Direct Healthcare Professional Communication

10 November 2025

Libtayo® (cemiplimab) 350 mg concentrate for solution for infusion: Batch / lot number and expiry date may become illegible following sanitisation and wiping of vial label

Dear Healthcare Professional,

Regeneron Ireland DAC ("**Regeneron**"), in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **The batch / lot number and expiry date on the Libtayo® 350 mg vial label may become illegible upon sanitisation / disinfection followed by physical wiping of the vial during the initial preparation of the infusion.**
- **The Libtayo batch / lot number and expiry date should be recorded from the vial label before sanitisation / disinfection.**
- **Neither product efficacy nor patient safety is impacted by this issue.**

Background

Libtayo® (cemiplimab) (350 mg IV Q3W) is a programmed cell death-1 (PD-1) monoclonal antibody that is indicated as a monotherapy for the treatment of adult patients with advanced cutaneous squamous cell carcinoma, basal cell carcinoma, and cervical cancer. Libtayo as a monotherapy or in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with advanced non-small cell lung cancer (see Sections 4.1 of the summary of product characteristics, SmPC).

Each carton of Libtayo contains 1 glass vial with 7 ml of concentrate for solution for infusion.

Regeneron has received customer complaints from the United Kingdom and the European Union related to the labelling details on the product vial. The batch / lot number and expiry information on the vial may become illegible following sanitisation and physical wiping of the vial label during aseptic preparation of the infusion at hospital pharmacies.

Regeneron advises that the batch / lot number and expiry date from the vial is recorded in advance of sanitisation/disinfection.

This issue is limited to the exterior of the vial due to the type of ink being used for printing of the variable data on the vials. No adverse events related to this defect have been reported.

Please note that the batch / lot number and expiry date are also laser etched on the outer carton of the drug product, which contain the individual vials, and these details are not impacted by this issue.

Based on Regeneron's assessment of this event, there is no impact on the medicine; neither product efficacy nor patient safety has been impacted by this issue.

Regeneron is actively working on updating the Libtayo vial label to ensure the printed information is resistant to fading/erasure when subject to physical wiping post application of a sanitising agent.

For further details on the preparation and administration of Libtayo please refer to the product information.

Call for reporting

Reporting suspected adverse reactions allows for continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system below:

<Insert local national reporting system information from EMA Appendix V>

When reporting a suspected adverse reaction, please provide the name of the product associated with the event, as well as the batch number and the expiration date of the product.

▼Libtayo is subject to additional monitoring. This will allow quick identification of new safety information.

Company contact point

If you have any questions or concerns, please contact <Insert local Regeneron contact information>