VELSIPITY

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0001	Update of section 4.4 to modify the macular oedema warning based on the evaluation of the cases of MO/cystoid MO reported in the etrasimod clinical studies and other S1P labels in the EU. The Package Leaflet and Annex II are updated in accordance. RMP version 1.5 has also been submitted. In addition, the	13/06/2024		SmPC, Annex II and PL	Based on the evaluation of the cases of macular oedema (MO) reported in the etrasimod clinical program, all 4 participants with TEAEs of MO/cystoid MO had potential risk factors for macular oedema prior to MO being reported. The PI was updated accordingly to advise for an ophthalmologic exam to be conducted prior to therapy for at risk

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	MAH took this opportunity to introduce editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				population whilst allowing physicians to initiate therapy to obtain the ophthalmic evaluation "within 3-4 months after treatment initiation consistent with other S1PRMs labels. For more information, please refer to the Summary of Product Characteristics.