<date>

Vyvgart 1,000 mg solution for injection (efgartigimod alfa): requirement to visually inspect vials from certain batches due to risk of contamination

Dear Healthcare professional,

argenx BV in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **Following a report concerning an isolated quality defect, it cannot be excluded that some vials from batch P99872C (batch numbers P99872CA, P99872CB and P99872CE) of Vyvgart 1 000 mg solution for injection may show visible signs of contamination (foreign material suspended in the liquid and/or attached to the inside of the vial).**
- **Visually inspect vials of Vyvgart 1 000 mg solution for injection before use, as per the instructions provided in the package leafet leaflet ('Important instructions for use'):**

  <u>Measures and instructions / recommendations for healthcare professionals:</u>
  - **Prior to administration, always check the appearance of the medicine in the pre-filled syringe/vial. The medicine should look clear to light yellow in colour. A little cloudiness is normal.**
  - **Do not use if the medicine is discoloured or contains particles.**
  - **Remind patients and caregivers to visually inspect each vial, as per the guidance in the package leaflet, and not to use any product with signs of contamination.**

Background information

Vyvgart is indicated as:

- an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive;
- monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins.

It is available in three pharmaceutical forms:

- Vyvgart 20 mg/mL concentrate for solution for infusion (for intravenous administration);
- Vyvgart 1000 mg solution for injection (for subcutaneous administration);
- Vyvgart 1000 mg solution for injection in pre-filled syringe (for subcutaneous administration).

Patients receiving Vyvgart as an injection, or their care provider, may inject the medicine themselves after the first 4 injections for CIDP or 5 injections for myasthenia gravis and appropriate training. The current quality defect arises from a single report concerning the suspected presence of mold in a vial of Vygart 1 000mg solution for injection.

If signs of contamination are observed the vial must not be used. Please notify argenx by email at medinfoEMEA@argenx.com and do not open or puncture the vial. Please secure the vial and await further instructions.

Call for reporting

Please report suspected product quality complaints and adverse drug reactions in patients treated with Vyvgart 1 000 mg solution for injection to medinfoEMEA@argenx.com and, in accordance with the national requirements, to <local agency> through <email, website, address> including product name and batch number if available.

Company contact point

If you have any questions, please contact argenx BV at medinfoEMEA@argenx.com.

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Vyvgart 1 000 mg solution for injection (efgartigimod alfa)
Marketing authorisation holder(s)	argenx BV
Safety concern and purpose of the communication	Requirement to visually inspect vials from certain batches due to risk of contamination
DHPC recipients	Hospitals and community pharmacists that have received product from the batch in question, or will receive such product in future. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	The DHPC will be distributed to recipients in the EU countries where the product has been distributed: Austria, Belgium, Luxembourg, Czech Republic, Hungary, Italy, Netherlands

Timetable *Delete steps which are not applicable*	**Date**
DHPC and communication plan (in English) agreed by CHMP	25 June 2026
Submission of translated DHPCs to the national competent authorities for review	02 July 2026
Agreement of translations by national competent authorities	09 July 2026
Dissemination of DHPC	23 July 2026