<Date>

Vabysmo (faricimab): tear in primary packaging of transfer filter needle (TFN) co-packaged with vial

Dear Healthcare Professional,

<Name of marketing authorisation holder> in agreement with the European Medicines Agency and <National Competent Authority> would like to inform you of the following:

Summary

Roche has identified individual instances of a tear in the primary packaging of the Transfer Filter Needle (TFN) co-packaged with Vabysmo vials.

- **It is important to examine the TFN packaging prior to use, as instructed in the Vabysmo product information. Please pay special attention to the potential presence of a tear as shown in the images below.**
- **If the TFN packaging is intact, continue as per product information with injection process.**
- **If the TFN packaging is damaged, the sterility of the TFN cannot be guaranteed and the entire unit of Vabysmo (i.e., Vabysmo vial+ TFN pack) must not be used as this may increase the potential risk of infection and/or intraocular inflammation associated with the intravitreal injection.**
- **To continue with the injection preparation, a new unit of Vabysmo must be used.**
- **Should you identify a damaged TFN pack within the supplied package of Vabysmo, please report this as a product complaint to Roche *<Affiliates should insert text as applicable per local requirements to provide instruction>* and *(Affiliates to edit following text as applicable per local requirements)* please send a photograph of the damaged TFN pack and/or the entire unit of Vabysmo to Roche (see details below) so that a replacement unit can be issued.**

Background Information

Vabysmo is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with:

- neovascular (wet) age-related macular degeneration (nAMD)
- visual impairment due to diabetic macular oedema (DMO)

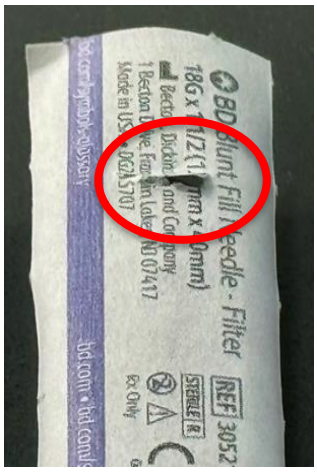
Through the quality assurance measures within Roche, a quality issue linked to the transfer filter needle (TFN), which is co-packaged with vials of Vabysmo, was identified on 24 May 2024.
The quality checks identified a tear in the primary packaging of one TFN. The tear is visible to the naked eye and located close to the needle hub of the TFN (see below). This issue has not been previously identified within Roche for Vabysmo. To date, this issue has been found in a limited number of batches of Vabsymo (Refer to table 1 below), with a rate of occurrence of up to 0.25% at the Roche packaging site.

A TFN from a damaged package may not be sterile and may potentially increase the risk of clinical complications, including infection and/or intraocular inflammation. To minimize patient risk a new unit of Vabysmo must be used, should a damaged package be identified, and the damaged product reported and/or returned to the manufacturer. To date, we have not received any reports of adverse events that could be linked to the presence of this issue in any marketed batches of Vabysmo.

Table 1: List of affected batches of Vabysmo distributed in EU member states

Batch Number	No of Units distributed	Product Distribution	Expiry Date
B1540B03	1566	Spain	Jun-2026
B1542B03	544	Spain	Jun-2026
B1532B08	48	Ireland	Apr-2026
B1537B11	3410	Czech Republic	Jun-2026
B1537B10’	7001	Spain	Jun-2026
B1526B28U1	477	France	Feb-2026
B1540B06	417	Greece	Jun-2026

Fig. 1: Examples of the TFN primary packaging observed pattern



Call for reporting

Healthcare professionals should report any product complaints or adverse events suspected to be associated with the use of Vabysmo co-packaged with transfer filter needle according to national reporting requirements.

Company contact point

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

Annexes *(if applicable)*

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

Yours sincerely,

<Company Name of Affiliate>

<Signature of authorised contact person>

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Vabysmo (faricimab)
Marketing authorisation holder(s)	Roche (as applicable depending on the territory)
Safety concern and purpose of the communication	Tear in the primary packaging of the transfer filter needle (TFN) that is co-packaged with the Vabysmo vial which may affect the sterility of the needle
DHPC recipients	Ophthalmologists and retina specialists. 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	Czech Republic, France, Greece, Ireland, Northern Ireland, Spain

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP/CMDh	27 June 2024
Submission of translated DHPCs to the national competent authorities for review	04 July 2024
Agreement of translations by national competent authorities	11 July 2024
Dissemination of DHPC	25 July 2024