<Date>

Emblaveo® (Aztreonam/Avibactam) 1.5 g/0.5 g powder for concentrate for solution for infusion: potential for cracked or broken vials

Dear Healthcare Professional,

PFIZER EUROPE MA EEIG in agreement with the European Medicines Agency (EMA) and <*Name of National Competent Authority*>, would like to inform you of the following:

Summary

- **Broken or cracked glass vials have been identified in batches of Emblaveo 1.5g/0.5g powder for concentrate for solution for infusion. Refer to Table 1 below for batches currently in circulation that are potentially impacted.**
- **Visually inspect all Emblaveo glass vials upon receipt of this letter paying special attention to the potential for damage.**
- **<u>Do not use the vial of Emblaveo</u> if the glass is damaged. As with any damaged vial, the potential risk to product integrity cannot be ruled out.**
- **Should you identify a damaged glass vial, please report this as a product complaint and send a photograph of the damaged glass vial to Pfizer (see Company Contact Point below).**
- **If the glass vial is not damaged, continue with the reconstitution and dilution process as per instructions in the product information.**

Background information

Emblaveo is a combination antibiotic used in the treatment of adult patients with acute and potentially life-threatening infections. Emblaveo is indicated for the treatment of the following infections in adult patients:

- complicated intra-abdominal infection;
- hospital acquired pneumonia, including ventilator associated pneumonia, and;
- complicated urinary tract infection, including pyelonephritis.

It is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients with limited treatment options (see sections 4.2, 4.4 and 5.1 of the summary of product characteristics).

Emblaveo is available as a freeze-dried powder in a 30 mL glass vial. The powder must be reconstituted with sterile water for injections and the resulting concentrate must then be immediately diluted prior to use. The reconstituted solution is a clear, colourless to yellow solution and is free of visible particles. Standard aseptic techniques should be used for solution preparation and administration.

Pfizer received confirmed complaints of broken vials of Emblaveo. An investigation was initiated, which included review of batch filling, lyophilization and packaging processes, and laboratory analysis of the glass vials. The root cause for the damage to the glass vials was attributed to glass-to-glass contact of the 10 pack vials during handling activities on the packaging line coupled with insufficient support from the glued carton partitions (automated packaged vials) or absence of carton partitions (for hand-packed vials) within the secondary carton.

As part of the investigation, retain and reference samples from all distributed batches of Emblaveo and batches that were still in control at the manufacturing site were inspected. The rate of occurrence of the defect was low at 0.03%.

Refer to Table 1 below for a list of potentially affected batches of Emblaveo currently in circulation (including batches distributed, partially distributed and/or under Pfizer control) for EU/EEA Member States.

Healthcare professionals must visually inspect each vial upon receipt of this letter. If damage to the vial is observed, it should not be used. Additionally, the damaged vial should be reported as a product complaint via the Company Contact Point below.

To date, Pfizer has not received any reports of adverse events related to broken or cracked vials.

Table 1. List of batches currently in circulation

Country	**Batch number**
Germany	LC4976AB
Germany	LR0469AB
France	LC4976AC
France	LC7424AE
France	LR0465AA
Denmark	LC7424AC
Finland	LC7424AC
Norway	LC7424AC
Sweden	LC7424AC
Austria	LC7424AD
Austria	LR0469AA
Netherlands	LC7424AD
Netherlands	LC7424AF
Netherlands	LC4976AC
Netherlands	LR0469AA
Romania	LC7424AG
Romania	LR0469AC
Spain	LC7424AF
Spain	LR3663AA
Italy	LC7424AB
Portugal	LC7424AB

CALL FOR REPORTING – TO BE COMPLETED NATIONALLY

Please continue to report any suspect adverse drug reactions to the <Name of National Competent Authority>

<A reminder of the need and how to report adverse reactions in accordance with the national spontaneous reporting system>

<Mention if product is subject to additional monitoring and the reason why>

<Details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

COMPANY CONTACT POINT – TO BE COMPLETED NATIONALLY

Alternatively, suspected adverse reaction may also be reported to the marketing authorisation holders using the details provided below. If you have further questions or require additional information, please contact:

Company	Product name	Email	Phone	Fax

FURTHER INFORMATION

Detailed information on this medicine is available on the European Medicines Agency web site: Emblaveo | European Medicines Agency (EMA)

Yours sincerely,

<Name>
<Title>
Worldwide Safety and Regulatory

cc

<Name>, <Title>
<Name>, <Title>
<Name>, <Title>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Emblaveo ® (aztreonam/avibactam) 1.5g/0.5g powder for concentrate for solution for infusion
Marketing authorisation holder(s)	Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium
Safety concern and purpose of the communication	Emblaveo® (aztreonam/avibactam) 1.5 g/0.5 g powder for concentrate for solution for infusion: Potential for cracked and broken vials
DHPC recipients	Hospital specialists (infectiologists, critical care, pneumologist, hemato-oncologists, surgeons), hospital pharmacists, aseptic pharmacy hospital department, hospital nurses (infectiology, critical care, pneumology, hemato-oncology department, surgery). Professional medical societies in link with the above specialities (mainly infectiology and critical care). 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	Austria, Germany, Netherlands, Denmark, Sweden, Finland, Romania, France, Italy, Portugal, Norway, Spain

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	14/02/2025
Submission of translated DHPCs to the national competent authorities for review	21/02/2025
Agreement of translations by national competent authorities	28/02/2025
Dissemination of DHPC	14/03/2025