, preferably in combination with active vaccination, in unvaccinated individuals travelling in less than 2 weeks to areas of hepatitis A risk.
- Post-exposure prophylaxis in unvaccinated individuals within 2 weeks of hepatitis A virus exposure.

<Beriglobin is indicated for the treatment of the radiogenic mucositis.>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

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Annexes *(if applicable)*

<Link/reference to other available relevant information, such as information on the website of a competent authority>

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Beriglobin / Human normal immunoglobulin (IMIg)
Marketing authorisation holder(s)	CSL Behring GmbH
Purpose of the communication	Inform Health Care Professionals on the discontinuation of Beriglobin and mitigation measures to manage the marketing cessation.
MSC recipients	Target group for this letter includes specialists who treat patients with Beriglobin (e.g. specialists in internal medicine, specialists for infections, specialists in oncology, Health Care Professionals in public health services), general practitioners/family physicians, pharmacists, in all EU/EEA countries in which Beriglobin is marketed or imported. The target group can be further defined at national level, in agreement with the respective national competent authorities.
Member States where the MSC will be distributed	In agreement with the national competent authorities.

Timetable *[Delete steps which are not applicable]*	**Date**
MSC and communication plan (in English) agreed by SPOC WP	16 September 2025
MSC and communication plan (in English) agreed by MSSG	31 October 2025
Submission of translated MSCs to the national competent authorities for review	24 November 2025
Agreement of translations by national competent authorities	By 04 December 2025
Dissemination of MSC	11 December 2025